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Senate Hearings

Before the Committee on Appropriations

Departments of Labor,
Health and Human Services,
and Education, and Related
Agencies Appropriations

Fiscal Year 2013

112th CONGRESS, SECOND SESSION

S. 3295

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENT OF LABOR
NONDEPARTMENTAL WITNESSES

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES,
AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2013

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE
COMMITTEE ON APPROPRIATIONS
UNITED STATES SENATE

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

ON

S. 3295

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR,
HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED
AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2013, AND
FOR OTHER PURPOSES

**Department of Health and Human Services
Department of Labor
Nondepartmental Witnesses**

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**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2013**

WEDNESDAY, MARCH 7, 2012

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:05 a.m., in room SD-124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Kohl, Landrieu, Pryor, Mikulski, Brown, Shelby, Alexander, Johnson, Graham, and Moran.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. KATHLEEN SEBELIUS, SECRETARY

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

Madam Secretary, welcome back to the subcommittee. I want to start by commending you for the outstanding work you are doing to implement the Affordable Care Act (ACA) since President Obama signed it into law almost 2 years ago.

Some 3.6 million seniors—more than 42,000 in my State of Iowa—got discounts on their prescription drugs last year. Two-and-a-half million young adults are staying on their parents' insurance from graduation to age 26. I just ran into a family in Iowa where a student got off the family insurance, and then lost their job. That person came back on the family's insurance, went back to school again, took the college insurance, got out of school, came back on their family's insurance. And so it was a great comfort to this family to know that their child would not be without insurance coverage and they got insurance at the family rate.

Most important of all, 54 million Americans received a free preventative screening service in 2011 all because of ACA. And I believe this is the right track for healthcare in America. You know how strongly I feel about prevention and wellness.

Your Department is carrying out these reforms with great skill and dedication, and I commend you for your leadership.

More work remains, of course. Fiscal year 2013 is a key year for implementing ACA because it ends just 3 months before health insurance exchanges will open their doors in the States. On that day, we will fulfill a promise to bring affordable healthcare to 30 million uninsured Americans.

The President's budget request for fiscal year 2013 includes additional funding at Centers for Medicare & Medicaid Services (CMS) for creating these exchanges. As the chairman of this subcommittee and also of the authorizing committee, I am determined to help you finish the job. Reforming healthcare is not only the right thing to do, it will save taxpayers money and reduce the deficit and again move us more toward a real healthcare system rather than a sick care system.

The President's proposed budget also includes increases for key priorities like child care, Head Start, and rooting out fraud, waste, and abuse in Medicare and Medicaid.

However, there were two areas in which I was disappointed. One area is, of course, the cuts in the budget for the prevention fund. The prevention fund is something that was worked out in great detail, and all the different compromises were made when we passed the ACA. And then the President requested a cut of \$4.5 billion, which was then folded in the recent agreement by the Congress for a \$5 billion cut in the prevention fund, again penny wise, pound foolish. We will just take funding away from prevention, but boy, when you get sick, we will take care of you later on and it will cost us a lot more money. I do not know when we are going to learn that our mothers were right. An ounce of prevention is worth a pound of cure. And that is true in healthcare. But no. Take money out of the prevention fund.

The other part where I am disappointed is the lack of any additional funding for eliminating fraud and waste in healthcare. I chaired a hearing on this topic last February. Every \$1 that CMS spends on reducing fraud and waste returns \$7 to the U.S. Treasury in real dollars. The Budget Control Act of 2011 included a cap adjustment that encouraged the Congress to increase this funding by \$270 million, an amount that would have saved taxpayers well over \$1 billion. Yet, in conference at the insistence of the House majority, they refused any additional funding for this whatsoever in last year's bill. Again, penny wise and pound foolish.

I am pleased that the President has once again requested an increase for eliminating healthcare waste and abuse in this year's budget. And I would like to discuss this topic more with you later.

Some other provisions in the President's budget meanwhile are cause for concern. Once again, the President has proposed a nearly 50 percent cut to the Community Services Block Grants. This funding is critically important for community initiatives that provide a safety net for millions of low-income people across the country. The Congress rejected that cut last year. I expect it will do so again this year.

But overall, I believe the President's budget is a good start.

PREPARED STATEMENT

Madam Secretary, again, I commend you for your great leadership in these areas and especially what you are doing to implement ACA, and I look forward to hearing your testimony.

First, before I yield to the ranking member, Senator Shelby, for his opening remarks, I have received a statement from the full committee chairman, Senator Inouye. His statement will be inserted into the record at this point.

[The statement follows:]

PREPARED STATEMENT OF CHAIRMAN DANIEL K. INOUE

Mr. Chairman, thank you for chairing this hearing to review the President's fiscal year 2013 budget for the Department of Health and Human Services.

I would like to extend a warm aloha to Secretary of Health and Human Services, Kathleen Sebelius. These are challenging fiscal times, but I look forward to continuing to work with her to support critical investments in healthcare, disease prevention, social services, and scientific research.

Senator HARKIN. Senator Shelby.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman.

Secretary Sebelius, thank you for appearing today to discuss the fiscal year 2013 Department of Health and Human Services (HHS) budget.

We are living in difficult times. America's gross debt has increased more than \$5 trillion during President Obama's first 3 years in office, and the fiscal year 2013 budget request does nothing to curb spending or put our country on a fiscally sustainable path. In fact, the administration has built the fiscal year 2013 budget based, I believe, on the flawed philosophy of spend now, pay later. But as the turmoil in Greece is verifying, at some point the bill must be paid.

One of the key fiscal challenges facing the Federal Government is healthcare spending. In the last 20 years, total funding for HHS has tripled. Since 2001, the HHS's discretionary appropriation has increased by 45 percent. The President's answer to control health spending, the Affordable Care Act (ACA) that Senator Harkin referenced, continues to grow our Nation's deficit, and its bills are piling up.

In the fiscal year 2013, the budget requests a \$1 billion increase in discretionary dollars for the Centers for Medicare & Medicaid Services to continue implementation of ACA activities. This is in addition to the \$15.4 billion in mandatory funding ACA directly appropriated since fiscal year 2011. By combining discretionary and mandatory funding streams, the majority of ACA circumvents the yearly appropriations process that is crucial to providing transparency and oversight to funding decisions.

As we attempt to rein in Federal spending, it is clear that a comprehensive view to fund the healthcare programs is necessary. Instead of using budgetary smoke and mirrors, I believe we should examine all sources of funding, discretionary and mandatory, before the Appropriations Committee here determines an appropriate level of discretionary funding. Many programs advertise their baseline reduction when, in fact, they are recipients of significant man-

datory funding from ACA. Agencies and programs I believe should no longer deceive the American taxpayer by arguing that spending is reduced when they also receive mandatory funding from ACA that supplements and, in many cases, greatly increases their spending level.

It is also critical here that our subcommittee carefully consider the effects of ACA's mandatory funding on important healthcare programs that may not be able to continue if the act is not repealed. The administration has used ACA's mandatory spending, which is not subject to a vote by the Congress every year, to back-fill key and discretionary programs. The administration then diverts discretionary dollars to fund new programs. If ACA is repealed, many important programs like community health centers and the section 317 immunization program at the Centers for Disease Control will be in jeopardy because their base funding provided by the Department of Labor, HHS appropriations has been so significantly reduced.

I believe it is time to stop deceptive budgeting. We should be looking at the resources programs need for the fiscal year and not necessarily their long-enjoyed funding history. The Congress should carefully review programs to ensure funding is targeted to those that are the most successful and achieve the best results.

PREPARED STATEMENT

That is why I am disappointed that the administration has cut funding for the National Institutes of Health (NIH). In the last 30 years, biomedical research has yielded significant scientific discoveries that have extended life, reduced illness, and cut healthcare costs considerably. Secretary Sebelius, your budget request, I believe, abandons our Nation's commitment to advancing medical research. In fact, the request does not keep pace with biomedical research inflation, and as a result, in inflationary adjusted dollars, NIH is nearly 20 percent below where they were just 10 years ago. Our Nation's leading researchers will never find a cure, I believe, for the debilitating diseases that affect us without a commitment to advancing medical research. I believe it is critical to invest in biomedical research to ensure the United States continues to make progress toward medical discoveries that improve our lives and make treatment more effective and lower overall healthcare costs.

I look forward to hearing from you this morning, but these are some of the concerns that I think we should look at.

[The statement follows:]

PREPARED STATEMENT OF SENATOR RICHARD C. SHELBY

Secretary Sebelius, thank you for appearing today to discuss the Department of Health and Human Services (HHS) fiscal year 2013 budget.

We are living in difficult times. America's gross debt has increased more than \$5 trillion during President Obama's first 3 years in office, and the fiscal year 2013 budget request does nothing to curb spending or put our country on a fiscally sustainable path.

In fact, the administration has built the 2013 budget based on the flawed philosophy of spend now, pay later. But as the turmoil in Greece is verifying, at some point the bill must be paid.

One of the key fiscal challenges facing the Federal Government is healthcare spending. In the last 20 years, total funding for HHS has tripled. Since 2001, the Department's discretionary appropriation has increased by 45 percent.

The President's answer to control health spending, the Affordable Care Act (ACA), continues to grow our Nation's deficit, and its bills are piling up.

In fiscal year 2013, the budget requests a \$1 billion increase in discretionary dollars for the Centers for Medicare & Medicaid Services to continue implementation of ACA activities. This is in addition to the \$15.4 billion in mandatory funding the ACA directly appropriated since fiscal year 2011. By combining discretionary and mandatory funding streams, the majority of ACA circumvents the yearly appropriations process that is crucial to providing transparency to funding decisions.

As we attempt to rein in Federal spending, it is clear that a comprehensive view to fund healthcare programs is necessary.

Instead of using budgetary smoke and mirrors, we should examine all sources of funding—discretionary and mandatory—before the Appropriations Committee determines an appropriate level of discretionary funding. Many programs advertise their baseline reduction, when, in fact, they are recipients of significant mandatory funding from ACA. Agencies and programs should no longer deceive the American taxpayer by arguing their spending is reduced when they also receive mandatory funding from ACA that supplements and, in many cases, greatly increases their spending level.

It is also critical that our subcommittee carefully consider the effects of the ACA's mandatory funding on important healthcare programs that may not be able to continue when the act is repealed. The administration has used the ACA's mandatory spending, which is not subject to a vote by the Congress every year, to backfill key discretionary programs. The administration then diverts discretionary dollars to fund new programs.

When ACA is repealed, many important programs like community health centers and the section 317 immunization program at the Centers for Disease Control will be in jeopardy because their base funding provided by the Labor, Health and Human Services, and Education, and Related Agencies appropriations bill has been so significantly reduced.

It is time to stop deceptive budgeting. We should be looking at the resources programs need for this fiscal year and not necessarily their long-enjoyed funding history. The Congress should carefully review programs to ensure funding is targeted to those that are the most successful and achieve the best results.

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Our Nation's leading researchers will never find a cure for the debilitating diseases that affect us without a commitment to advancing medical research. It is critical to invest in biomedical research to ensure the United States continues to make progress towards medical discoveries that improve lives, make treatment more effective, and lower overall healthcare costs.

Mr. Chairman, I look forward to working with you this year to craft a bill that balances the needs of our healthcare system within our country's fiscal restraints.

Senator SHELBY. Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Shelby.

Kathleen Sebelius became the 21st Secretary of the Department of Health and Human Services on April 29, 2009. In 2003, she was elected Governor of Kansas and served in that capacity until her appointment by President Obama as the Secretary. Prior to her election as Governor, she served as the Kansas State Insurance Commissioner. She is a graduate of Trinity Washington University and the University of Kansas.

My notes tell me this will make the Secretary's fifth appearance before this subcommittee since her appointment. You have always been forthright with us, Madam Secretary. We appreciate your being here. Your statement will be made a part of the record in its entirety, and please proceed as you so desire.

SUMMARY STATEMENT OF KATHLEEN SEBELIUS

Secretary SEBELIUS. Well, thank you, Chairman Harkin and Ranking Member Shelby, and members of the subcommittee. A little shout-out to my home State senator, Senator Moran. And I appreciate the invitation to discuss the President's fiscal year 2013 budget for HHS.

Our budget helps create an American economy built to last by strengthening our Nation's healthcare, supporting research that will lead to tomorrow's cures, and promoting opportunities for America's children and families so everyone has a fair shot to reach his or her potential. It makes the investments we need right now, while reducing the deficit in the long term, to make sure that the programs that millions of Americans rely on will be there for generations to come.

I look forward to our discussion and answering your questions about the budget. But first, I would like to just share some of the highlights that fall under the jurisdiction of this subcommittee, which oversees almost \$70 billion of our Department's nearly \$77 billion discretionary budget.

HEALTHCARE REFORM

Over the last 2 years, as the chairman said, we have worked to deliver the benefits of ACA to the American people. Thanks to the law, more than 2.5 million additional young Americans are already getting coverage through their parents' health plans. More than 25 million seniors across the country have taken advantage of the free recommended preventive services under Medicare. And small business owners are getting tax breaks on their health bills that allow them to hire more employees.

This year, we will build on that progress by continuing to support States as they work to establish affordable insurance exchanges by 2014. Once these competitive marketplaces are in place, they will ensure that all Americans have access to quality, affordable health coverage.

Because we know that a lack of insurance is not the only obstacle to care, our budget also invests in the healthcare workforce. This budget supports training more than 7,100 primary care providers and placing them where they are needed most.

It also invests in America's network of community health centers. Together with the 2012 resources, our budget will create more than 240 new access points for patient care, along with thousands of new jobs. Altogether, health centers will provide access to quality care for 21 million people, 300,000 more than were served last year.

This budget also continues our administration's commitment to improving the quality and safety of care by spending health dollars more wisely. It means investing in health information technology. It also means funding the first-of-its-kind Center for Medicare & Medicaid Innovation which is partnering with physicians, nurses, hospital administrators, private payers, and others who have accepted the challenge to develop a new, sustainable healthcare system.

In addition, our budget ensures that 21st century America will continue to lead the world in biomedical research by maintaining funding for NIH.

HEALTHCARE FRAUD, WASTE, AND ABUSE

At the same time, the budget recognizes the need to set priorities, making difficult tradeoffs and ensure we use every \$1 wisely. That starts with support for President Obama's historic push to stamp out waste, fraud, and abuse in the healthcare system. Over the last 3 years, every \$1 we have put into healthcare fraud and abuse control has returned more than \$7 to taxpayers. Last year alone, these efforts recovered more than \$4 billion. And just last week, our administration arrested the alleged head of the largest individual Medicare and Medicaid fraud operation in history. Our budget builds on those efforts by giving law enforcement the technology and data to spot perpetrators early and prevent payments based on fraud from going out in the first place.

The budget also contains more than \$360 billion in health savings over 10 years, most of which comes from reforms to Medicare and Medicaid. These are significant, but they are carefully crafted to protect beneficiaries. For example, we propose significant savings in Medicare by reducing drug costs, a plan that both puts money back in the Medicare Trust Fund and puts money back in the pockets of Medicare beneficiaries.

PREPARED STATEMENT

The budget makes smart investments where they will have the greatest impact, and it puts us all on a path to build a stronger, healthier, more prosperous America for the future.

Again, thank you, Mr. Chairman and members of the subcommittee, and I look forward to this discussion.

[The statement follows:]

PREPARED STATEMENT OF KATHLEEN SEBELIUS

Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, thank you for the invitation to discuss the President's fiscal year 2013 budget for the Department of Health and Human Services (HHS).

The budget for HHS invests in healthcare, disease prevention, social services, and scientific research. HHS makes investments where they will have the greatest impact, build on the efforts of our partners, and lead to meaningful gains in health and opportunity for the American people.

The President's fiscal year 2013 budget for HHS includes a reduction in discretionary funding for ongoing activities and legislative proposals that would save an estimated \$350.2 billion over 10 years. The budget totals \$940.9 billion in outlays and proposes \$76.7 billion in discretionary budget authority, including \$69.6 billion under the purview of this subcommittee. This funding will enable HHS to:

- strengthen healthcare;
- support American families;
- advance scientific knowledge and innovation;
- strengthen the Nation's health and human service infrastructure and workforce;
- increase efficiency, transparency, and accountability of HHS programs; and
- complete the implementation of the American Recovery and Reinvestment Act.

STRENGTHEN HEALTHCARE

Delivering Benefits of the Affordable Care Act to the American People.—The Affordable Care Act (ACA) expands access to affordable health coverage to millions of Americans, increases consumer protections to ensure individuals have coverage when they need it most, and slows increases in health costs. Effective implementa-

tion of the ACA is central to the improved fiscal outlook and well-being of the Nation. The Centers for Medicare & Medicaid Services (CMS) is requesting an additional \$1 billion in discretionary funding to continue implementing the ACA, including Affordable Insurance Exchanges, and to help keep up with the growth in the Medicare population.

Expand and Improve Health Insurance Coverage.—Beginning in 2014, Affordable Insurance Exchanges will provide improved access to insurance coverage for millions of Americans. Exchanges will make purchasing private health insurance easier by providing eligible individuals and small businesses with one-stop shopping where they can compare benefit plans. New premium tax credits and reductions in cost-sharing will help ensure that eligible individuals can afford to pay for the cost of private coverage through Exchanges. Fiscal year 2013 will be a critical year for building the infrastructure and initiating the many business operations critical to enabling Exchanges to begin operation on January 1, 2014. The expansion of health insurance coverage for millions of low-income individuals, who were previously not eligible for coverage, also begins in 2014. CMS has worked closely with States to ensure they are prepared to meet the 2014 deadline and will continue this outreach in fiscal year 2013.

Many important private market reforms have already gone into effect, providing new rights and benefits to consumers that are designed to put them in charge of their own healthcare. The ACA's Patient's Bill of Rights allows young adults to stay on their parents' plans until age 26 and ensures that consumers receive the care they need when they get sick and need it most by prohibiting rescissions and lifetime dollar limits on coverage for care, and beginning to phase out annual dollar limits. The new market reforms also guarantee independent reviews of coverage disputes. Temporary programs like the Early Retiree Reinsurance Plan and the Pre-Existing Condition Insurance Plan are supporting affordable coverage for individuals who often face difficulties obtaining private insurance in the current marketplace. Additionally, rate review and medical loss ratio (MLR) provisions helps ensure that healthcare premiums are kept reasonable and affordable year after year. The already operational rate review provision gives States additional resources to determine if a proposed healthcare premium increase is unreasonable and, in many cases, help enable State authorities to deny an unreasonable rate increase. HHS reviews large proposed increases in States that do not have effective rate review programs. The MLR provisions guarantee that, starting in 2011, insurance companies use at least 80 percent or 85 percent of premium revenue, depending on the market, to provide or improve healthcare for their customers or give them a rebate.

Strengthen the Delivery System.—ACA established a Center for Medicare & Medicaid Innovation. The Innovation Center is tasked with developing, testing, and—for those that prove successful—expanding innovative payment and delivery system models to improve quality of care and reduce costs in Medicare, Medicaid, and the Children's Health Insurance Program. Since the Innovation Center began operations it has undertaken an ambitious agenda encompassing patient safety, coordination of care among multiple providers, and enhanced primary care. These projects can serve as crucial stepping stones towards a higher-quality, more-efficient healthcare system.

Ensuring Access to Quality Care for Vulnerable Populations.—Health centers are a key component of the Nation's healthcare safety net. The President's budget includes a total of \$3 billion, including an increase of \$300 million from mandatory funds under the ACA, to the health centers program. This investment will provide Americans in underserved areas—both rural and urban—with access to comprehensive primary and preventive healthcare services. Together with 2012 resources, HHS' budget will create more than 240 new access points for patient care. Overall, HHS' investment in health centers will provide access to quality care for 21 million people, an increase of 300,000 additional patients over fiscal year 2012. The budget also promotes a policy of steady and sustainable health center growth by distributing ACA resources over the long-term. This policy safeguards resources for new and existing health centers to continue services and ensures a smooth transition as health centers increase their capacity to provide care as access to insurance coverage expands.

Improving Healthcare Quality and Patient Safety.—ACA directed HHS to develop a national strategy to improve healthcare services delivery, patient health outcomes, and population health. In fiscal year 2011, HHS released the National Strategy for Quality Improvement in Health Care, which highlights three broad aims:

- better care;
- healthy people and communities; and
- affordable care.

Since publishing the National Strategy for Quality Improvement in Health Care, HHS has focused on gathering additional input from private partners and aligning new and existing HHS activities with the strategy. HHS will enhance the strategy by incorporating input from stakeholders and developing metrics to measure progress toward achieving the strategy's aims and priorities. Already, the strategy is serving as a blueprint for quality improvement activities across the country.

Investing in Innovation.—HHS is committed to advancing the use of health information technology (IT). The budget includes \$66 million, an increase of \$5 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate the adoption of health IT and promote electronic health records (EHRs) as tools to improve both the health of individuals and the healthcare system as a whole. The increase will allow ONC to provide more assistance to healthcare providers as they become meaningful users of health IT. Furthermore, through the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act, CMS is providing hospitals and medical professionals who participate in Medicare and Medicaid with substantial incentive payments for the adoption and meaningful use of EHRs. As of February 1, 2012, CMS had made incentive payments to more than 23,600 providers who have met the objectives for meaningful use in the Medicare EHR Incentive program and more than 19,600 providers who have adopted, implemented, or upgraded EHRs, or met meaningful use objectives in the Medicaid EHR Incentive program. By encouraging providers to modernize their systems, this investment will improve the quality of care and protect patient safety.

SUPPORT AMERICAN FAMILIES

Healthy Development of Children and Families.—HHS oversees many programs that support children and families. The fiscal year 2013 budget request invests in early education, recognizing the role high-quality early education programs can play in preparing children for school success.

Investing in Education by Supporting an Early Learning Reform Agenda.—The fiscal year 2013 budget supports critical reforms in Head Start and a child care quality initiative that, when taken together with the Race to the Top—Early Learning Challenge, are key elements of the administration's broader education reform agenda designed to improve our Nation's competitiveness by helping every child enter school ready for success.

On November 8, 2011, the President announced important new steps to improve the quality of services and accountability at Head Start centers across the country. The budget requests more than \$8 billion for Head Start programs, an increase of \$85 million more than fiscal year 2012, to maintain services for the 962,000 children currently participating in the program. This investment will also provide resources to effectively implement new regulations that require grantees that do not meet high-quality benchmarks to compete for continued funding, introducing an unprecedented level of accountability into the Head Start program. By directing taxpayer dollars to programs that offer high-quality Head Start services, this robust, open competition for Head Start funding will help to ensure that Head Start programs provide the best available early education services to our most vulnerable children.

The budget includes \$300 million for a new child care quality initiative that States would use to invest directly in programs and teachers so that individual child care programs can do a better job of meeting the early learning and care needs of children and families. The funds would also support efforts to measure the quality of individual child care programs through a rating system or another system of quality indicators, and to clearly communicate program-specific information to parents so they can make informed choices for their families. These investments are consistent with the broader reauthorization principles outlined in the budget, which encompass a reform agenda that would help transform the Nation's child care system to one that is focused on continuous quality improvement and provides more low-income children access to high-quality early education settings that support children's learning, development, and success in school.

Keeping America Healthy.—The President's budget includes resources necessary to enhance clinical and community prevention, support research, develop the public health workforce, control infectious diseases, and invest in prevention and management of chronic diseases and conditions.

Tobacco Prevention Activities.—Tobacco use kills an estimated 443,000 people in the United States each year. Despite progress in reducing tobacco use, 1 in 5 high school students and adults continue to smoke, costing our Nation \$96 billion in medical costs and \$97 billion in lost productivity each year. The budget includes \$586 million in funding from the Centers for Disease Control and Prevention (CDC), the

National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to further help reduce smoking among teens and adults and support research on preventing tobacco use, understanding the basic science of the consequences of tobacco use, and improving treatments for tobacco-related illnesses. HHS is striving to reduce adults' annual cigarette consumption in the United States from 1,281 cigarettes per capita to 1,062 cigarettes per capita by 2013.

Million Hearts Initiative.—The Million Hearts Initiative is a national public-private initiative aimed at preventing 1 million heart attacks and strokes over 5 years, from 2012 to 2017. It seeks to reduce the number of people who need treatment and improve the quality of treatment that is available. It focuses on increasing the number of Americans who have their high blood pressure and high cholesterol under control, reducing the number of people who smoke, and reducing the average intake of sodium and trans fats. To achieve this overall goal, the initiative will promote medication management and support a network of EHR registries to track blood pressure and cholesterol control, along with many other public-private collaborations. In fiscal year 2013, the budget requests \$5 million for CDC to achieve measurable outcomes in these areas.

Preventing Teen Pregnancy.—The budget includes \$105 million for the Office of the Assistant Secretary for Health for teen pregnancy prevention programs. These programs will support community-based efforts to reduce teen pregnancy using evidence-based models and promising programs needing further evaluation. The budget also includes \$15 million in funding for CDC teen pregnancy prevention activities to reduce the number of unintended pregnancies through science-based prevention approaches. Additionally, the budget would repurpose unobligated funds to create a new teen pregnancy prevention program specifically targeted to youth in foster care, who are at particularly high risk of becoming teen parents.

Protect Vulnerable Populations.—HHS is committed to ensuring that vulnerable populations continue to receive critical services during this period of economic uncertainty. For example, the Administration for Children and Families (ACF) budget requests includes a \$7 million increase in funding for the Family Violence Prevention programs in order to expand shelter capacity and services and to support higher call volume to the domestic violence hotline.

Preventing and Treating HIV/AIDS.—The fiscal year 2013 budget includes \$3.3 billion for domestic HIV/AIDS activities to increase the availability of treatment to people living with HIV/AIDS in the United States, improve adherence to medications, and support prevention programs in States and communities. This total investment includes \$1 billion, an increase of \$67 million, to increase access to life-saving treatments through the AIDS Drug Assistance program, and \$236 million, an increase of \$20 million, to support care provided by HIV clinics across the country.

This total also includes \$826 million for CDC's domestic HIV/AIDS prevention activities, an increase of \$40 million more than fiscal year 2012, to support grants to health departments to reduce new HIV infections, identify previously unrecognized HIV infections, and improve health outcomes. In addition, funds will support research, surveillance, evaluation, and implementation of high-impact prevention programs among HIV-affected populations. In fiscal year 2013, CDC will award grants to 69 State and local health departments to implement HIV/AIDS prevention programs according to a revised funding algorithm instituted in fiscal year 2012, which better aligns the distribution of prevention resources with the disease burden rather than with historical AIDS data. CDC will also support up to 36 jurisdictions for an expanded testing initiative to focus on groups at highest risk for acquiring HIV such as men who have sex with men, African Americans, and injection drug users.

Refugee Transitional and Medical Services.—The budget requests \$805 million to provide time-limited cash and medical assistance to newly arrived refugees, helping them become self-sufficient as quickly as possible, and to provide shelter for unaccompanied alien children until they can be placed with relatives or other sponsors, repatriated to their home countries, or receive relief under U.S. immigration law. Additional funding will primarily cover rising medical costs—many refugees have spent their lives in camps where medical care is limited or nonexistent—and serve the growing number of unaccompanied alien children made eligible for benefits under the Trafficking Victims Protection Reauthorization Act of 2008.

Elder Justice.—The budget includes \$43 million for the Administration on Aging (AOA) to address the growing problem of elder abuse, neglect, and exploitation which affects more than 5 million seniors annually. Research indicates that older victims of even modest forms of abuse have dramatically higher morbidity and mortality rates than nonabused older people. To combat this abuse, the budget provides \$8 million for newly authorized Adult Protective Services Demonstration grants,

along with \$9 million in ongoing funding for State grants to raise awareness of elder abuse and neglect and for resource centers and related activities that support nationwide elder rights activities. The budget also includes \$17 million for the Long-term Care Ombudsman Program to improve the quality of care for the residents of long-term care facilities by resolving complaints on behalf of residents.

Keeping People in Communities.—Part of HHS’ strategic plan includes enabling seniors to remain in their own homes with a high-quality of life for as long as possible through the provision of home and community-based services, including supports for family caregivers. Some seniors, if unable to remain independent in the community, will be forced to move into a nursing home at a significant potential cost to Medicaid. The budget includes \$1.4 billion in AOA to help seniors stay in their homes through home and community-based supportive services, senior nutrition programs, and Caregiver Support programs. The budget also proposes to transfer the Senior Community Service Employment program from the Department of Labor (DOL) to the AOA. This move provides greater alignment with the agencies that provide supportive services.

Community Services Programs.—The budget includes \$400 million for community services programs. This funding level includes \$350 million for the Community Services Block Grant (CSBG), and proposes to use a system of standards and competition to target the funds to high-performing agencies that are most successful in meeting community needs. In support of the Healthy Food Financing Initiative, \$10 million is available to fund community development corporations to eliminate food deserts by improving access to grocery stores, farmers’ markets, and other venues for healthy, affordable groceries. Additionally, \$20 million is requested for the Community Economic Development program to sponsor enterprises providing employment, training, and business development opportunities for low-income Americans.

Vulnerable Youth.—The ACFs’ budget includes an additional \$5 million as part of a cross-agency effort to identify and test new ways to strengthen services for disconnected youth—14- to 24-year-olds who are neither working nor in school. This \$5 million will be utilized in close cooperation with an additional \$5 million requested by the Department of Education and \$10 million from DOL. In addition to the funding request, the administration proposes a general provision in the appropriations act to support a limited number of “performance partnerships” that would provide States and localities with enhanced flexibility in determining how services are structured in return for strong accountability for results.

Reduce Foodborne Illness.—The budget reflects the administration’s commitment to transforming our Nation’s food safety system into one that is stronger and that reduces foodborne illness and includes an increase of \$17 million above fiscal year 2012 to support CDC’s role in implementing the Food Safety and Modernization Act. HHS will continue to modernize and implement a prevention-focused domestic and import safety system. Collaboratively, the Federal Drug Administrative (FDA) and CDC are working to decrease the rate of Salmonella Enteritidis illness in the population from 2.6 cases per 100,000 to 2.1 cases per 100,000 by December 2013. In fiscal year 2013, CDC will enhance surveillance systems and designate five Integrated Food Safety Centers of Excellence at State health departments.

ADVANCE SCIENTIFIC KNOWLEDGE AND INNOVATION

Biomedical and Behavioral Research.—The fiscal year 2013 budget maintains funding for the NIH at the fiscal year 2012 level of \$30.9 billion, reflecting the administration’s priority to invest in innovative biomedical and behavioral research that spurs economic growth while advancing medical science to improve health. NIH is generating discoveries that are opening new avenues for disease treatment and prevention and revolutionizing patient care. In fiscal year 2013, NIH will seek to take advantage of such discoveries by investing in basic research on the fundamental causes and mechanisms of disease, accelerating discovery through new technologies, advancing translational sciences, and encouraging new investigators and new ideas.

National Center for Advancing Translational Sciences.—In fiscal year 2013, NIH will continue to implement National Center for Advancing Translational Sciences (NCATS), established in fiscal year 2012, in order to re-engineer the process of translating scientific discoveries into new medical products. Working closely with partners in the regulatory, academic, nonprofit, and private sectors while not duplicating work going on in the private sector, NCATS will strive to identify innovative solutions to overcome hurdles that slow the development of effective treatments and cures. A total of \$639 million is proposed for NCATS in fiscal year 2013, including \$50 million for the Cures Acceleration Network.

Medical Countermeasure Development.—The HHS Medical Countermeasure Enterprise includes initiatives across the Department covering the spectrum of medical countermeasure development, from early biological research to stockpiling of approved products. The fiscal year 2013 budget includes \$547 million for the Biomedical Advanced Research and Development Authority, an increase of \$132 million more than fiscal year 2012, to develop and improve next-generation medical countermeasures (MCM) in response to potential chemical, biological, radiological, and nuclear threats. The budget also provides \$50 million to establish a strategic investment corporation that would function as a public-private venture capital fund providing companies developing MCMs with the necessary financial capital and business acumen to improve the chances of successful development of new MCM technologies and products. Together, these investments will provide HHS with new tools to enhance the success of medical countermeasure development.

Enhancing Healthcare Decisionmaking.—The HHS budget includes \$599 million for research that compares the risk, benefits, and effectiveness of different medical treatments and strategies, including healthcare delivery, medical devices, and drugs, including \$78 million from the Patient-Centered Outcomes Research Trust Fund (PCORTF) established by the ACA. Evidence generated through this research is intended to help patients make informed healthcare decisions that best meet their needs. This level of funding will primarily support research conducted by NIH, core research activities within the Agency for Healthcare Research and Quality, and data capacity activities within the Office of the Assistant Secretary. Resources from PCORTF will support comparative clinical effectiveness research dissemination, improved research infrastructure, and training of patient-centered outcomes researchers. HHS core research will be coordinated to complement projects supported through PCORTF and through the independent Patient-Centered Outcomes Research Institute.

STRENGTHEN THE NATION'S HEALTH AND HUMAN SERVICE INFRASTRUCTURE AND WORK FORCE

Investing in Infrastructure.—A strong health workforce is key to ensuring that more Americans can get the quality care they need to stay healthy. The budget includes \$677 million, an increase of \$49 million more than fiscal year 2012, within Health Resources and Services Administration (HRSA) to expand the capacity and improve the training and distribution of primary care, dental, and pediatric health providers. The budget will support the placement of more than 7,100 primary care providers in underserved areas and begin investments that expand the capacity of institutions to train 2,800 additional primary care providers more than 5 years.

The fiscal year 2013 budget also supports State and local capacity for core public health functions. Within the Prevention Fund allocation, CDC will invest \$20 million in new activities to coordinate with public health laboratories to improve efficiency through proven models, such as regionalizing testing in multi-State laboratories. To ensure an effective public health workforce, the budget requests \$61 million, of which \$25 million is through the Prevention Fund, for the CDC public health workforce to increase the number of trained public health professionals in the field. CDC's experiential fellowships and training programs create a prepared and sustainable health workforce to meet emerging public health challenges. In addition, the budget requests \$40 million in the Prevention Fund to maintain support for CDC's Public Health Infrastructure program. This program will assist health departments in meeting national public health standards and will increase the capacity and ability of health departments in areas such as information technology and data systems, workforce training, and regulation and policy development.

INCREASE EFFICIENCY, TRANSPARENCY, AND ACCOUNTABILITY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS

Living Within Our Means.—HHS is committed to improving the Nation's health and well-being while simultaneously contributing to deficit reduction. The fiscal year 2013 discretionary request demonstrates this commitment by maintaining ongoing investments in areas most central to advancing the HHS mission while making reductions to lower-priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the fiscal year 2013 request includes more than \$2.1 billion in terminations and reductions to fund initiatives while achieving savings in a constrained fiscal environment. Many of these reductions, such as the \$177 million cut to the Children's Hospital Graduate Medical Education Payment program, the \$327 million cut to CSBG, and the \$452 million cut to the Low Income Home Energy Assistance Program (LIHEAP) were very difficult to make but are necessitated by the current fiscal environment.

Regarding LIHEAP, the administration proposes to adjust funding for expected winter fuel costs and to target funds to those most in need. The request is \$3 billion, \$452 million below the fiscal year 2012 level and \$450 million more than both fiscal year 2008 and fiscal year 2012 request. With constrained resources, the budget targets assistance where it is needed most. The request targets \$2.8 billion in base grants using the State allocation the Congress enacted for fiscal year 2012. The request also includes \$200 million in contingency funds, which will be used to address the needs of households reliant on home delivered fuels (heating oil and propane) should expected price trends be realized, as well as other energy-related emergencies.

In September 2011, the administration detailed a plan for economic growth and deficit reduction. The fiscal year 2013 budget follows this blueprint in its legislative proposals, presenting a package of health savings proposals that would save more than \$360 billion more than 10 years, with almost all of these savings coming from Medicare and Medicaid. Medicare proposals would encourage high-quality, efficient care, increase the availability of generic drugs and biologics, and implement structural reforms to encourage beneficiaries to seek value in their healthcare choices. The budget also seeks to make Medicaid more flexible, efficient, and accountable while strengthening Medicaid program integrity. Together, the fiscal year 2013 discretionary budget request and these legislative proposals allow HHS to support the administration's challenging yet complementary goals of investing in the future and establishing a sustainable fiscal outlook.

Program Integrity and Oversight.—The fiscal year 2013 budget continues to make program integrity a top priority. The budget includes \$610 million in discretionary funding for Health Care Fraud and Abuse Control (HCFAC), the full amount authorized under the Budget Control Act of 2011 (BCA). The budget also proposes to fully fund discretionary program integrity initiatives at \$581 million in fiscal year 2012, consistent with the BCA. The discretionary investment supports the continued reduction of the Medicare fee-for-service improper payment rate; investments in prevention-focused, data-driven initiatives like predictive modeling; and HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiatives, including Medicare Strike Force teams and fighting pharmaceutical fraud.

From 1997 to 2011, HCFAC programs have returned more than \$20.6 billion to the Medicare Trust Funds, and the current 3-year return-on-investment of \$7.2 recovered for every \$1 appropriated is the highest in the history of the HCFAC program. Last year these efforts recovered more than \$4 billion. The budget proposes a 10-year discretionary investment yielding a conservative estimate of \$11.3 billion in Medicare and Medicaid savings and 16 program integrity proposals to build on the ACA's comprehensive fraud fighting authorities for savings of an additional \$3.6 billion over 10 years.

Additionally, the budget includes funding increases for significant oversight activities. The request includes \$84 million for the Office of Medicare Hearings and Appeals, an increase of \$12 million, to continue to process the increasing number of administrative law judge appeals within the statutory 90-day timeframe while maintaining the quality and accuracy of its decisions. The budget also includes \$370 million in discretionary and mandatory funding for the Office of Inspector General (OIG), a 4-percent increase from fiscal year 2012. This increase will enable OIG to expand CMS Program Integrity efforts in areas such as HEAT, improper payments, and focus on investigative efforts on civil fraud, oversight of grants, and the operation of new ACA programs.

Additionally, Durable Medical Equipment (DME) Competitive Bidding is providing competitive pricing, while continuing to ensure access to quality medical equipment from accredited suppliers, which will save Medicare \$25.7 billion over 10 years and help millions of Medicare beneficiaries save \$17.1 billion in out-of-pocket costs over 10 years. The budget proposes to extend some of the efficiencies of DME Competitive Bidding to Medicaid by limiting Federal reimbursement on certain DME services to what Medicare would have paid in the same State for the same services. This proposal is expected to save Medicaid \$3 billion over 10 years.

Consolidate and Improve Activities Related to Prevention and Behavioral Health.—The budget includes \$500 million within SAMHSA for new, expanded, and refocused substance abuse prevention and mental health promotion grants to States and tribes. To maximize the efficiency and effectiveness of its resources, SAMHSA will use competitive grants to identify and test innovative prevention practices and will leverage State and tribal investments to foster widespread implementation of evidence-based prevention strategies.

The budget also consolidates funding for initiatives aimed at addressing chronic disease prevention. Chronic diseases and injuries represent the major causes of mor-

bidity, disability, and premature death and heavily contribute to the growth in healthcare costs. The budget aims to improve the health of individuals by focusing on prevention of chronic diseases and injuries rather than focusing solely on treating conditions that could have been prevented. Specifically, the budget allocates \$379 million, an increase of \$129 million more than fiscal year 2012, to a new integrated grant program in CDC that refocuses disease-specific grants into a comprehensive program that will enable health departments to implement the most effective strategies to address these leading causes of death. Because many inter-related chronic disease conditions share common risk factors, the new program will improve health outcomes by coordinating the interventions that can reduce the burden of chronic disease.

Senator HARKIN. Thank you very much, Madam Secretary.

Madam Secretary, I am going to yield my opening position to Senator Mikulski who has to go chair another hearing here very shortly.

STATEMENT OF SENATOR BARBARA A. MIKULSKI

Senator MIKULSKI. Thank you very much, Mr. Chairman, for yielding.

Senator Inouye is indisposed this morning and I am going to chair the Department of Defense appropriations hearing. So it is really the day of shooting straight.

I am only 4 foot 11, so you cannot see me, but you have certainly been able to hear me.

Secretary SEBELIUS. I can see you.

IMPROVING HEALTHCARE QUALITY

Senator MIKULSKI. Let me get right to my question, Madam Secretary.

I want to thank you for the great job you are doing. I want to thank you for your respect of implementing the laws that the Congress passes, your respect for the Constitution and all of its amendments, and also creating the sense of your agencies working with the Congress. My work with Dr. Margaret Hamburg on the Prescription Drug User Fee Act (PDUFA), the way she has reached out in her agency to the business community has really been I think a model of how to work to keep our people safe and yet to not shackle them with unnecessary regulation.

Let me get to my question on quality. When we worked on ACA, Senator Harkin, of course, was one of the leaders on the bill and on prevention. I worked with him on that. And I worked on the quality initiatives. The goal was two things: one, not only to improve access, but by improving quality, we could save lives and save money. We have the home of Dr. Pronovost at Hopkins, the famous Pronovost checklist.

My question to you is, "How are we training the cadre of scientists and physicians in the area of quality medical delivery services?" I have been advised by the School of Public Health and Dr. Pronovost himself that there is this whole body of knowledge that could be taught at great schools of medicine and public health where it would not be just a few leaders like Pronovost, but we would be training people in the science of healthcare delivery and developing it so they would be in communities, they would become hospital administrators, et cetera. Would you look at all of your programs to see how we could encourage that?

Secretary SEBELIUS. I would be delighted to work with you on that, Senator Mikulski.

I can tell you that what is happening now is very exciting for the next generation of providers and administrators because I think for the first time across this country, there is a focus and highlight on real changes, transformations in the delivery system, and a lot of that is focused on taking the best practices which exist in pockets—and certainly the checklist is a great example of that—but bringing them to scale and having every health system in the country adopt some of these practices in a much more timely fashion. So through our Innovation Center and through the Partnership for Patients, which now has engaged more than 5,000 partners, private employers, payers, and hospital systems, we are actually capturing the quality programs and—

Senator MIKULSKI. But you are going to need people to do this.

Secretary SEBELIUS. You bet.

Senator MIKULSKI. And just as we have skilled surgeons, those who do the hands-on medicine, for those to advise those in the practice of medicine, hospital administrators, Governors looking at how to handle an increasing, burgeoning Medicaid costs. So would you look at that and respond to me?

Secretary SEBELIUS. Yes, I would.

CHILD CARE QUALITY INITIATIVES

Senator MIKULSKI. My second and last question will be child care quality initiatives. I chair the subcommittee on Children and Families. We have had extensive hearings on reauthorizing the Child Care Development Block Grant. We have bipartisan cooperation. I cannot say enough about Senator Burr's work, how we are working together.

My question goes, as we look forward to access, there is also child safety and child quality. There has been a recent story on "Nightline" that our current laws are inadequate in terms of background checks and so on. So we want to increase access, keep it affordable. But my God, when you go to a day care center, you have got to make sure that the people who are the day care providers, number one that it is a safe environment and also their education and training. Could you comment? Have you seen the "Dateline" story?

Secretary SEBELIUS. I have not seen the "Dateline" story, but I have read the clips about it.

Senator MIKULSKI. You know what I mean.

Secretary SEBELIUS. Absolutely.

Senator MIKULSKI. I know of your work as Governor and child advocate, do you have any comments or would you like to respond in writing because we hope to reauthorize this program, and we are looking to advice and guidance from the Department.

Secretary SEBELIUS. Well, we very much are eager to work with you, and I think you have articulated very well the principles around which we think reauthorization should occur, not only making sure that there are additional slots for families, knowing that child care is really one of the work-friendly programs—you cannot go to work if your children are not in a safe and secure place—but also knowing that way too many parents either do not have a way

to understand what is going on in the system and do not have the confidence that any place they put their child is a high-quality care system. So improving quality and getting that information into the hands of parents, sort of the rating system, so parents really can make the best choice for themselves and their children is an effort that is underway, as you know, and we think has to be part of the framework for reauthorization.

Senator MIKULSKI. Madam Secretary, my time is up, and Senator Harkin has been gracious. What we are looking at is how we can improve that background check without adding more cost and more regulation and, second, really how we get to the training of these child care workers and how they have perhaps a career ladder like we have done in nursing, CNA, licensed practical nurse, so they see a career.

Secretary SEBELIUS. And, Senator, just so you know a little bit about my history, I went to the legislature in Kansas when my children were 2 and 5, and this became an issue that was near and dear to my heart and has been ever since. That was a very long time ago, but child care was something I was living at the time, so it became one of my causes. And I very much look forward to working with you.

Senator HARKIN. Thank you, Senator Mikulski.

Thank you, Madam Secretary.

Senator Shelby.

NATIONAL INSTITUTES OF HEALTH FUNDING

Senator SHELBY. Thank you.

Madam Secretary, the 2013 budget proposal, with the Public Health Service Act evaluation tap increase included, reduces NIH's budget by \$215 million below fiscal year 2012. How will NIH maintain its scientific rigor and innovation when the budget request does not keep pace with the biomedical inflation rate? Do we not have a problem here?

Secretary SEBELIUS. Well, Senator, I first of all share your belief that continuing to make sure that America leads the world in biomedical research is a critical priority for the future, and we look forward to working with the Congress around the tap issue as we move forward.

Having said that, I can tell you that Dr. Collins has allocated resources within NIH's budget, which is currently funded at the level that it was funded last year, and made sure that we continue to fund new grants. His report is that the fiscal year 2013 budget level will allow him to increase the grants by about 7.7 percent. An additional 672 new grants will be funded. He is also very appreciative of the notion that working with the Congress, the National Center for Translational Sciences was funded, and he is moving ahead on that. There are new resources where he feels is an enormously promising area to recapture and refocus some of the energy, as well as the Cures Acceleration Network has additional resources. So this budget not only reflects our desire to make sure that we continue to fund new scientific discoveries but also to focus the resources on the areas that are the most promising strategies for the future.

HEALTH INSURANCE EXCHANGES

Senator SHELBY. In another area, the fiscal year 2013 budget proposal includes \$864 million for the implementation of the new health insurance exchanges. HHS has already received \$1 billion in ACA for the implementation activities and will receive a little more than \$1 billion more in mandatory funding for the exchange in 2013. Why is it necessary to appropriate an additional \$864 million for exchanges?

Secretary SEBELIUS. Senator, the request before this subcommittee for the additional resources for the Centers for Medicare & Medicaid Services (CMS) reflects the fact that we anticipate that the first \$1 billion funding that was included in ACA in 2010 will be fully spent by the end of fiscal year 2012. The good news is we are spending significantly under what was estimated by the Congressional Budget Office (CBO) which estimated, at the time of passage, that we would need about \$1 billion a year to implement this. So here we are looking at the end of 2012, and the first \$1 billion will be spent in the 2½ years since implementation.

What we are requesting with the \$800 million for new resources is basically a one-time cost to build the framework for the Federal exchange which will be run out of CMS. We are not clear at this point how many States will actually opt to run their own State-based exchanges, how many States will be in a so-called partnership where the Federal exchange will run part of the program and they will run part and how many will fully run. But we need an infrastructure, an IT system, an outreach system, an enrollment system. So this is the request for 2013 which again is not an ongoing request, but it is basically to build that framework for the federally funded exchanges.

ANTIDEFICIENCY ACT VIOLATIONS

Senator SHELBY. Madam Secretary, in the area of Antideficiency Act violations, a lot of us are concerned about the series of Antideficiency Act violations by your Department and the lack of a corrective action to address these unlawful funding practices.

Last July, you notified us that the Department had 47 violations that amounted to more than \$1.4 billion in illegal funding practices. At a time when the Department is receiving a historically high level of funding, I believe it is critical that you follow the letter of the law here.

Clearly, there are significant weaknesses over there. Are you following the recommendations of the Office of Inspector General (OIG), or are you trying to just ignore those past violations and move to a clean slate? What is going on?

Secretary SEBELIUS. Well, Senator, as we notified the committees in July, we were made aware that there were 47 contracts that were improperly funded dating back to 2002. I would say the positive news about that is that the contracts were not structured properly according to the Antideficiency Act, but the monies were all appropriately spent. They were not overspent.

Having said that, we took this violation very seriously. We self-reported it. We have engaged in a really robust activity at the Department working with the OIG, as well as working with GAO, on

everything from changing policies and procedures. We have trained 12,000 staff members on how this has to be done. We have gone back through the corrections and we would be delighted to give you in writing the full report on what has occurred so far and how seriously we take this. We do take it very, very seriously.

Senator SHELBY. Thank you.

IMPACT OF SEQUESTRATION

Senator HARKIN. Thank you, Senator Shelby.

Here is the order I have. I will ask the next round of questions for 5 minutes and then Senators Alexander, Brown, Johnson, Landrieu, Moran, Kohl, and Graham will speak.

Madam Secretary, next January we are facing a possible sequestration to reduce the national debt. I applaud the President for presenting a fair and responsible budget to help avert this outcome except in the areas I noted in my opening statement. It is critical for this subcommittee to understand the potential impact of this possible sequestration. CBO estimated that most non-defense discretionary programs would face a cut of up to 7.8 percent. Others, such as the Center on Budget and Policy Priorities, think the cut could be even larger. But for the sake of discussion, we will go with CBO's number of 7.8 percent.

My question. Have you looked at this? Could you give us some idea of what would be the impact of a 7.8-percent cut to programs like Head Start, the Child Care and Development Block Grant that you and Senator Mikulski were discussing, AIDS Drug Assistance Program, senior nutrition, all the other areas? What would be the impact of that 7.8-percent cut?

Secretary SEBELIUS. Well, Mr. Chairman, as you well know, within our Department the application of sequestration becomes even more complicated. We have some programs that would be fully shielded from any cuts. We have some programs which are limited to a 2-percent cut, which means that there would be an even harsher application of sequestration across the board on our programs.

So we think if it were a close to 8-percent cut, we would lose about 1 million slots in both Head Start and Child Care. I am sorry. Not 1 million. One hundred thousand slots in Head Start and Child Care. About 75,000 children would lose their places in Head Start and about 25,000 in Child Care.

We have about 17 million meals that would not be delivered to seniors relying on congregate meals and home delivery.

The AIDS Drug Assistance program would have to reduce its caseload by more than 12,000 people who are currently receiving antiretroviral drugs.

And the NIH budget, which I know is a concern to members of this subcommittee, would lose about \$2.5 billion. NIH is 40 percent of our budget. They would take a huge hit, and we think that research project grants would decline by—about 2,300 grants would be discontinued. More than one-quarter of the number estimated for fiscal year 2012 would be gone, and that would be about one-third of a reduction. One-third of the programs that we are estimating for fiscal year 2013 would cease to exist.

So it would have a huge impact across our Department and particularly for the areas that are not shielded and therefore would take an even more significant hit.

Senator HARKIN. Well, thank you, Madam Secretary. I am going to be asking that same question when the Secretaries of Labor and Education and the NIH Director are up here also. We have heard a lot from the defense community about what would happen to their portion of national security if they had a 7.8-percent cut. I think it is important for the American people to know about the rest of our national security because as President Truman once said so eloquently so many years ago, he said our national security is not measured just in tanks and guns alone but also in the health, welfare, and education of our people.

Secretary SEBELIUS. And as you know, these programs affect real people every day and are often life and death issues.

HEALTHCARE FRAUD, WASTE, AND ABUSE

Senator HARKIN. Exactly. Well, thank you.

Last, could you address the fraud and waste issue that I mentioned in my opening statement? We had that Budget Control Act cap adjustment that allowed a \$270 million increase, but when we got to conference, my friends on the other side of the aisle said no, and so we did not get that. What does that mean in terms of not returning money to the taxpayers?

Secretary SEBELIUS. Well, over the last 3 years, as I said, Mr. Chairman, we have been able to return about \$7 for every \$1 invested. So a \$270 million cut is significant. We know that our OIG had plans for the use of those resources to further expand some of our footprint on the ground to new strike forces in new cities, and those will have to be on hold. And we would love to work with you in a full funding for this program, which I think is an absolute win-win situation to stop people from stealing health dollars, taxpayer dollars, to continue to build our data analytic system so that we can do far more prevention on the front end and to have the boots on the ground to go after the perpetrators who we think are committing these outrageous acts of fraud and stop them quickly on the ground.

Senator HARKIN. Thank you, Madam Secretary.
Senator Alexander.

MEDICAID

Senator ALEXANDER. Thanks, Madam Secretary. Welcome. Thank you for coming.

I have just two preliminary comments and then a question.

Senator Mikulski mentioned Prescription Drug User Fee Act (PDUFA), and I wondered if we could not pause for a moment of bipartisan cooperation. We have four authorizing laws that establish fees for prescription drugs, medical devices, biosimilar drugs, and generic drugs, and we call them PDUFA, Medical Device User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Act. And I wonder if we could have a prize for an elegant replacement for all of those ridiculous names that we just throw around up here.

Secretary SEBELIUS. I have to say it took me most of the last 3 years to learn what people were even talking about when they would mention those to me. So I am all for it.

Senator ALEXANDER. Good. Well, I will work with the chairman and we will see what we can do about that.

I wanted to mention simply to you—and I will write you a letter about this—the Tennessee Poison Control Center. It is a very small program located at Vanderbilt University, but when kids get in trouble at home, they can telephone this poison control center and the parent gets talked through what to do about it rather than their going to the emergency room. It is 80 percent paid for by State and local funding. The Federal Government has a share of it. It saves about \$11 million a year, people think, in emergency room costs. And I just wanted to call it to your attention and you do not need to respond to it now. But I think it is worth noting the importance of it.

I wanted to just ask you a question in sort of a Governor-to-Governor way. You were a Governor. I was a Governor. We have these wistful—or at least I do—thoughts of those days as if they were trouble-free and everything was great, which is not exactly true, but it was a wonderful experience.

And I am worried that the new healthcare law has created a situation where we are 1 budget year away from a ticking time bomb in the States for Governors as they seek to comply with the Federal requirements for expansion of Medicaid and then Federal requirements for paying doctors who want to serve people who get Medicaid. I know our former Governor, a Democrat, Governor Bredesen, called that the mother of all unfunded mandates. He estimated that it will cost Tennessee an additional \$1.1 billion between 2014 and 2019. The Federal Government helps with that for a while, but then it is fully a State responsibility.

And then we add to that by a Federal requirement that doctors be reimbursed, providers be reimbursed for seeing Medicaid patients, which needs to happen otherwise it is a ticket to a bus that does not run. So people need to be able to see a doctor. But that adds another \$324 million a year to our State. And we are already in a situation where rising healthcare costs are squeezing money out of our State budgets that otherwise would be spent for higher education.

Now, this is not something new with President Obama. This has been going on for 30 years. I used to deal with it in Tennessee almost every year. I imagine you dealt with it as Governor of Kansas. You get down to the end of the budget process and you have got money either for Medicaid or the University of Kansas, the University of Tennessee, and it is a very difficult choice. And the healthcare costs keep going like this. And as a result in Tennessee last year, there was a 16-percent increase in State Medicaid spending, a 15-percent decrease in State support for higher education. That is not a Washington cut. That is a real cut. And so tuition goes up at the universities and quality goes down.

So as I said, this is not new. I first suggested to President Reagan a long time ago that we have a swap, that the Federal Government take all the Medicaid and the States take all of elementary and secondary education. Former Senator Kassebaum from

Kansas came up with a similar idea in the 1980s because of this combination of Federal controls and State spending.

Do we not have to do something to give States more flexibility in dealing with Federal Medicaid mandates in order to avoid exporting fiscal instability from Washington to State capitals that has the primary effect of squeezing down the quality of public higher education and raising tuition for the students who go there? And if that is a problem and it is going to start in the next budget year, 2014, can you suggest anything that we could do to make it easier?

Secretary SEBELIUS. Well, Senator, I did deal as you did with these budget challenges at the State level, and I have dealt actively since I came to this position with my colleagues around the country who are coping with this.

I will provide you in writing with some of this analysis, but just to give you a little snapshot. At least in the last 3 years, State share of spending on Medicaid is actually reduced nationally. Their overall budget share that they were spending on Medicaid in 2007 was higher than it was in 2010, which is the last full year that we have. Per capita costs for Medicaid have dropped in that period of time. They were above \$2,200 a person. They are now down below \$1,800 a person for the Medicaid budgets on average. And the overall State expenditures have dropped during that period of time. Some of that was clearly helped by the Federal resources that were put in as part of the American Recovery and Reinvestment Act, but the State picture is actually different.

The final thing that I asked our folks to do in terms of just analysis is look at underlying healthcare costs, which are continuing to rise, compared to higher education costs. And actually higher education costs are now up 63 percent in the last decade. And healthcare spending is up about 40 percent. So you are absolutely right. This is an ongoing challenge. It is one that people are coping with.

I would tell you that the Medicaid expansion that is on the horizon for 2014 is some pretty good news for States, and it is not only fully paid for by the Federal Government for the first 4 years, but the Federal share stays for the newly insured population between 100 and at the lowest 90 percent by the time the decade ends, so that the largest share that the State will pay in that period of time for millions of newly insured folks is a 10 percent match.

Having said that, States now absorb enormous amounts of costs for uncompensated care where people are coming into community hospitals, are in the workforce, and States are paying a share of that cost out of taxpayer dollars. So on balance, I think this is an opportunity to not only have a payment system under a lot of folks, get them in a healthier condition, but also I think States—ironically those who have the lowest-insured population are the biggest winners in some ways that have had not very generous Medicaid systems and have the most people that will actually become fully insured as part of this program.

We are also paying careful attention to the provider issue. As you say, there is a requirement that doctors who take care of Medicaid patients will be paid at the Medicare rate for the first 2 years fully out of Federal dollars. It is not a State mandate. It is fully out of Federal dollars. We know that it is not a long-term strategy. We

look forward to working with the Congress on a long-term strategy, but again, there is no mandate beyond those 2 years and there is no mandated State funding beyond those 2 years.

Senator ALEXANDER. Mr. Chairman, I am out of time and I would welcome that information.

Secretary SEBELIUS. I would be happy to provide it.

[The information follows:]

Medicaid spending in 2010 was estimated to be approximately 15.8 percent of State general fund spending but was 17.4 percent in 2006.

Numerous experts agree that States will actually realize a net savings from the provisions of the Affordable Care Act. States and local governments are estimated to save \$70–80 billion in State-funded health coverage or uncompensated care. A subsequent Urban Institute analysis estimates that the costs to States from the Medicaid expansion will be more than fully offset by other effects of the legislation, for net savings to States of \$92 to \$129 billion from 2014 to 2019.

Senator ALEXANDER. Nevertheless, our former Governor says these mandates are \$1.2 billion over 5 years in increased costs just for the expansion and \$324 million a year for the Medicaid reimbursement requirement.

Senator HARKIN. Thank you.

Senator Brown.

PRIMARY CARE WORKFORCE

Senator BROWN. Thank you, Mr. Chairman.

I note from the Secretary's comments that in those States where there was not a lot of support, at least from their elected officials, for ACA, those are the ones, because they are the poorer States, that tend to get the most. It is an interesting irony.

First of all, thank you, Madam Secretary. Thank you for last week for coming to Ohio, and the support you have shown for Project One really means a lot for my State. Thank you for that.

Thank you too for what you did, what CMS did, and what Federal Drug Administration (FDA) did on the progesterone issue, that pharmaceutical, the P7 to 17P, the progesterone that saved a huge—that have prevented a huge number of preterm births, resulted in tens and tens of thousands of babies born healthy instead of born with all kinds of illnesses and disabilities. And the work that you did, stepping up, having the FDA telling local compounders and local doctors and hospitals not to—to resist the cease and desist order and then the work that Mr. Berwick did at CMS in encouraging—in going to the States so that more and more States are using the progesterone at much less cost to taxpayers and to insurers than they are the KV Pharmaceuticals Makena. It has made a huge difference in public health.

I want to talk about a couple other programs that are involved in preterm birth rates. The Community Health Access Program in Mansfield, my hometown, trains community health workers to address the health needs of at-risk pregnant women, low-income White and African-American women in two different ZIP codes, and Richland County sort of invented this program. The local officials did, local doctors, local foundations, and dropped the low-birth-weight baby rate from twice the national average to below the national average. And using that program, the Community Health Access program, as a model, we added the community health work-

ers to the list of disciplines on which area health education centers should focus. I mean, that was the good news.

Also, the good news is the program of the maternal, infant, and early childhood home visiting program which has made a huge difference in after the babies are born, making sure they get the proper services—well, starting with prenatal care up through early education for children. Now, that is the good news.

The good news also is that the budget includes \$400 million for the maternal and infant home visiting programs. The bad news is that health education centers are zeroed out in this year's budget, funded at \$27 million in fiscal year 2012. It means increasing shortages of primary care providers especially in those rural and underserved areas.

My question is what will happen to the number of primary care workers if these programs are eliminated. How do we make up for this? I mean, it clearly saves large amounts of money when people get to the doctor, get proper nutrition, get prenatal care the way they should and babies are born healthy instead of born with all kinds of illness and disabilities. What is going to happen to the number of primary care workers? What do we do about this with these cuts?

Secretary SEBELIUS. Well, Senator, we are trying to focus as many resources throughout the Department as we have on increasing the primary care workforce, and that is everything from shifting graduate medical education slots to new funding for the National Health Service Corps for primary care providers has been tripled in the last 3 years, and we want to continue that effort. We are looking at all the strategies that we have, payment rates to encourage primary care choices for medical students, and a series of activities. So we certainly share your concern around that.

I know that you and I have talked before about your Mansfield, Ohio success program, and I wanted to bring to your attention that we have recently launched an initiative we are calling Strong Start under the Center for Medicare & Medicaid Innovation that will be working with the March of Dimes, with the American College of Ob-Gyns, with providers across this country around a focus on births that occur 39 weeks and beyond, knowing that there is a huge health difference between preterm babies and post-term babies and that appropriate prenatal care, maternal information, encouraging hospitals to reduce the number of voluntary preterm deliveries that they are willing to engage in and adopting some of the best practices that you have in Ohio. I would love to get you some information about this program because actually there may be some ways to take what you have learned in Mansfield and make sure that we can not only spread it in Ohio but in various other parts of the country. But it is an initiative we think is not only hugely important to reduce long-term health costs, but good for moms, good for babies, good for the long-term community survival. So we are really looking at how to bring this program to scale throughout the country.

Senator BROWN. Thank you.

Mr. Chairman, I will only make a comment, if I could, not another question. A comment.

First of all, thank you for that. The Mansfield program has already spread to a couple other Ohio cities.

I will make one comment about—you had mentioned Graduate Medical Education (GME) slots. A subset of that—and this is not a question, just a comment, if you would—is children’s GME. Every administration in both parties cuts back this program after we began it. I first introduced it in the House in 1998, I think, after a visit to Akron Children’s Hospital. We need a unique way, a separate way of funding graduate medical education for children because it does not fit in, obviously, the Medicare funding stream that creates money for GME. Every year a President cuts it or eliminates it. We need to get it back up at least to the level of \$250 or \$300 million, which it has been many of the last few years. Chairman Harkin has been very helpful to that in the past. Many of my Republican colleagues too. It was a very bipartisan effort in the House when I first started it. And we will figure out a way to do that. I know you do not oppose it, but I know you know that we will restore it and come up with the money. And I appreciate that shift of responsibility every year.

But thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Brown.

Senator JOHNSON.

HEALTHCARE COST ESTIMATES

Senator JOHNSON. Thanks, Mr. Chairman.

Madam Secretary, welcome.

I would like to concentrate on the cost estimates of the healthcare law because that is what I was concentrating on last year and there has certainly been new information to surface since then.

So I would like to first start out by just pointing out that when they passed Medicare back in 1965, they estimated it out 25 years and said it would cost \$12 billion in 1990. In fact, it ended up costing \$109 billion, nine times the original cost estimate. So I do not have a great deal of faith in some of these estimated numbers, and I certainly do not have faith in the estimates for Obamacare.

In the President’s fiscal year 2013 budget just released, he has increased the mandatory outlays for health insurance exchanges by \$111 billion from \$367 billion in his last year’s budget to \$478 billion. Is that correct?

Secretary SEBELIUS. Yes, Sir.

Senator JOHNSON. The Community Living Assistance Services and Support program (CLASS Act)—I think we end up recognizing that that was not going to work out. That was not going to be financially solvent. So that was \$86 billion of the claimed \$143 billion of deficit reduction in the first 10 years. Correct?

Secretary SEBELIUS. The original estimate, yes.

Senator JOHNSON. Right. And the original estimate for deficit reduction in the first 10 years was \$143 billion. Correct?

Secretary SEBELIUS. Yes.

Senator JOHNSON. So now we have reduced that \$143 billion by \$86 billion by not getting revenue from the CLASS Act and now \$111 billion because we have increased the mandatory cost of the exchanges. Correct?

Secretary SEBELIUS. I am assuming the numbers are correct. I am sorry. I do not have them.

Senator JOHNSON. They are.

So when you add those together, that is \$197 billion added to the first 10-year cost estimate of Obamacare. So now we are, instead of saving \$143 billion, adding \$54 billion to our deficit. Correct?

Secretary SEBELIUS. Sir—

Senator JOHNSON. We will submit that for the record. That is basically true. So instead of saving \$143 billion by this administration's own figures and budget, we are now adding \$54 billion to our deficit in the first 10 years. To me that would be the first broken promise.

It is true that the President said that by enacting this healthcare law, every family would save \$2,500 per year in their family insurance plan. Correct?

Secretary SEBELIUS. He said that once the exchanges are up and running and you have an affordable marketplace, the insurance estimates were that the rates would go down by about \$2,500, yes. That has not occurred yet clearly.

Senator JOHNSON. The Kaiser Family Foundation has already released a study saying that the average cost for family healthcare plans is up \$2,200. Correct?

Secretary SEBELIUS. Again, there is no new marketplace yet for insurance policies.

Senator JOHNSON. But the cost is already up. I mean, we are already different by \$4,700. It is going to be hard to get us down to \$2,500 as cost savings. I would consider that broken promise number two.

It is also true that President Obama very famously said, "If you like your doctor, you will be able to keep your doctor. Period. If you like your healthcare plan, you will be able to keep your healthcare plan. Period." No one will take it away no matter what.

Now, we have granted quite a few waivers, about 1,200 to 1,700 waivers on about 4 million Americans. Correct?

Secretary SEBELIUS. I have no idea what waivers you are talking about.

Senator JOHNSON. Those are waivers—

Secretary SEBELIUS. Doctors and health plans? Is that—

Senator JOHNSON. Just waivers from having to implement portions of the healthcare law that probably would have forced those workers off their employer-sponsored care.

Secretary SEBELIUS. Again, I would be happy to answer these questions, but I have no idea what waivers you are talking about.

Senator JOHNSON. The waivers that HHS has granted to employers.

Secretary SEBELIUS. To do what?

Senator JOHNSON. Not having to implement sections of the healthcare law.

Secretary SEBELIUS. There have been waivers granted to employers, yes.

Senator JOHNSON. And had those waivers not been granted, chances are those employees probably would have lost their employer-sponsored care. Correct?

Secretary SEBELIUS. I have no idea. I mean, I am happy to answer those one at a time and look at the waivers and see what—

Senator JOHNSON. Unfortunately, I am pretty short on time.

The CBO alone estimated that 1 million people would lose their employer-sponsored care. Now, I think that is a wildly underestimated figure. The McKinsey Group has surveyed employers and said that 30 to 50 percent of employers plan on dropping coverage as soon as the healthcare law is implemented. Douglas Elmendorf I think has even admitted that that is credible evidence for him to retake a look at that estimate.

The decision an employer is going to have is pretty linear. They can pay \$15,000 for a family plan or pay the \$2,000 penalty, and they are not exposing their employees to financial risk. They are making them eligible for \$10,000 subsidies if they make a \$64,000 household income.

Are you sure that only 1 million people—only 1 million people—will lose their employer-sponsored care? Last year you said there are 180 million to get coverage through their exchanges. Are you certain that only 1 million people are at risk of losing their employer-sponsored care and get put in those exchanges?

Secretary SEBELIUS. Sir, you are quoting a CBO number. All we have to go on is what has happened in Massachusetts where actually more people have coverage today with the exchange, with a very similar framework, than did before. They have not lost employer coverage. More employers have come back into the market. So the practical application of a State-based exchange on the ground with similar penalties and a similar framework is employer coverage rose. It did not decrease.

Senator JOHNSON. It is not similar because those employees lose coverage for 6 months before they are eligible for the exchanges, and there are not these types of subsidies that create a huge incentive for employers to drop coverage and make their employees eligible.

Bottom line here. The cost of this healthcare law is so uncertain. Do you not think we maybe ought to put the brakes on it? You know, Nancy Pelosi said we have to pass this law to figure out what is in it. What I do not want to see is we have to implement it to figure how it is going to bust a hole in our already horribly broken budget.

Secretary SEBELIUS. Well, I would just say, Senator, the statistics you gave on the rising healthcare costs for families and small business owners that Kaiser put out recently is the very reason that we desperately need a new insurance market. The private insurance market is basically on a death spiral where younger and healthier people are dropping out, where small employers who cannot afford to pay 18 percent more than their large employers are dropping out.

Doing nothing is really not an option. We now have 50 million uninsured in this country, and that number has gone up year in and year out, and the costs continue to rise. So a new market with competition putting people in a larger pool, making companies compete on the basis of price and quality, not who can lock out folks with a pre-existing condition or drop them out or drive them out of the market is desperately needed by millions and millions of

Americans, which was part of the driving force of passing the healthcare law.

Senator JOHNSON. Madam Secretary, if 50 percent of employees lose their coverage, that will cost us \$500 billion a year, not \$95 billion.

Thank you, Mr. Chairman.
 Senator HARKIN. Thank you.
 Senator Kohl.

PHYSICIAN PAYMENTS

Senator KOHL. Thank you, Mr. Chairman.

Madam Secretary, I would like to ask you about implementation of the Physician Payments Sunshine Act which, as you know, is a law that I worked on with Senator Grassley. The Physician Payments Sunshine Act requires transparency that will help prevent conflicts of interest, while at the same time highlighting the legitimate and necessary relationships between doctors and industry.

In my State of Wisconsin, the Milwaukee Journal Sentinel wrote a series of reports on problems that arise when consumers do not know these payments are exchanging hands. And recently leading national newspapers published editorials supporting the Physician Payments Sunshine Act. Industry and consumer groups alike are calling for CMS to act on this piece of legislation.

With all of this support, I would like to ask you what the delay that has occurred is all about.

Secretary SEBELIUS. Well, Senator, we share your interest in making sure that this act is fully realized and think it is a very important issue for consumers to know exactly what is going on.

We had a proposed rule in December 2011. The comment period closed on February 17. So about 3 weeks ago. We are working with comments and stakeholders and we fully intend to publish a final rule later this year so our collection of data can begin before the end of 2012. And we would be eager to work with you on full implementation.

Senator KOHL. Could I request that you make a strong effort to push up that implementation time to no later than the first half of this year?

Secretary SEBELIUS. Well, as I say, we have got the comments in and, again, we will work aggressively to get this in place. But the comment period closed on February 17, and we are doing outreach to stakeholders and others reviewing the comments and we will make every effort to get it published as soon as possible and get data collection beginning this year.

Senator KOHL. Thank you very much.
 Senator HARKIN. Senator Kohl, thank you.
 Senator Graham.

AFFORDABLE CARE ACT WAIVERS

Senator GRAHAM. Thank you, Mr. Chairman.
 Thank you, Madam Secretary, for coming over.

Very quickly about the waivers. As I understand it, there have been, oh, several million people covered by a waiver from your Department basically saying to the healthcare entity we are going to

waive the requirements in Obamacare for your organization. Do you know how many people have received that waiver?

Secretary SEBELIUS. Senator, again, there are a variety of different provisions of the law where we were given some administrative authority. So people in the so-called mini-med plans who had some kind of health coverage but not a robust plan—a number of those employers were given waivers knowing that the mini-meds cease to exist in—I can get you in writing the numbers and the different categories, but I do not know off the top of my head.

Senator GRAHAM. I would appreciate that.

What percentage of those plans are union plans?

Secretary SEBELIUS. I can tell you in the waivers that we have given, the union waivers were, I think, the fourth-lowest category. Private employers were number one. City and State governments were number two. I think the education system was number three, and then I think union plans were in the fourth category.

Senator GRAHAM. Okay. So city and State governments. Union plans were four.

What I would like from you is a detailed analysis of the number of waivers given, the number of plans affected, the number of people within those plans, and what percentage of those plans happen to be union plans.

Secretary SEBELIUS. I would be glad to do that.

[The information follows:]

Starting in 2014, the Affordable Care Act bans annual dollar limits on coverage of essential health benefits. Until then, annual limits are restricted under the Department of Health and Human Services (HHS) regulations published in June 2010.

For plan years starting between September 23, 2010 and September 22, 2011, plans generally may not impose an annual dollar limit on coverage of essential benefits such as hospital, physician, and pharmacy benefits of less than \$750,000. The minimum annual dollar limit is \$1.25 million for plan years starting on or after September 23, 2011, and \$2 million for plan years starting between September 23, 2012 and January 1, 2014. For plans issued or renewed beginning January 1, 2014, all annual dollar limits on coverage of essential health benefits will be prohibited.

A small number of workers and individuals currently have access to only limited-benefit, or “mini-med,” plans with lower annual limits than are generally permitted by law and which provide very limited protection from high healthcare costs. Estimates by employers and insurers indicate that requiring mini-med plans to comply with the new rules could cause mini-med premiums to increase significantly. This increase in premiums could force employers to drop coverage leaving some workers without even the minimal insurance coverage they have today.

In order to protect coverage for employees in mini-med plans until more affordable and more valuable coverage is available in 2014, the law and regulations issued on annual limits allow HHS to grant temporary waivers from this one provision of the law (PHS Act, section 2711(a)(2)) if compliance with annual-limit requirements would result in a significant decrease in access to benefits or a significant increase in premiums. Plans that have received such waivers must comply with all other provisions of the law, and, as a condition of the waiver, were required to alert consumers that the plan has restrictive coverage and includes low annual limits. Additionally, these waivers are temporary and after 2014, no waivers of the annual limit provision are allowed.

The following chart breaks out approved waiver applicants by type. Please note that the annual limit waiver data is publicly available at http://cciio.cms.gov/resources/files/approved_application_for_waiver.html and includes: applicant information, denials, reconsiderations, and health reimbursement arrangements.

Type of Plan	Number of waivers
Self-Insured employers	722
Multi-Employer plans	417
Non-Taft Hartley union plans	34

Type of Plan	Number of waivers
Health insurance issuers	50
State-Mandated policies	5
Association plans	3

MEDICAID FUNDING

Senator GRAHAM. I appreciate that.

Now, Medicaid. You know this program well. In South Carolina, as I understand it, if the Medicaid eligibility is expanded and implemented in 2014 as envisioned by Obama healthcare, my State will be required to come up with close to \$1 billion of new State funding over a 6- or 7-year period. That is pretty true throughout the country. Is it not?

Secretary SEBELIUS. No, Senator, it actually is not. And I had some of this discussion with Senator Alexander, and I continue to have it with Governors. The way the law is constructed, actually the first number of years of the plan is fully federally funded, 100 percent Federal funding.

Senator GRAHAM. How many years of Federal funding?

Secretary SEBELIUS. There are 4 years where it is 100 percent, and the Federal funding then goes from 100 to the lowest in a decade that the Federal Government contributes is 90 percent of the——

Senator GRAHAM. What about the next decade?

Secretary SEBELIUS. The next decade is not described in this bill, but what you are talking about is the budget window. What I keep hearing about is this concern that somehow in the next several years there will be \$1 billion in South Carolina taxpayer money and that——

Senator GRAHAM. I guess my concern is that we are expanding Government healthcare programs, to me, that need to be reformed, not expanded. And you may not hear this when you talk to Governors, but I sure hear it from Democrats and Republicans. They are worried to death about Medicaid expansion as proposed in Obamacare.

So I have got a simple proposition. Would you allow a State to opt out of Medicaid expansion if they chose to under Obama healthcare?

Secretary SEBELIUS. Senator, what we have supported from the beginning and actually asked that it be accelerated is if a State has a proposal to cover the same number of people, to provide health coverage, and has a different methodology for doing that, we would be eager to take a look at that and work with them around that.

Senator GRAHAM. Well, but my question is would you allow a State to just simply opt out because they have responsibility for their citizens. The only way they can opt out is to do it the way you approve of. Is that right?

Secretary SEBELIUS. Well, Senator, as you know, I do not even have the authority. Right now, the law provides for us to give an accelerated option to a State plan.

Senator GRAHAM. What if the Congress said to all the States if you want to stay in Obama healthcare Medicaid expansion, you

can, but if you want out because you think it is going to bankrupt your State, you have that option. Would you oppose that?

Secretary SEBELIUS. I would, Senator, without an alternative for what happens to those folks. Would they be eligible for the exchange which would be a more expensive strategy?

MEDICARE SOLVENCY

Senator GRAHAM. Well, I guess what I am saying is that Medicare and Medicaid are really Federal Government programs. Do you think Medicare is in a world of hurt financially?

Secretary SEBELIUS. I think that the long-term solvency of Medicare is a topic that needs to absolutely be discussed.

Senator GRAHAM. Would you agree that Medicare and Medicaid have grown in unsustainable ways, and without serious reform, those two programs alone are going to bankrupt the country? And I guess my concern is before you add another Government program where you subsidize the private sector with a Government plan, I would like to fix the two that are going to bankrupt the country. And do you have a plan to save Medicare from insolvency?

Secretary SEBELIUS. Well, as you know, Senator, in ACA, we began—

Senator GRAHAM. Does President Obama—and I will end this. My time is up. Does President Obama in his budget or anywhere else have a plan that would adjust the age for eligibility, means test for higher incomes in terms of premium subsidies? Is there a plan the President has come up with in the last 3 years to save Medicare from bankruptcy?

Secretary SEBELIUS. Has he proposed a means test or raising the age? No, Sir.

Senator GRAHAM. Has he proposed a plan to save Medicare from bankruptcy?

Secretary SEBELIUS. He has proposed certainly a plan that adds seriously to the life of Medicare. This budget continues that effort, and we are eager to work on an even longer-term strategy.

Senator GRAHAM. Finally, if Paul Ryan comes up with a plan to make Medicare more sustainable and fiscally sound over the next 75 years, would you at least applaud him for trying?

Secretary SEBELIUS. Well, I think that what I have seen so far, Senator, from Congressman Ryan is really blowing up the program as we know it, not sustaining it. But I would be eager to engage in any conversations about protecting beneficiaries, fulfilling our commitment to long-term health benefits, and finding a sustainable way moving forward.

Senator GRAHAM. Thank you.

Senator HARKIN. Senator Pryor.

HEALTHCARE EXCHANGES

Senator PRYOR. Thank you, Mr. Chairman.

I wish that Senator Johnson were still here because I think that if I understand correctly, Madam Secretary, the CBO at some point this month is going to update the healthcare baseline and give us some updated numbers about healthcare. So that will be helpful. But I would like to see those when they come out and maybe visit with you further about that.

Let me, though, jump into something that you mentioned a few moments ago in answering Senator Graham's questions about healthcare exchanges. I would like to get an update from you on where you are, as the Federal Government, but also where the States are in terms of setting up the exchanges. Where are they in that process?

Secretary SEBELIUS. Well, Senator, every State in the country, I think with the exception of two, have actually drawn down a planning grant. A number are moving ahead with the next level of implementation. We have laid out a strategy and are working actively with States around the country around basically a choice of three pathways. Either the State fully runs their insurance exchange and will be up and going and we will certify them for activity somewhere in 2013. A State can, on the other hand, engage in a so-called partnership program where the Federal Government will run pieces of the program and they will run other pieces. And the final is that they decide that they are fully not going to engage and that the Federal exchange will take care of the exchange activities in their State.

And States are in a variety of activities. A number have legislation pending this year. Some are issuing executive orders. So we will know more definitively by the end of this calendar year where exactly are the host of States because there are a lot kind of in that middle space where they are trying to figure out if they are going to be fully up and running or in a partnership.

Senator PRYOR. My impression is that the exchange part of healthcare reform is very important because it could—at least in theory—make health insurance much more available to many more people and hopefully you would get a better value for the dollars you spend on healthcare. So I would encourage you to keep pushing and keep trying that.

Secretary SEBELIUS. We definitely are.

MEDICARE FRAUD

Senator PRYOR. And also one other thing that Senator Graham asked about was Medicare and the sustainability of Medicare. I know that one of the things you have been working on is trying to come up with a better way to quantify the amount of real fraud in Medicare. And I think everybody in this room wants to do that and wants to know exactly how much fraud there is and how we can identify it and stop it better than we have in the past. So, as I understand it, you are working on some new measures on fraud. What is your timetable for trying to have these new fraud measures in place so we will have a better sense of how much actual fraud is in the system?

Secretary SEBELIUS. Well, I think, thanks to the resources that we were given as part of ACA, which actually is the toughest anti-fraud legislation ever passed in this country, we have some new data analytic tools. Part of that led to this takedown of the Texas doctor who allegedly committed about \$375 million worth of fraud with home health agencies. But part of it is a predictive analytic system that finally catches us up with the private sector. A lot of that is in place now.

Senator PRYOR. It is really great.

Secretary SEBELIUS. We did not have it 2 years ago and it is now there. We brought the billing systems into one place. We can now watch what is happening in one spot and share it with law enforcement.

Senator PRYOR. And it is in real time now?

Secretary SEBELIUS. You bet. You bet.

Senator PRYOR. That was one of the problems before.

Secretary SEBELIUS. It did not exist. There were 12 different billing systems with Medicare. So it was almost impossible to track what was actually happening real time.

Senator PRYOR. I would love it if some of your folks could come into our office.

Secretary SEBELIUS. We would be glad to do that.

Senator PRYOR. You do not have to do it. I know you have got staff who can brief my staff and me.

Secretary SEBELIUS. Now, Dr. Peter Budetti is the head of that unit, and we have never had an administrator at CMS who has actually been in charge of anti-fraud activity.

HEALTH PROFESSIONS

Senator PRYOR. Let me just make two really closing comments because I am going to run out of time here.

We have a program in Arkansas, the Arkansas Area Health Education Centers (AHEC) program. It works very well in our State. We have eight of these little regional offices. They are pretty much satellites of our medical school. They do a lot of training. They provide lots of important healthcare in eight different places around the State that people would not have access to otherwise.

I am concerned that when I look at the President's budget, we are looking at cuts there, and I am afraid about cutting those programs. I do not know about every other State, but our program works very, very well. It is really a key component of trying to provide better healthcare all across the State, and obviously, like some other States here, we have some poverty issues and some real challenges in rural Arkansas trying to get healthcare providers, specialists and even primary care physicians, nurses, and dentists to some places in our State. I would hope you would look at Arkansas because we have an AHEC program that works very well. In fact, Senator Tom Coburn—medical doctor—is a product of that. He actually went through the Arkansas AHEC in western Arkansas.

And the last thing I wanted to say is just thank you for helping with a Bureau of Health Professions issue. I want to thank you all for working very diligently to help correct a provider shortage designation in Lepanto, Arkansas, which again is one of these communities that just has almost no access to healthcare and you have paved the way for them to get a physician there in rural Arkansas. So thank you for doing that.

Secretary SEBELIUS. Good. Glad it worked.

Senator HARKIN. Senator Moran.

CRITICAL ACCESS HOSPITALS

Senator MORAN. Mr. Chairman, thank you.

Secretary, nice to see you. Glad our paths have crossed this morning.

Just a couple of questions. First of all, I assume that you had a role to play in the President's budget, and I wanted to raise with you or at least ask you to assure me that the cuts in the critical access hospital program you think are appropriate or necessary. The President's budget has a couple of proposals. One is a mileage restriction. Depending upon what that mile might turn out to be, it affects from a small number to a large number of critical access hospitals in Kansas, and then a reduction in the so-called 101 percent of costs to 100 percent of costs. And I think we would agree that the word "cost" does not cover the cost.

As you know, in our State, those critical access hospitals in many ways determine the future of a community, and the absence of their presence, no physicians, and the citizens reluctantly decide they no longer can call home home.

I wanted your thoughts on the reductions in spending related to critical access hospitals.

Secretary SEBELIUS. Well, Senator, you and I have talked about this in the past, and I do share your concerns about access to healthcare particularly in rural areas and know how important that is to community survival. I do think that in a better budget time, this would not have been recommended, but I think that the framework of a possible 10-mile differential, if there is another hospital within a 10-mile radius, then it is unlikely that that is a critical access hospital because there is another choice in a relatively close space.

And making sure that 100 percent of payment is paid—it is not reduced below 100 percent. It is 100 percent. I think working on then the definition of what that cost means is a secondary issue, and I would be glad to work with you on that. But paying 100 percent I think is very important.

Senator MORAN. Well, I would agree that if we actually paid 100 percent of actual costs, that is a different story than paying 101 percent of something less than costs or paying 100 percent of something less than costs. And so the definition of what is actual costs needs attention, and the percentage would become much less important if actual costs were actually covered.

I assume that the mileage change, if enacted, would be retroactive, would be current, and so hospitals that currently receive a critical access hospital designation would lose that. I would indicate that one of the things that has troubled me from the very beginning of this conversation about the mileage restriction is you can have two critical access hospitals within 10 miles, 25 miles, 20 miles, whatever that number is. Both of them then are affected by the change, and you lose the designation for both hospitals to be a critical access hospital, which very well may eliminate access anyplace within that region. And so this being prospective, taking into account the consequences to two hospitals in the same radius, I think this needs to receive greater thought than just a strict mileage requirement.

Secretary SEBELIUS. Well, and again, we would be happy to work with you on that issue because that certainly is not the intent. As you say, applied arbitrarily, what you described could happen, but we will be glad to work with you on that.

NATIONAL INSTITUTES OF HEALTH FUNDING

Senator MORAN. I welcome that.

The other topic I wanted to raise was NIH funding. The President's budget is a continuation of the current levels of funding. Budgeting is about priorities. And I understood from your testimony but from a conversation that you had with Senator Shelby, NIH indicates that—or at least the administration indicates that through new grant management policies, more can be done with less, I think is the summary of what is being suggested.

But I notice that, for example, the CMS budget goes up \$1 billion while the budget for NIH is held constant. And if there is more bang with the buck, more able to do more with less, I wonder why that is not applicable elsewhere and why it seems to be directed toward NIH. I worry when there is not a consistent availability of money at NIH, that we begin to lose the infrastructure, the commitment of young people to research and to science wanting to pursue that career and know that they have a place to go to work. I think NIH is critical in our global competitiveness, and ultimately in saving healthcare costs that the chairman talks about, preventive medicine, NIH has a significant component to play in finding the cures and treatments that in the long run save dollars. So in that sense, for the quality of life and for the economics, NIH is something that is very important, and while other items within your budget received increases, NIH did not. And those priorities—I would welcome your thoughts on that.

Before I run out of time 37 seconds ago, I have invited the Acting Administrator of CMS to Kansas, and I would ask you to help me accomplish that goal. Since I have been in the Congress now for 15 years, I have invited every CMS Administrator to come to our State. Over the years, two have accepted that invitation. And I certainly would welcome the opportunity to have Ms. Tavenner with us in Kansas and get a feel for how we deliver healthcare in our State and to meet with providers and patients. And if you can encourage your Acting CMS Administrator to join your Senator in your home State, I would appreciate that very much.

Secretary SEBELIUS. I will certainly follow up on that with Marilyn. I know she is eager to get out and about and around the country. So I did not know that invitation was pending.

Let me just, if I can, Mr. Chairman, briefly address the NIH situation, which again we share this priority.

I would say that the requests for the new resources at CMS are, one, due to the growing needs in both the Medicare program with the baby boomers coming in. There are about \$200 million dedicated to Medicare and Medicaid issues, and the \$800 million is, again, basically a one-time cost for infrastructure.

I do think the NIH budget with a new opportunity for clinical and translational science awards, which has an additional budget allocation with Dr. Collins able to allocate just under an 8-percent increase in new grants, about 670 new grants—we are trying to drive the resources toward just what you describe which is the most strategic way to keep not only young people involved and engaged but keep the acceleration of promising breakthroughs on the

horizon. And he feels that this is a budget that does accomplish those goals.

Senator MORAN. Thank you, Madam Secretary. I will submit a question to you in writing related to Part D preferred network plans. If you could respond to the subcommittee, have the Department respond to the subcommittee, I would appreciate it.

Secretary SEBELIUS. Sure.

Senator MORAN. Thank you, Mr. Chairman.

Senator HARKIN. Senator Landrieu.

HEALTHCARE REFORM

Senator LANDRIEU. Thank you, Madam Secretary. And I want to commend you for your tenacity and your focus on helping stand up a major reform, very few reforms of its nature in our Nation's history, as we try to press forward on the dream and goal of every American, being able to access affordable healthcare. It has been tried by many Presidents—Democrats and Republicans—in the past, and President Obama, with your leadership and with our help, despite organized and ferocious and in some cases vicious opposition from the other side, are actually beginning to implement the opportunity for every person, regardless of whether they come from a rural area, a suburban area, or an urban area, whether they are white, black, Hispanic, Asian, whether they have a full-time job or a part-time job, whether they have a pre-existing condition, a birth defect that they were born with, an accident that they get into, that they actually would not have to go bankrupt or die on the side of the road, that they would actually have quality care. It is quite remarkable.

There are only a few countries in the world that have achieved that, some at great expense. Others are struggling with it. There are only a handful of countries that are trying to be as sophisticated in their private-public partnership. And as you know, we are not doing that by running government programs. We are doing it in an attempt to work with the private sector to provide this kind of care.

And the numbers that you gave to Senator Alexander were particularly telling, that the cost per person seems to be coming down. Opportunities for new affordable insurance are showing themselves because I am personally a little tired of Republican Governors out there whining that the reasons that they have to cut higher education is because of the increase in spending for healthcare. Part of the reasons that their budgets are shrinking is because they are giving tax cuts they cannot afford. They are giving tax credits to corporations that should be paying taxes in their State.

The second point that I want to make, Mr. Chairman, is that it is not just the Federal Government's responsibility to provide healthcare services to our citizens. It is a responsibility of the State, the Federal Government, and local government. When did this become a complete Federal problem? So State Governors need to man up and woman up and do their job to provide funding necessary to help kids that are born with defects, birth defects, to help their people that get into car accidents and lose their legs, their arms, their eyes, their ears, lose their hearing, and stop whining.

Now, if they can come up with a better plan, if the Republicans—which they have not in 3 or 4 years or 5 years to fix this, then I will listen. Until then, we are going to implement the plan that we passed.

CHILD WELFARE AND ADOPTION ASSISTANCE

Now, my question, which is a small part of your budget, but as you know, it is my focus. Your entire budget, which is \$16.2 billion, does a tremendous amount of good to help families in America. I guess we have about 150 million families. We have 300 million people, 2 people per family. I am just roughly estimating—125 million families. You do a lot in this budget for their health, for helping them with day care so many of our families can go to work, providing good healthcare.

A small number of our families, as you know, are very, very fragile and in critical situations, and we have tried with this subcommittee to give you some special funds to help keep these families together and particularly help children that get separated from their families. We call them orphans, children in foster care. They only represent one-half of percent of all the children in America are in foster care.

So I just want to point you to your Child Welfare and Adoption Assistance program of about \$362 million, the Chafee program \$45 million for training of foster youth, the \$39 billion for adoption incentives, and the \$63 million for promoting safe and stable families. We have worked across the aisle here for many years. While we do fight about healthcare, we really do not fight about adoption and foster care.

And I just want to ask you and bring to your attention that your Department, prior to you getting there but continuing under your good leadership, has increased the number of adoptions from 14,000 in 1990 to 52,000 this year. That is an incredible—

Secretary SEBELIUS. That is a big jump.

Senator LANDRIEU. It is a big jump, Madam Secretary, and I want to thank you. A lot of this work was done by the Clinton administration. This was a big priority for President Clinton and First Lady Hillary Clinton. But I think that is a real testimony, Mr. Chairman, to your leadership as well. We have increased domestic adoptions from 14,000 a year to 52,000 a year.

My question would be could you look more closely at these numbers that I have shared with you and see if you can more strategically align them with the goal of bringing this number up, Madam Secretary, from 52,000 to about 100,000. We have got to double it. That is the number of children that are available for adoption, but we are not connecting them well enough to a home. We are either failing to keep them with their birth families or we are not connecting them to be adopted. And you have got some resources in here specifically programmed by the Congress. So could you comment on that?

And I want to thank you for your appointment of George Sheldon who seems to be a real expert in this area and has been working closely with us on it.

Secretary SEBELIUS. Well, Senator, I would be remiss if I did not recognize your incredible leadership and tenacity around these

issues looking out for kids who often do not have a champion, and you certainly have been one.

We have a request before the Congress in this budget to increase spending by \$250 million in the foster care and permanency area, \$2.8 billion over 10 years. And it would be a new initiative to incentivize all kinds of improvements in foster care, requiring child support payments to be used in the best interest of the child rather than offset State and Federal welfare costs that often can be conflicting.

So we agree that resources need to be increased and we need to do a better job targeting those strategic resources to make sure that these programs are enhanced, and we would really look forward to working with you who have thought about this for a long time and have some, I think, very good ideas about how to improve the well-being of our children in foster care, the transitioning issues, I know, you know, the huge step to provide healthcare to the kids aging out of foster care, the same way that other kids can be on their parents' plan. These are our children. So carrying them on a healthcare plan.

We have a new proposal, Senator, that I will make you aware of which really deals with the reallocation of the State funding which currently is not accessed around abstinence-only education. A number of States have just said we are not going to take those resources. We would like to reallocate those funds and focus on pregnancy prevention in foster youth where the data is pretty alarming in terms of how many young girls end up becoming pregnant. So there are some strategies across our budget that I think focus some new resources.

Senator LANDRIEU. Well, I would only say, Mr. Chairman, you have been very generous, but you are both in an excellent position to focus on this because really focusing on the needs of foster children, particularly helping them stay in the schools that give them the stability. And, Mr. Chairman, as the chairman of the Education Committee, I think there can be a tremendous amount of—there is a lot of interest of Senators on both parties, and I think we can make advancements.

But remember that the best support for a child is a good parent. You know, we can give all the government services we want, but if we could just help these children get into the arms of a loving, responsible adult, either to the mother that they were born to with help and support or to an aunt or a kin or a relative or to someone in the community, that is the best prevention of pregnancy and jail and mental illness is to have a good, loving parent. So if we could just focus our efforts, build on this great, extraordinary work—we have doubled the number of children finding forever-homes—I would be grateful and so will the children.

Secretary SEBELIUS. I look forward to working with you.

COMMUNITY TRANSFORMATION GRANTS

Senator HARKIN. Thank you very much, Senator Landrieu. And I join the Secretary in thanking you for your great leadership in all the years you have been here in this area. I think you have provided just sort of a beacon for the rest of us to follow in how we are going to address this issue of our foster kids and kids that just

have a tough life and making sure that they just have a little bit more gentle care and loving care. So I thank you for your great leadership in that area.

Madam Secretary, I am going to start a second round, but I guess I am going to be the only one.

The one other thing I want to cover with you is something near and dear to my heart that I have worked on for a long time. I put it in ACA as part of the prevention and wellness program, and it was called Community Transformation Grants. This was based upon earmarking things that we had done in the past and looking at what the community has done. We had some tests around the country to see how communities could come to join together, such as getting grocery stores, YMCAs or YWCAs, schools, businesses to figure what they could do in a community-based setting to provide for healthier lifestyles. And that is why it was called a Community Transformation Grant.

In fiscal year 2011, \$145 million was allocated to this Community Transformation Grant. The CDC announced a competition that, for most of the country would require statewide programs. For example, in Iowa, Dubuque or Des Moines could not apply on their own; they had to be part of a statewide application. Well, that is not what we intended. As I look at the guidance put out by CDC, to be eligible, grantees had to serve either a city of 400,000 or more or a State. So in most States, YMCA or community health centers could not even apply directly. Grants were for \$1 per capita.

I often cite the Trust for America's Health. They did a very thorough study on this, and they found that investments in prevention could produce savings within 5 years based upon spending of \$10 per person.

So we can take that \$145 million and just sort of spread it around, but I am not certain it is going to have that much of an impact unless it is targeted. So that is why we wanted it to be community-based programs.

Also, the CDC said funding must be used on a minimum of three goals, reducing obesity by 5 percent, reducing smoking rates by 5 percent, increased access to preventative services by 5 percent. Now, again, maybe States are equipped to do all that, but in a lot of cases, community groups have just one focus. The CDC is now making them focus on the three specific goals.

Well, that is not what we intended. So in our Senate bill last year, we got language in there to continue the program your Department designed but requiring that all new funds be used to support community-based programs. As I said earlier, because of the opposition by the Republicans on the Senate side and the House Republicans, we were not able to get the bill through. However, the language is there in the Senate bill.

What I would like to seek from you is a commitment that the \$81 million increase that we had this year. I want to make sure that all new funding is in accordance with the language we put in the Senate bill. I cannot do anything about the \$145 million. It is already out there. And I just wanted to know your sentiments on that.

Secretary SEBELIUS. Well, Senator, Mr. Chairman, I certainly share your belief, although you have been at this a lot longer than

I have, that the ounce of prevention is probably 10 pounds of cure. I mean, it is a strategy that we have to engage in. We think Community Transformation Grants can be a critical part of that testing strategies. As you know, there are some set-asides for rural communities and tribal communities to make sure that there is a representation in rural and frontier areas as well as larger communities and statewide programs.

So 61 States and communities had received awards in 2011, and I know your interest in broadening the applicability. We will work with your office around the framework for moving forward. There are some issues around how many folks can really move the needle, but we would be eager to work with your office around what the next steps are.

Senator HARKIN. Well, I appreciate that. Take a look at the language that we put in. I would love to work with you on it. This is something that we have been doing for a long time on this subcommittee, and we funded, as I said through the earmarking process, and some have failed, some have not. We kind of know what works, and it is on a community basis, not on a statewide basis. And certainly I never intended that it would only go to cities of 400,000 or more. Sometimes the smaller community can have a bigger impact just because they are smaller, people know each other, they can get together better in a smaller community sometimes. So a community of 40,000–50,000 can make great strides even better than perhaps a large metropolitan area. And then the idea of \$1 per person might have some effect, but certainly not the kind of impact that a larger amount in more targeted areas would have. So I look forward to working with you on that.

NATIONAL INSTITUTES OF HEALTH FUNDING

Last, I wanted to bring up the issue of community health centers, again something that we worked very hard on in ACA. Senator Sanders was also one of the leaders in that area on the authorizing committee. But we wanted to increase the number of community health centers prior to 2014. We wanted to get as many out there as possible. Yet, the President's budget proposed to hold back \$280 million of the \$300 million increase for fiscal year 2013. That is the budget we are working on.

Now, I know all about the funding cliff that is out there in 2015, but that funding cliff was about \$3.6 billion. Our intention on putting this money in there was to get as many community health centers up and running prior to 2014. It was not to smooth it out.

So again, I am hopeful that we can use all of the additional \$300 million to get as many centers up and running as possible before January 2014. We can worry about and take care of that funding cliff sometime later, but the most important thing is to get them up and running.

Secretary SEBELIUS. Well, again, Mr. Chairman, I think your interest and passion in this area is not only well known but one that we share. Community Health Centers have been a resounding success, high-quality, lower-cost, preventive and primary care, often taking care of needs well beyond healthcare that impact people's health and well-being. As you know, the budget does anticipate an additional 200 sites be funded with the resources that we have re-

quested, but we would again work with your subcommittee. I think there is a great deal of concern about the out-years and the cliff and how to make sure that we do not end up in a situation where having opened a lot of sites, we cannot staff them, we cannot fund them. So we would be eager to work with you around the best strategy to get people the desperately needed care.

Senator HARKIN. Well, thank you, Madam Secretary. Just tell OMB I am not in favor of what they are trying to do. All right?

Secretary SEBELIUS. I would be happy to convey that message.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. Madam Secretary, thank you. Do you have anything else that you want to add for the record?

Secretary SEBELIUS. No, Sir.

Senator HARKIN. Thank you very much.

Secretary SEBELIUS. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTION SUBMITTED BY SENATOR TOM HARKIN

NATIONAL HEALTH SERVICE CORPS AND TITLE X

Question. To receive title X funding, a clinic is required to prove to Health Resources and Services Administration (HRSA) that they either provide or have in place referral agreements to provide comprehensive primary care services. Yet the Guttmacher Institute has shown that the biggest hurdle for title X clinics that want to participate in the National Health Service Corps (NHSC) is proving that they provide or have referral agreements to provide comprehensive primary care services. If HRSA is certain the clinics provide those services in one ongoing grant program and audits them regularly to ensure compliance, why would good standing in that program not be sufficient proof of those services for another HRSA program?

Clinics that only receive title X funding provide the only primary care many low-income women receive, and they are plagued by the same workforce shortages as other clinics. Obstetrician/gynecologist and nurse midwife are two eligible categories for health professionals who participate in the NHSC. Furthermore, like other NHSC-eligible entities, clinics with only title X funding are required to serve anyone who walks through the door—women and men—in their communities regardless of income at free or reduced cost. What plans does the Department have to ensure that HRSA programs have a common definition for what constitutes providing comprehensive primary care services?

Answer. The NHSC has taken steps through its refined policy to better inform sites of the program's definition of comprehensive primary care so that the site approval process is open and transparent. The program recognizes that many women, as well as men, use women's health clinics as their primary care provider because it meets their healthcare needs or may be the only provider in their community.

The NHSC has published a new version of its Site Reference Guide, which defines comprehensive primary care as, "the delivery of preventive, acute, and chronic primary health services in an NHSC-approved specialty. NHSC-approved primary care specialties are adult, family, internal medicine, general pediatric, geriatrics, general psychiatry, mental and behavioral health, women's health, and obstetrics/gynecology. Comprehensive primary care is a continuum of care not focused or limited to gender, age, organ system, a particular illness, or categorical population (e.g. developmentally disabled or those with cancer). Comprehensive primary care should provide care for the whole person on an ongoing basis."

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

NATIVE HAWAIIAN HEALTHCARE

Question. I appreciate that under your leadership the budget request for the Health Resources and Services Administration (HRSA) continues to support the Native Hawaiian Health Care Program, which improves the health status of Native Hawaiians by making health education, health promotion, and disease prevention services available through the support of the Native Hawaiian Health Care Systems. As you may be aware in 2010, the Department of Health and Human Services (HHS) consultation policy as related to American Indians and Alaska Natives was revised and the new formal consultation policy eliminated Native Hawaiians and their health organizations (NHOs). It is my understanding, that since that time Native Hawaiians and their NHOs have asked HHS to re-establish a separate formal consultation policy for Native Hawaiians. Native Hawaiians have among the highest morbidity rates of any ethnic or racial population for major chronic diseases, and consultation with the Native Hawaiian community could help to tailor HHS policies, programs, and priorities to improve health outcomes. Please describe the best path forward for HHS and the Native Hawaiian community to engage on health issues of concern. Is the reissuance of an HHS consultation policy for Native Hawaiians and their health organizations possible?

Answer. HRSA understands the importance of supporting the Native Hawaiian Health Care Program, and will review existing relationships and partnerships with the Native Hawaiian community to determine the appropriate steps for moving forward, including the consideration of revised policies.

Question. The Native Hawaiian Health Care Improvement Act (42 U.S.C. 11701) is the major Federal statute providing for a comprehensive approach to improving the health and well-being of the indigenous peoples of Hawaii. The act states that the Secretary of HHS provide the President with a progress report on meeting the Federal policy of "improving the health of Native Hawaiians to the highest possible level." The President, in turn, transmits the report to us in the Congress. When can my office anticipate receiving a copy of that report?

Answer. HHS is committed to addressing the health needs and well-being of Asian American, Native Hawaiian, and Pacific Islander (AANHPI) populations. The Affordable Care Act (ACA) has mobilized HHS efforts and has served as the underlying framework for the development of the HHS AANHPI Agency Plan. The HHS plan illustrates measurable objectives that the Department will pursue to raise the visibility of AANHPI health issues, healthcare and human services disparities. This plan is meant to elevate AANHPI issues across the Department under the leadership of the Assistant Secretary for Health. I am pleased to provide a copy of the agency plan to your office which outlines, in detail, the components and accomplishments related our current work on improving data collection.

The plan includes four overall-arching health goals to improve the well-being of AANHPIs. These goals include how the Department will carry out its plan to prevent, treat and control Hepatitis B infections in AANHPI communities, work to improve reporting of data, foster workforce diversity by developing workforce pipelines for AAs and NHPs, and address some of the key health issues that specifically impact NH and PI populations. The plan also addresses a wide-ranging set of issues, including breast and cervical cancer, diabetes and tuberculosis, prevention, surveillance and response, communicable diseases in the Pacific jurisdictions, laboratory testing, environmental issues, and vaccinations.

Our efforts to better serve Native Hawaiian populations and identify and understand health disparities will be enhanced through the efforts outlined in goal two. Detailed data is a fundamental step in identifying which populations are most at risk and what specific interventions are most effective in attaining improved healthcare quality for specific populations. HHS will continue to increase the capacity to collect more reliable health data for AANHPI populations to better understand the need of these growing populations. Efforts to improve data collection include:

- Substance Abuse and Mental Health Services Administration:
 - Enhance the quality of data collected within Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use & Health (NSDUH) for AANHPI populations.
- Centers for Disease Control and Prevention:
 - The fiscal year 2013 budget includes \$161,833,000 for health statistics, an increase of \$23,150,000 more than the fiscal year 2012 level to accomplish many of the activities described below.
 - Continue oversampling of Asian Americans in the National Center for Health Statistics' (NCHS) National Health Interview Survey (NHIS).

- Include an oversampling of Asian Americans in the 2011–2014 National Health and Nutrition Examination Survey (NHANES).
- Implementation of section 4302 of ACA regarding data collection on race, ethnicity, sex, primary language, and disability status. This will provide an opportunity to obtain disaggregated data on AA, NH, and PI communities.
- Develop improved tools for accessing and analyzing vital statistics and survey data for small populations.

We look forward to improving our data collection, reporting and disaggregation of race, ethnicity, and primary language data related to the AANHPI community and to provide you with additional data related to the health objectives outlined in the Native Hawaiian Health Care Improvement Act. We look forward to including this information in the annual AANHPI Agency Plan end of year report.

ALIGNING HAWAII'S PREPAID HEALTH CARE ACT AND THE AFFORDABLE CARE ACT

Question. Hawaii has traditionally experienced a much lower rate of uninsured individuals due to the landmark State law, the Prepaid Health Care Act (PHCA), which requires employers to provide healthcare coverage to full-time employees. As the State works to implement elements of ACA, questions have arisen regarding the ability for Hawaii's law to interact with the ACA in a manner that would allow Hawaii residents maximum benefits. Will there be further guidance from HHS, specific to Hawaii's healthcare environment, on how the Prepaid Health Care Act can work in conjunction with the requirements of the ACA? Is it HHS' desire for Hawaii to maintain the requirements of the PHCA?

Answer. HHS is committed to working with the State of Hawaii regarding the coordination of the PHCA and ACA. HHS also works with our Federal partners in ACA implementation, such as the Department of the Treasury and the Department of Labor, on these issues, as necessary. Conversations about specific interactions have already begun.

COMPACT OF FREE ASSOCIATION

Question. In 1986, the United States entered into Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands. In 1994, the United States entered into a similar relationship with the Republic of Palau. The Compacts set forth the bilateral terms for government, economic, and security relations between the United States and the Freely Associated States (FAS), and the laws approving the Compact set forth the U.S. policy context and interpretation for Compacts. Section 141 of the Compact provides that certain FAS citizens "may be admitted to, lawfully engage in occupations, and establish residence as a nonimmigrant in the United States and its territories." However, the Congress also stated, in section 104(e)(1), that "it is not the intent of Congress to cause any adverse consequences for an affected jurisdiction." It is estimated that affected areas of the United States are spending upwards of \$200 million annually for healthcare, education, and other services for FAS migrants, including high-cost treatments such as dialysis and chemotherapy. These costs are increasing annually. Public health officials are particularly concerned about the rate of certain diseases such as tuberculosis and Hansen's disease, which have high incidence rates in Micronesia and among recent Compact migrants.

House Report 112-331 directs the Department of the Interior to "meet regularly with officials from the Freely Associated States, other Federal agencies and affected jurisdictions, and develop and implement a comprehensive plan to mitigate the costs of Compact migration." Please provide an update on the work of agencies within HHS on this interagency working group. How best can HHS assist States and territories in meeting the health and social service needs of Compact migrants?

HHS/Office of Assistant Secretary for Health (OASH), Region IX assists States and territories in meeting the health and social service needs of Compact migrants by managing the following activities:

- The OASH, Region IX office is coordinating with other HHS Operating Divisions (OPDIVS) on Pacific health issues; providing guidance on strategies and policy development that promote Pacific health and reduce health disparities; and participating in meetings of the Workgroup on Asian, Native Hawaiian, and Pacific Islander issues (WANHPPI) and Insular Areas HHS Policy Group (IHHSPG).
- The OASH, Region IX office is developing relationships with Micronesian Chief Executives Summit (MCES) policy leaders to advocate for increased health awareness, environmental health issues, and health disparities reduction; ensuring health and environmental health issues are elevated on the MCES agen-

- da; and participating in semiannual MCES meetings to promote status of health and environmental health issues.
- The OASH, Region IX office is improving the capacity to secure grants, and strengthen grant management and financial accountability capacity in the Pacific by increasing grant awareness by making knowledge of Federal grant funding opportunities more readily available to U.S. Associated Pacific Islands (USAPI) health departments and communities.
 - The OASH, Region IX office is promoting awareness of noncommunicable diseases (NCDs) crisis and Federal, nongovernmental organization (NGO) and international assistance for programs and policy development to prevent NCDs.
 - HHS Region 9 (RIX) is collecting NCD plans and promising practices from all the Pacific jurisdictions, report is forthcoming.
 - NCD program funding from CDC's consolidated grant program addresses diabetes prevention and treatment, tobacco control, and behavioral risk.
 - The Pacific Chronic Disease Coalition, a PIHOA affiliate, has been extremely active in supporting the development of NCD prevention programs in all of the USAPI.
 - The OASH, Region IX office is assisting Pacific health departments in addressing current, emerging, and emergency health issues including MDR-TB, Hansen's disease and dengue fever coordinating with CDC, HRSA, Department of Defense (DOD), World Health Organization, Pacific Regional Office (WHO/WPRO) and Secretariat for the Pacific Community (SPC), and DOI.
 - The OASH, Region IX office is involved in conversations with States and territories receiving Compact migrants, clarifying the circumstances in which Medicaid can be used to pay for emergency services. Although Compact migrants are not eligible for Medicaid, certain emergency services can be covered under the Medicaid program at the regular Federal Medical Assistance Percentage (FMAP).
 - The OASH, Region IX office is increasing the collection, accuracy, and utilization for health services of Maternal-Child Health (MCH) data in the USAPIs. In collaboration with HRSA's Title V MCH grant program, and in conjunction with WHO/WPRO, SPC and PIHOA data strengthening/HIT, there are efforts to determine weaknesses and revisions in current data collection, analysis, and utilization for health planning and service delivery.
 - The OASH, Region IX office is providing technical assistance to the USAPI nursing programs, including the Robert Wood Johnson (RWJ) Pacific PIN nursing grant, to enhance the capacity and quality of USAPI nursing programs.
 - The OASH, Region IX office is fostering recognition of the behavioral/mental health disparities in Pacific populations and creating resource linkages with potential resources SAMHSA, HRSA, CDC, Veterans Affairs, DOD, HI & Pacific M/DOH, NGOs including faith-based organizations, WHO/WPRO, and SPC.
 - The OASH, Region IX office is assisting USAPI health profession programs in incorporating emergency response content into their curricula. Coordinating with WPRO/WHO, CDC, ASPR, Medical Reserve Corps (MRC), HRSA, DOD, and the Red Cross regarding trainings and emergency prep curricula for health professions programs and assisting in establishing contacts to aid them in providing relevant trainings to nursing personnel and nursing programs.
 - The OASH, Region IX office is collaborating with Office of Minority Health Resource Center (OMHRC), HRSA, CDC, SAMHSA, WHO/WPRO, SPC, PIHOA, DOI, and Telecommunications and Information Policy Group (TIPG)/Pan-Pacific Education and Communication Experiments by Satellite (PEACESAT) on training opportunities for enhancing data, surveillance programs, and the combined utilization of HIT and tele-health to enhance service delivery and accessibility, to enhance capacity in data collection/analysis/surveillance that leads to better health services planning and service delivery.
 - The OASH, Region IX office is assisting in enhancement of the RIX Medical Reserve Corps program in the Pacific, collaborating with RIX MRC consultant to develop and strengthen MRC units in the Pacific.
- HHS/HRSA and CDC assists States and territories in meeting the health and social service needs of Compact migrants and Hansen's disease by managing the following activities:
- HRSA's National Hansen's Disease Program (NHDP) offers assistance in selected aspects of HD control, such as training and technical assistance in the Republic of the Marshall Islands (RMI). NHDP intends to collaborate with other agencies such as CDC and WHO to assist in HD awareness and training and participate in activities similar to the meeting with WHO and others in Majuro in 2010, and the HD training workshop at NHDP headquarters in Baton Rouge.

NHDP initiated preliminary training via video teleconference through PEACESAT in collaboration with HHS Region IX.

—CDC provides technical assistance for the public-health related aspects of HD, including development and evaluation of surveillance systems, epidemiologic support such as outbreak and cluster investigation, and case reporting. The CDC notifies state and territorial health departments and the NHDP of patient immigration into the United States, facilitating patient care. In addition, the CDC is providing direct assistance for capacity development of the RMI TB Control Program.

HIV/AIDS PREVENTION FUNDING

Question. The fiscal year 2013 President's budget request includes an increase of \$40.231 million more than fiscal year 2012 level for Domestic HIV/AIDS Prevention and Research. The increase provides additional funding to achieve the goals of the National HIV/AIDS Prevention Strategy. What measures will HHS use to assess the impact of the funding priority and will the funds targeted for State and local programs be prioritized to states and localities most impacted by previous shortfalls?

Answer. CDC aligns its HIV program priorities with the National HIV/AIDS Strategy (NHAS). The agency uses data from national HIV surveillance, behavioral surveillance, and program monitoring systems to assess progress toward achieving NHAS goals, as well as its own HIV prevention plans' impact objectives. These measurements, which are listed on page 80 of CDC's proposed budget for fiscal year 2013, are as follows:

Prevent New HIV Infections

By 2015, reduce the annual number of new HIV infections by 25 percent—NHAS goal.

By 2015, reduce the HIV transmission rate by 30 percent—NHAS goal.

By 2015, increase the percentage of people living with HIV who know their serostatus to 90 percent—NHAS goal.

Increase the percentage of people diagnosed with HIV infection at earlier stages of disease (not Stage 3: AIDS)—2013 target: 47.5 percent.

Increase the proportion of adolescents (grades 9–12) who abstain from sexual intercourse or use condoms if currently sexually active—2013 target: 86.9 percent.

Increase Linkage to and Impact of Prevention and Care Services With People Living With HIV/AIDS

By 2015, increase the percentage of persons diagnosed with HIV who are linked to clinical care to 85 percent—NHAS goal.

Increase the percentage of HIV-infected persons in publicly funded counseling and testing sites who were referred to partner services—2013 target: 73.5 percent.

Increase the percentage of HIV-infected persons in CDC-funded counseling and testing sites who were referred to HIV prevention services—2013 target: 68 percent.

Increase the number of States that report all CD4 and viral load values for HIV surveillance purposes—2013 target: 36.

Increase the number of States with mature, name-based HIV surveillance systems—2013 target: 50.

Reduce the number of new AIDS cases among adults and adolescents per 100,000—2013 target: 12.7.

CDC actively monitors and publicly reports on these national objectives each year as data are available. In addition, CDC's Division of HIV/AIDS Prevention aligns its program priorities with the principles of high-impact prevention, which represent the scientific foundation for its HIV prevention efforts. More information is available at: <http://www.cdc.gov/hiv/strategy/hihp/>.

In order to monitor progress at the State and local level, CDC asks grantees to submit semi-annual progress reports that describe the implementation of HIV prevention program activities, and identify barriers and challenges to meeting programmatic objectives. CDC also uses site visits and conference calls with grantees, and its own surveillance and monitoring systems, to monitor grantee performance and develop plans for further improve performance, which involves the provision of capacity building, training, or other technical assistance.

CDC would use the increased funding requested for fiscal year 2013 to address priorities in NHAS. Specifically, CDC would increase HIV Adolescent and School Health funding over the fiscal year 2012 level for cooperative agreements to States, cities, territories, and tribes. This would enable HIV priority areas to develop and implement health policies, programs, and practices, as well as improve HIV and sex education efforts across the country. CDC would also restore funding to several national NGOs that provided professional development and technical assistance to

State and local education agencies, health agency partners, and other organizations working in school health.

Of the increase proposed for HIV Prevention by Health Departments and National Programs to Identify and Reach Highest-Risk Populations, CDC would award \$22 million directly to State and local health departments. The increased funds are expected to improve the capacity of jurisdictions to conduct core HIV surveillance activities, and improve the use of surveillance and other programmatic data to improve HIV testing, retention, and re-engagement in medical care activities. Through its recent funding opportunity announcements, CDC emphasized the importance of aligning resources to better match the geographic burden of the HIV epidemic throughout the United States. This resulted in an equitable approach to CDC's HIV funding; additional funding for CDC would reflect a continuation of this approach. It is likely that a proportion of jurisdictions that experienced decreases in HIV funding would be recipients of these increased funds for HIV surveillance and prevention; however, CDC will prioritize the distribution of increased resources according to the burden of HIV.

VIRAL HEPATITIS SCREENING

Question. The Congress enacted \$10 million under ACA in fiscal year 2012 for viral hepatitis screening. Please provide an overview of how the funds were utilized. Additionally, please provide an overview of how local and State health departments are participating in the formation and implementation of the national viral hepatitis strategy.

Answer. In fiscal year 2012, CDC will use the increase provided for viral hepatitis to increase the proportion of persons with chronic viral hepatitis who are aware of their infection and who are referred to medical care. CDC is planning projects that involve direct provision of screening for at risk populations, evaluation of testing activities, and public and provider education to raise awareness of the need for viral hepatitis screening and provide the skills to do so. Specifically, CDC will provide resources to organizations to increase testing for at risk populations in multiple settings including federally Qualified Health Centers, local health department clinics (e.g., STD clinics or HIV/AIDS settings), correctional settings, intravenous drug use treatment centers, and community-based organizations. The resources will target efforts to reach persons at highest risk for severe hepatitis C virus (HCV)-related morbidity and mortality, communities experiencing health disparities related to hepatitis B (e.g., foreign born populations and their children) and hepatitis C (African Americans and current and former incarcerated populations), and young persons at risk for HCV-related to drug use. CDC will support a public awareness campaign for HCV, currently under development, and expand it to address chronic hepatitis B virus (HBV)—targeted to those populations most at risk for chronic HBV infection. CDC will also develop and disseminate education and training materials targeting public health and private sector healthcare professionals. These materials will build capacity to assess, test, and medically manage chronic HCV and HBV infection.

HHS invited partners from State and local health departments, including HIV and STD directors and Adult Viral Hepatitis Prevention Coordinators (AVHPC), to participate in the development of Combatting the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis (Action Plan). In particular, health department representatives participated in two community engagement meetings held by HHS on June 29, 2010, and September 21, 2010, with health departments constituting a significant percentage of the participants at both meetings. At the first meeting, participants had the opportunity to comment on issue areas proposed by HHS, propose additional areas, suggest particular issues that HHS should address, and identify ways to make the Action Plan as meaningful and useful as possible. Input from that engagement session strongly influenced and helped to shape the draft of the Action Plan. After developing the first draft of the Action Plan, HHS held the second meeting to solicit feedback about its contents. Health department representatives and other viral hepatitis stakeholders offered suggestions to strengthen, improve, and focus elements of the Action Plan. This feedback was a vital component in development of the final version of the Action Plan.

HHS and CDC will continue to work closely with state and local health departments to achieve the goals set forth by the Action Plan. The Action Plan recognizes the important role health departments must play in coordinating local efforts to advance viral hepatitis prevention and control activities. Numerous action steps in the Action Plan specifically mention AVHPC and other health department staff.

TUBERCULOSIS IN HIGH-RISK AREAS

Question. Senate Report 112–084 requested that the CDC “review the epidemiology of TB in States and territories with more than double the average rate of TB cases.” Please provide a status update on CDC’s findings.

Answer. CDC analyzes and reports tuberculosis (TB) cases and rates annually. Jurisdictions with case rates that are more than twice the national average rate of 3.4 cases per 100,000 (provisional 2011 data) include Alaska (9.3), Hawaii (8.95), and the District of Columbia (8.9). Territories with more than twice the average national rate include the Commonwealth of the Northern Mariana Islands (67.3), Guam (55.3), Federated States of Micronesia, (136.7), the Republic of the Marshall Islands (227.7), and Palau (47.7).

CHILDREN’S HOSPITALS GRADUATE MEDICAL EDUCATION

Question. The President’s budget for fiscal year 2013 proposes \$88 million to fund the Children’s Hospitals Graduate Medical Education (CHGME) program. CHGME was funded at a level of \$267.8 million in 2012. Even at CHGME’s current annual funding level, children’s hospitals struggle to train enough pediatricians and pediatric specialists to keep up with the growing demand. CHGME funds support graduate medical training at freestanding children’s hospitals all over the United States. The importance of this program is especially acute in my home State where our CHGME recipient hospital—Kapiolani Medical Center for Women and Children—is the only tertiary children’s hospital for the entire State of Hawaii and Pacific Basin. Kapiolani currently trains 6 to 10 pediatric residents per year and of the those trained, more than 30 percent choose to continue to practice in Hawaii after their residency. I am concerned that the proposed level of funding does not adequately support the gains we have made in pediatric health and ensuring access to care. If CHGME is not adequately funded, who will train these providers and support the future primary care workforce for our Nation’s children?

Answer. We recognize the vital role that children’s hospitals and pediatric providers play in providing quality health care to our Nation’s children.

The fiscal year 2013 CHGME funding level continues to support direct costs for training pediatric residents at independent children’s hospitals. This payment provides support for resident salaries, expenditures related to stipends and fringe benefits for residents, salaries and fringe benefits of supervising faculty, cost associated with providing the GME training program, and allocated institutional overhead costs.

The fiscal year 2013 budget retains the incentive to maintain total resident levels. The administration recognizes that research has indicated that there is a significant shortage of pediatric subspecialists, resulting in children with serious illnesses being forced to travel long distances—or wait long periods—to see a pediatric specialist. In response to these shortages, the fiscal year 2013 President’s budget includes \$5 million to implement the Pediatric Specialty Loan Repayment (PSLR) program that was authorized in ACA. Under this program, loan repayment agreements will be authorized for pediatric specialists who agree to work in underserved areas.

While both the CHGME Payment and the PSLR programs support the pediatric medical workforce, the focus of each is different. The CHGME Payment Program serves the purpose of providing residency training in Children’s Hospitals through the payments made to Children’s Hospitals, while the PSLR program is designed to assist pediatric specialists more directly and increase the number of pediatric specialists in underserved areas.

 QUESTIONS SUBMITTED BY SENATOR HERB KOHL

Question. Secretary Sebelius, more than a year ago I wrote to you with Senator Snowe to express strong concern about proposed regulations that your Department has drafted regarding the Genetic Information Nondiscrimination Act (GINA). We raised two concerns. First, the proposed rule extends to private long-term care insurance the prohibition under GINA of the use of genetic information. This extension occurred despite clear congressional intent and history to exclude GINA in long-term care. Second, we objected to the proposed GINA expansion because a rule barring the use of genetic information would effectively cripple the long-term care insurance industry and leave millions without access to coverage.

Given that Federal efforts to expand long-term care coverage have stalled and the administration’s decision not to implement the Community Living Assistance and Support Services (CLASS) program, this proposed expansion comes at a particularly precarious time for the long-term care industry. As we are relying on private indus-

try to accelerate its efforts and provide more coverage, the Federal Government should not inappropriately stymie these efforts.

Will you assure that the Department of Health and Human Services (HHS) will eliminate its expansion of GINA to long-term care insurance and continue to allow private long-term care insurers to use genetic information in the final rule, as the Congress intended?

Answer. I appreciate your concerns with the Department's proposed rule, which would prohibit long-term care insurers from using genetic information for underwriting purposes. A final rule to implement the GINA protections has been developed and is currently under review as part of a larger omnibus Health Insurance Portability and Accountability Act (HIPAA) privacy and security rule. As the rule has not yet been published, the Department is not in a position to discuss the final policies. However, be assured that in developing the final rule, the Department has been carefully considering the views expressed in response to the proposed rule and the potential impact of the proposed rule on the long-term care market.

Question. I would like to follow up with you on an issue I raised in a November 15, 2011 letter I sent to CMS Administrator Berwick along with Senators Schumer, Gillibrand, Casey, and Klobuchar regarding the viability of farmer cooperative-provided health insurance plans under the Affordable Care Act (ACA). As you know, dairy cooperatives have a long history of providing their members with high-quality, low-cost coverage that is specially tailored to the needs of farmers. These plans are very important to me as I helped secure funding to create such plans in my home state of Wisconsin.

As you know, under ACA, only individuals who purchase insurance through the State Exchanges qualify for the advanced premium tax credit. Unfortunately, this creates a financial incentive for thousands of lower-income farmer cooperative members to leave their cooperative-offered plan for the Exchange, which, in turn, would leave the farmer cooperative risk pool severely degraded. This outcome would inevitably lead to higher prices for remaining farmer coop members and is ultimately likely to lead to an elimination of dairy cooperative-sponsored coverage. This would be an unfortunate, and unintended, outcome of ACA, given the important and trusted role that dairy cooperatives play in the lives of their members.

My colleagues and I have been pursuing, along with other groups, including some representatives of organized labor, a proposal to allow for section 1334 of ACA to serve as a mechanism by which nonprofit insurance providers like farmer cooperatives and Taft-Hartley plans, could offer their coverage through the multi-state exchanges, thus allowing for their lower-income members to avail themselves of the advanced premium tax credit. This approach could benefit both interests by providing continued access for cooperative-offered plans and the Taft-Hartley plans while staying within the construct of ACA.

I want to see these efficient, successful, and popular plans continue and ask that you address the issue as soon as possible. Will you look into this important issue and help find a regulatory solution for this unintended problem?

Answer. The Department is considering options to address these concerns. The administration is fully supportive of farmers receiving coverage through these farmer-owned cooperatives and intends to take feasible actions to preserve these organizations as health insurance options for American farmers. Farmers who do not receive such coverage will have access to Exchanges to obtain coverage through a qualified health plan, and may be eligible for premium tax credits and reduced cost-sharing of out of pocket costs. Eligibility for such benefits may depend upon the nature of the coverage available through a farmer-owned cooperative, and the farmer's income.

Question. I have been in contact with you and the Food and Drug Administration (FDA) about the FDA's proposed rule to improve pregnancy drug labeling. As you know, an estimated 75 percent of pregnant women use between four to six prescriptions or over-the-counter drugs during their pregnancy. Since 1997, the FDA's Pregnancy Labeling Task Force has worked on updating the pregnancy labeling system and FDA issued proposed rule with revised labeling guidelines in 2008.

In my previous inquiries, you have told me that the drug labeling rule is a priority for the FDA. But the proposed rule has been lingering since 2008. As of today, in March 2012, FDA has not yet issued a final rule governing the labeling of drugs for women during pregnancy. Is FDA planning on issuing the FDA pregnancy rule in 2012? Since this pregnancy rule is a priority for FDA, can you commit to finalizing the rule in 2012?

Answer. FDA is committed to finalizing a rule that will improve drug labeling for women who are pregnant, and we are diligently working to issue this important rule. Because of the complexity of this rule and the time required to review and fi-

nalize this rule, it is not possible to say whether the final rule will publish during 2012.

However, we want to emphasize that, in addition to finalizing the pregnancy and lactation rule, FDA has other important and ongoing projects related to the health of pregnant and lactating women. The Maternal Health Team and other offices in the Center for Drug Evaluation and Research are developing regulations, guidance documents, and procedures related to the use of medicines during pregnancy and lactation. For example, on April 30–May 1, 2012, FDA is holding a “Public Workshop on Developing Animal Models of Pregnancy to Address Medical Countermeasures for Influenza.”

In addition, FDA has issued five scientific guidances relating to pregnancy and lactation that support women’s health:

- Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities;
- Establishing Pregnancy Exposure Registries;
- Pharmacokinetics During Pregnancy and Lactation;
- Evaluating the Risks of Drug Exposure in Human Pregnancies; and
- Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

TITLE X FAMILY PLANNING PROGRAM

Question. Federally funded family planning health centers are facing increased demand, with more than 4 in 5 centers reporting an increase in clients who are uninsured and more than two-thirds reporting a decrease in the proportion of clients able to pay the full fee for their services. Not surprisingly but of great concern—1 in 4 women now report having put off a gynecological or birth control visit to save money in the past year. As the rates of uninsured steadily climb and many families lack access to basic healthcare services, these health centers struggle—with severely limited funding—to meet the ever increasing unmet need.

What role do you see title X playing in an environment where increased need and increased costs are stretching women’s health centers resources thin, consequently making it difficult for American families to access their most basic healthcare services?

Answer. The Title X Family Planning program continues to play a critical role in ensuring access to high-quality, client-centered, and affordable primary and preventive health services to millions of uninsured and underinsured men, women, and adolescents at more than 4,000 health centers across the United States, including federally qualified health centers, free-standing clinics, hospitals, and State and local health departments. Title X-funded services include contraceptive counseling and related services, physical exams, screening and treatment for sexually transmitted infections, HIV testing, clinical breast exams, and cervical cancer screening. In 2010, 90 percent of clients had incomes at or below 200 percent of the Federal Poverty Level.

In addition to supporting basic healthcare services for about 5 million individuals, the title X program also provides support for the family planning infrastructure across the Nation, including critical support for training and salaries for reproductive health providers. The Title X program also has had a long history of establishing the rules governing the delivery of high-quality family planning services in clinic settings—a role the program will continue to play. The Department of Health and Human Services (HHS) also anticipates that title X centers will remain critical sources of care for vulnerable populations who are uninsured as well as individuals who will be newly insured or Medicaid eligible under the Affordable Care Act (ACA). These centers will play an important role in achieving a key goal of ACA—improving access to affordable preventive healthcare.

While resources have been stretched thin, HHS fully anticipates that the program will continue to provide services through a broad range of community-based providers as well as leverage multiple sources of Federal and State funding, including Medicaid, state family planning dollars where available, the Maternal and Child Health Block Grant, and the Social Services Block grant. Although difficult to predict, it is possible that after the full implementation of the ACA, the payer mix will change at some family planning centers to include a greater share of funding from private insurance and Medicaid. The ACA requires that most private insurance cover certain contraceptive services with no cost-sharing. As demand continues to increase, title X sites will continue to support high-quality services delivered by ex-

perienced clinicians and a solid infrastructure able to address the needs of women, men, and vulnerable populations.

CONTRACEPTION

Question. According to the Guttmacher Institute, in 2006 only about one-half of the women who needed or wanted publicly funded family planning were able to receive those services, so won't requiring insurance plans to cover contraception help fill a public health gap that publicly funded family planning funding streams are not able to meet?

Answer. Before ACA, too many Americans didn't get the preventive healthcare they need to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce healthcare costs. An estimated 20.4 million women are currently receiving expanded preventive services without cost-sharing because of ACA.

On average, a woman uses contraception for 30 years of her life, with the average cost of contraception at \$50 per month.

By eliminating cost-sharing requirements for certain preventive services under most plans, ACA is improving access to these services. The guidelines for women's preventive services ensure that women have access to a comprehensive set of preventive services and fill the gaps in current preventive services guidelines for women's health. This means that most women will no longer have to pay often burdensome co-payments, co-insurance, and deductibles in order to access necessary preventive services such as contraception, breastfeeding support, and domestic violence screening. By removing coverage barriers, these guidelines will help improve access to comprehensive quality healthcare for all American women.

Question. Opponents of insurance plans being required to coverage contraception claim that contraception does not actually lower healthcare costs in the long-term, but doesn't every \$1 spent on family planning services stand to save \$4 in pregnancy related healthcare?

Answer. Actuaries and experts agree that covering contraception actually saves money for insurance companies. The cost of contraception coverage is low and tends to be more than offset by the savings that result from improved health and fewer unplanned pregnancies. For example:

- A study by the National Business Group on Health estimated that it would cost employers 15–17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and indirect costs such as employee absence and reduced productivity.
- When contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase.
- Fifteen States including Pennsylvania have family planning demonstration programs under Medicaid that have significantly expanded coverage of these services without increasing State or Federal costs.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH'S SPOKANE RESEARCH LABORATORY

Question. As you know, the work conducted at the National Institute for Occupational Safety and Health's (NIOSH) Spokane Research Laboratory is vital to maintaining and improving the health and safety of workers in industries including metal and nonmetal mining throughout the Western United States. Over the last 3 years, the Spokane Research Laboratory has undergone internal reorganization that could lead to the Laboratory's closure, which would greatly impact the health and safety of Western United States miners. As one of NIOSH's lowest-cost laboratories, the work done at the Spokane Research Laboratory is also conducted at a value to taxpayers.

What plans do you have to continue the critical work of Western United States mine health and safety research at the Spokane Research Laboratory?

Answer. NIOSH continues to address the priority needs of all coal, metal, and nonmetal mineworkers, including those working at mines located in the Western United States through its national mining safety and health research program. The Office of Mine Safety and Health Research (OMSHR) maintains staff in Spokane, Washington and Pittsburgh, Pennsylvania who are assigned to the full range of projects in their research portfolio, and OMSHR plans to continue serving the needs of all of its customers and stakeholders through the work of staff at both the Spokane and Pittsburgh campuses.

Question. Will you provide me with the Spokane Research Laboratory's fiscal year 2009–2013 budget allocations for staff/personnel, including full-time equivalent employee levels; and facilities maintenance and construction?

Answer.

NIOSH Spokane	Fiscal year 2009	Fiscal year 2010	Fiscal year 2011	Fiscal year 2012	Fiscal year 2013
Full-time equivalent	50	50	45	38	36
Personnel costs	\$5,384,634	\$5,444,656	\$4,926,490	\$4,142,030	\$3,942,030
Facilities maintenance/construction costs	\$601,335	\$480,330	\$689,559	¹ \$2,607,462	\$757,462

¹ Fiscal year 2012 includes one-time funding (\$1.85 million) to install a new fire suppression system in the Spokane facility.

The CDC's Web site states that its mission is to: ". . . collaborate to create the expertise, information, and tools that people and communities need to protect their health," and that this mission is to be accomplished by working with partners to ". . . detect and investigate health problems, and conduct research to enhance prevention." The CDC follows this mission statement with a pledge to the American people that includes a commitment to: "base all public health decisions on the highest quality scientific data, openly and objectively derived."

Question. How does the CDC plan to fulfill its mission and maintain their pledge to the American people to "base all public health decisions on the highest quality scientific data" within the area of workplace safety if they have eliminated funding for the Education and Research Centers and the National Occupational Research Agenda's Agricultural, Forestry, and Fishing Programs?

Answer. The fiscal year 2013 budget eliminates the Education and Research Centers and the Agricultural, Forestry, and Fishing Sector of the National Occupational Research Agenda because in a resource-constrained environment, these programs are a lower priority relative to other CDC programs.

When NIOSH's Education and Research Centers were originally created almost 40 years ago, there were a limited number of academic programs focusing on industrial hygiene, occupational health nursing, occupational medicine, and occupational safety. Now, many schools of public health include coursework and many have specializations in these areas. CDC will continue to provide technical assistance to the Education and Research Centers despite the proposed elimination of grant funding.

The Agricultural, Forestry and Fishing Sector, when compared to other CDC programs, is considered lower-priority in terms of CDC's core mission and its ability to have a national impact on improved health outcomes. In fiscal year 2013, CDC will focus on other sectors of research within the National Occupational Research Agenda to promote widespread adoption of improved workplace safety and health practices based on research findings.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

EXCHANGES

Question. As you said in your testimony, fiscal year 2013 will be a critical year for building the infrastructure and initiating the many business operations that are vital for the exchanges to begin operating in 2014.

I understand that your agency has been working hard to build out the Federal exchanges in States that have officially declared that they are not intending to partner with Federal Government on this issue. As you know, Louisiana is one of these States.

I want to stress to you how important it is to me, and to the people of Louisiana, that we have a strong exchange in our State. I stand by ready to assist you in creating a high-functioning Federal exchange in Louisiana.

In the absence of partnership from State government, it will be very important to work with other stakeholders in Louisiana, such as consumer groups and providers, to ensure that the Federal exchange is as robust as possible.

My question is: what plans does HHS have for engaging with nongovernment stakeholders and advocates within the States, particularly in States where the State government declines to partner with the Federal Government on this important issue?

Answer. HHS is working diligently with our Federal and State partners to ensure Affordable Insurance Exchanges are available to all Americans by January 2014. Much of the needed infrastructure work will occur in 2012, and beginning in 2013, major business processes will become operational in anticipation of open enrollment in October 2013.

HHS is committed to the successful implementation of the Federally Facilitated Exchanges (FFE's). The FFE's will coordinate with many State experts, including

State Medicaid Agencies related to eligibility for insurance affordability programs, State Departments of Insurance related to certification and oversight of qualified health plans, and the State Governor's offices for intergovernmental affairs. The FFEs will also coordinate with nongovernment stakeholders such as the insurance community—beyond those offering qualified health plans—when operating Reinsurance and Risk Adjustment, and consumer groups who can help us understand each State's unique characteristics and challenges. We will provide more information about our plans to engage nongovernment stakeholders once we have a complete understanding of which States plan to implement their own Affordable Insurance Exchanges and which States plan to participate in the FFEs.

HEALTH CENTERS

Question. Last August, the Health Resources and Services Administration (HRSA) announced the winners of the New Access Point grant. There were a total of 67 awards announced throughout the country.

I was very concerned that not a single applicant from Louisiana was chosen to receive the award, despite the demonstrated competency of many of the applicants and the clearly established need for community health services throughout our state. The absence of additional New Access Point grantees in our State leaves many of our non-federally qualified health centers (FQHCs) without the resources they need to meet the needs of their community.

The President's fiscal year 2013 request includes \$3 billion for health centers, including an additional \$300 million in mandatory money from the Affordable Care Act (ACA). You say that this money will provide 240 New Access Points.

I will work to help ensure you receive the money your agency needs to fund these New Access Points, and I urge you to carefully consider all qualified applications from all States, particularly those that did not receive any awards in fiscal year 2012.

Answer. As you know, the funding for fiscal year 2011 Health Center New Access Points was extremely competitive. In fiscal year 2011, HHS received 810 applications and funded 67 grants. In fiscal year 2012, HHS anticipates that up to \$145 million will be available to support approximately 220 new access points grants. The funding will support the fiscal year 2011 approved but unfunded applications following the rank order list consistent with statutory health center requirements to make awards for fiscal year 2012. The fiscal year 2011 applicants will be required to submit information in March to verify continued eligibility for a New Access Point award. HHS anticipates making awards in June or July 2012. In addition, HHS anticipates awarding \$20 million to support Beacon Communities long-term improvements in quality of care, health outcomes and cost efficiencies; \$43 million for technical assistance to enhance the operations and performance of health centers, and \$5 million for HIV/AIDS services to support enhanced HIV/AIDS treatment.

In fiscal year 2013, the budget includes \$19 million to establish approximately 25 new access points. These grants will support new full-time service delivery sites for the provision of comprehensive primary and preventive healthcare services to approximately 150,000 additional people.

NATIONAL INSTITUTES OF HEALTH—INSTITUTIONAL DEVELOPMENT AWARD PROGRAM

Question. The National Center for Research Resources (NCRR), an institute within the National Institutes of Health (NIH), houses a program called the Institutional Development Award (IDeA program).

The IDeA program funds research in states that are traditionally underrepresented within the NIH, including Louisiana.

In the fiscal year 2012 HHS budget, the Congress increased the funding for the IDeA program by \$46 million. However, for the fiscal year 2013 budget year, the President proposes a \$48 million decrease. It appears that this money is being taken away in order to help fund the new National Center for Advancing Translational Sciences (NCATS).

At a time when NIH budgets are flat, and when the most heavily funded States will continue to be funded as they always have, why would the administration propose reducing the one pot of money that is specifically designed for States that have traditionally been underfunded?

Answer. For fiscal year 2012, the IDeA program was provided with a 21-percent increase in the congressional appropriation, or approximately \$50 million, in funding over fiscal year 2011, while most other NIH programs were held relatively flat. For fiscal year 2013, the budget proposes \$225 million for the IDeA program, about the same as the fiscal year 2011 level, and approximately \$50 million below fiscal year 2012. The IDeA program is valued by NIH and gives many investigators at

less research-intensive institutions an opportunity to contribute to biomedical research. Within a constrained budget environment, NIH believes that the IDeA program should not be treated differently than most other programs in the fiscal year 2013 NIH budget which are flat with fiscal year 2011. With regard to NCATS, the fiscal year 2013 budget requests an increase because of the need for innovative solutions to the bottlenecks currently in the development pipeline that hinders the movement of basic research findings into new diagnostics and therapeutics for patients. The request for IDeA is made in the context of the total NIH budget and not as a particular offset to any one program or line item.

LOW-INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. I was dismayed to see that the budget again asks for another cut to Low-Income Home Energy Assistance Program (LIHEAP). Because of the way the LIHEAP law is written, warm weather States, growth States, and States experiencing high-energy prices don't receive a fair share of the funding except for that portion of Base grant appropriations more than the \$2 billion mark.

With an estimated 825,000 living in poverty, Louisiana has the second-highest poverty rate in the nation. Although 75,000 households were helped by LIHEAP in 2011, it is possible that only about 52,000 can be reached under the fiscal year 2013 budget request. High summer temperatures are life-threatening especially to the at-risk populations we expect LIHEAP to help, and last summer was one of the hottest on record.

I am concerned that further reducing LIHEAP imperils Louisiana households with seniors, disabled, and preschoolers. I believe the core of this program needs to be much better funded if these most vulnerable of children and families are to be given a fair shot at their potential.

Please provide the subcommittee with the latest-available State-by-State estimates of the LIHEAP-eligible populations that cannot be met at the requested funding level. I recognize that such estimates are inherently imprecise, but believe they would nonetheless greatly help our decisionmaking and understanding.

Answer. I understand your concern about the responsiveness of LIHEAP to cooling costs in States like Louisiana. While the Congress did not provide contingency funds in fiscal year 2012, the fiscal year 2013 President's budget does include \$200 million giving us the ability to respond to weather or other emergencies.

The impact of the fiscal year 2013 request level on the number of LIHEAP-eligible households unserved by the program depend on a number of factors including the impact of the economy on the number of poor households, and State-level decisions on eligibility and payment levels. The number of households served is also affected by contributions from other sources including utility companies and good neighbor funds. For example, in fiscal year 2008, the most recent year where we have complete data, there were roughly 33.5 million LIHEAP eligible households. With an appropriation of \$2.57 billion, the program served an estimated 5.4 million households with heating assistance and an estimated 500,000 households with cooling assistance.¹ The most recent data, from special tabulations of the Census Bureau's 2010 American Community Survey which is based on a national sample of households, indicates that the number of LIHEAP-eligible households increased to 37.1 million in fiscal year 2010. Preliminary fiscal year 2010 program data shows that with an appropriation of \$5.1 billion, the program provided heating assistance to 7.4 million households, cooling assistance to 900,000 households, and crisis assistance (both heating and cooling) to 2.3 million households. The fiscal year 2013 President's budget includes \$3.02 billion for LIHEAP, a 17-percent increase more than fiscal year 2008 enacted and last year's budget request. Unfortunately, there are too many variables to estimate how the additional funding will affect the percentage of eligible households receiving LIHEAP in fiscal year 2013.

SCHOOL-BASED HEALTH CENTERS

Question. School-based health centers (SBHCs), a program that you have voiced your support for on numerous occasions, was not funded in the administration's fiscal year 2013 budget.

Understanding that SBHCs are a vital safety net provider for our school-aged children across the country and a federally authorized program, can you please inform the subcommittee of your plans for funding the SBHC authorization for the 2014 fiscal year?

¹ See the following link for State-level information: http://www.acf.hhs.gov/programs/ocs/liheap/publications/FY08_congressional_state_data.html#TableIII2.

In addition, would you offer some examples on how the administration will support community health centers looking to form partnerships with school districts and local health departments that currently operate SBHCs within the service area of the community health center?

Answer. ACA appropriated \$200 million from fiscal year 2010–2013 to address capital needs, including new construction, alteration/renovations and equipment-only projects, to improve delivery and support expansion of services at school-based health centers. While funds have only been provided for the capital grants, experience has demonstrated that capital funding can significantly expand service delivery. In addition, SBHCs may apply for the Community Health Center New Access Point funding to support new healthcare service delivery sites, if they meet the health center program eligibility criteria. HRSA will continue to offer technical assistance to communities interested in developing partnerships and formal affiliations that support the provision of primary healthcare to underserved populations, including school-aged children. Priorities for the fiscal year 2014 budget are in the preliminary stages of development. Programs with existing authorizations will be given appropriate consideration in the context of the total agency budget formulation process, including the SBHC program.

CENTERS FOR DISEASE CONTROL AND PREVENTIONS CHRONIC DISEASE PROGRAM
CONSOLIDATION

Question. Would you please tell me specifically how the Coordinated Chronic Disease Prevention and Health Promotion program will be structured and how the funding for the components of the consolidation will operate?

Answer. The budget includes \$379 million, an increase of \$129 million more than fiscal year 2012, for the Coordinated Chronic Disease Prevention program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke. Because many inter-related chronic disease conditions share common risk factors, the new programs will improve health outcomes by coordinating the interventions that can reduce the burden of disease and disability. Programmatic activities that advance prevention and control of each disease will focus on epidemiology and surveillance, environmental interventions that promote healthful behaviors, work with the healthcare system to more effectively deliver quality clinical and other preventive services, and community-clinical supports for lifestyle interventions for those living with or at high risk of developing chronic conditions.

The proposed structure and funding for the Coordinate Chronic Disease Prevention and Health Promotion program will be operationalized through a new 5-year cooperative agreement cycle. Funding will be allocated to States, tribes, and territories on a formula and competitive basis. Approximately one-third of grant funding will be formula based and the remaining two-thirds will be allocated competitively.

Specific components of the proposed fiscal year 2013 program include:

- Core, formula-based awards of approximately \$82 million to State, tribal, and territorial health departments based on population size and chronic disease burden. Allocations for States will be based on a combination of population and poverty level. Poverty and chronic disease are closely related factors. This proposed allocation methodology is similar to the allocation formula used for the fiscal year 2011 Coordinated Chronic Disease grant program. The proposed formula-based allocation methodology for eligible tribal entities and territorial health departments will include a base amount and an increment based on population size. Core formula-based funding will build and strengthen State health department capacity and expertise to effectively prevent chronic disease and promote health. This capacity and expertise includes:
 - Ensuring that every State has a strong foundation to support chronic disease prevention and health promotion;
 - Maximize the reach of categorical chronic disease programs in States by leveraging shared basic services; and
 - Provide leadership and expertise to work in a coordinated manner across chronic disease conditions and risk factors to most effectively meet population health needs, particularly for populations with the greatest health disparities.
- Competitive awards of approximately \$16 million to State, tribal, and territorial health departments for specific chronic disease prevention and health promotion interventions, including:
 - Strategies that support and reinforce healthful behaviors and expand access to healthy choices;

- Health systems interventions to improve the delivery and use of clinical and other preventive services, such as blood pressure control, appropriate aspirin use, and cancer screenings; and
- Community-clinical linkage enhancement to better support chronic disease self-management.
- The remaining funding will support:
 - Competitive awards to national organizations, national networks, and other entities to disseminate best practices and effective interventions; and
 - CDC's national chronic disease subject matter expertise; technical assistance to grantees; national program surveillance; evaluation and research activities; and program leadership.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

CONGENITAL HEART DISEASE

Question. Congenital heart disease (CHD) is one of the most prevalent birth defects in the United States and a leading cause of birth defect-associated infant mortality. Due to medical advancements more individuals with congenital heart defects are living into adulthood, unfortunately, our Nation has lacked a population-surveillance system across the life-course for CHD. The healthcare reform law included a provision, which I authored, that authorizes the Centers for Disease Control and Prevention (CDC) to expand surveillance and track the epidemiology of CHD across the life-course, with an emphasis on adults. The Consolidated Appropriations Act of 2012 provided the CDC with \$2 million in new funding for enhanced CHD surveillance. Please describe how CDC is using this funding. It is my understanding that some funding will go toward pilot projects and an interdisciplinary expert meeting. Please summarize the status of these initiatives and how they will advance CHD surveillance and improve our understanding of CHD and the disease's prevalence across subgroups (including age and race/ethnicity). If additional money is appropriated for CHD surveillance in fiscal year 2013, how would that funding be utilized?

Answer. In fiscal year 2012, CDC plans to provide support through cooperative agreements for CHD surveillance activities and to support a meeting of experts on CHDs across the lifespan. CDC developed a new funding opportunity announcement for CHD surveillance focused on adolescents and adults, which is planned for publication in May 2012. The purpose is to provide support through cooperative agreements for the development of robust, population-based estimates of the prevalence of CHDs focusing on adolescents and adults and better understand the survival, healthcare utilization, and longer-term outcomes of adolescents and adults affected by CHDs. CDC anticipates funding 3 to 4 pilot sites. This is planned as a 3-year cooperative agreement, and preliminary data is anticipated after 2 years of funding.

Also, CDC plans to support a meeting of experts on CHDs across the lifespan. This meeting will provide critical input to assist CDC in developing a public health research agenda for CHDs, and improve CDC's capacity to have a measurable public health impact on the lives of those with CHDs.

For the CHD expert meeting, CDC has formed a steering committee and developed a draft invitation list. The steering committee includes CDC and the National Institutes of Health (NIH) representatives, pediatric cardiologists, and adult CHD specialists. The steering committee has developed a list of potential invitees including pediatric cardiologists, adult CHD specialists, epidemiologists, economists, health services researchers, and other areas of expertise to guide the development of a prioritized public health research agenda for CHDs. The meeting is tentatively scheduled for September 10–11, 2012 and will be held at CDC's main campus in Atlanta, Georgia.

If additional funding is available in fiscal year 2013, CDC would provide supplements to existing pilot sites and enhance other ongoing activities based on the CHDs public health research agenda formulated by the CHD steering committee.

Question. There continue to be higher rates of mortality and serious disability at all ages among people with congenital heart disease compared to the general population. Could you please describe current efforts at Agency for Healthcare Research and Quality (AHRQ) and NIH to better understand healthcare utilization and treatment outcomes for congenital heart disease across the life-span?

Answer. AHRQ's research related to congenital heart disease focuses mainly on pediatric issues. This includes supporting the Children's Health Insurance Program Reauthorization Act (CHIPRA) Pediatric Quality Measures Program. While AHRQ has not yet developed specific measures of the quality of care for children with heart

disease, congenital heart disease is a major birth defect and a major cause of infant morbidity and mortality. Therefore its care can be significantly impacted by various measures, including those that will track:

- global pediatric patient safety;
- child hospital readmissions;
- neonatal costs, quality, and outcomes;
- neonatal and pediatric intensive care unit quality and outcomes;
- patient-reported outcomes and inpatient experiences of care; and
- identification of, and coordination of care for children with special healthcare needs.

AHRQ is also developing and supporting its Healthcare Cost and Utilization Project (HCUP), most notably the Kids' Inpatient Database (KID). KID is a unique and powerful database of hospital inpatient stays for children. It was specifically designed to permit researchers to study a broad range of conditions and procedures related to child health issues. KID includes data on volumes, costs, and charges of inpatient pediatric cardiac care. Researchers and policymakers can use KID to identify, track, and analyze national trends in healthcare utilization, access, charges, quality, and outcomes. For example, researchers at Children's Hospital Boston used KID data to examine factors associated with increased resource utilization for children with congenital heart disease. Furthermore, AHRQ is developing Pediatric and Inpatient Quality Indicators that include measures of procedure volume and risk-adjusted mortality following pediatric cardiac surgery. It is also supporting a contract on the prevention of Staph aureus infections in cardiac surgical patients, including adult survivors of congenital heart disease.

Within NIH, the National Heart, Lung, and Blood Institute (NHLBI) has made a significant investment in answering these important questions through support of targeted programs as well as a large portfolio of investigator-initiated grants. The Bench to Bassinet (B2B) program supports an extensive collaboration among multidisciplinary investigators to improve outcomes for patients with congenital heart disease.¹ Its longest-standing component is the Pediatric Heart Network (PHN) which conducts multicenter research in congenital heart disease.²

A major focus of PHN studies has been on the short- and long-term outcomes of medical and surgical interventions. One trial found that the initial surgical strategy typically used for infants with only a single functional heart-pumping chamber may improve short-term, but not intermediate-term, outcomes. The wealth of data obtained in this surgical study also allowed us to examine the considerable variation in medical care practice that existed across the 15 major academic centers that participated. Further analysis of this information is expected to shed light on how such variations affect outcomes and costs. Another PHN trial found that a commonly prescribed drug, enalapril, had no effect on outcomes. A follow-up study is now assessing whether this result has altered prescribing patterns in North America. An ongoing follow-up of a cohort of adolescents who have undergone staged surgical repair for single ventricle physiology is enabling us to examine the critical transition from pediatric to adult care. This transition has proven challenging for many who have serious CHD; appropriate care in adulthood is essential to optimizing their independence and function.

Another B2B component is a consortium studying the genetic underpinnings of congenital heart disease outcomes. In the initial 15 months, it has recruited some 3,000 children and adults (more than 20 percent are older than 18 years of age), along with many of their parents, to study both genetic causes of congenital heart disease and genetic contributions to treatment outcomes. Tetralogy of Fallot (a "blue-baby" defect), for instance, can result from at least 6 different genetic mutations. Once we know how the mutations influence outcomes, we will be able to risk-stratify patients for more- or less-intensive treatment and to offer personalized therapies.

NHLBI is funding the Pumps for Kids, Infants, and Neonates (PumpKIN) program to design, develop, test, and make available to infants and young children a number of advanced circulatory support devices for congenital and acquired cardiovascular disease resulting in heart failure.³ Currently, very few options exist for these vulnerable heart failure patients. The program includes two small implantable ventricular assist devices based on the latest technologies and two advanced integrated and compact extracorporeal membrane oxygenator systems. They have been designed to address troublesome shortcomings of circulatory support devices for children such as reliability, biocompatibility, infection, thrombosis, and size. The four

¹ <http://www.benchtobassinet.org/>.

² <http://www.pediatricheartnetwork.com/>.

³ <http://public.nhlbi.nih.gov/newsroom/home/GetPressRelease.aspx?id=2689>.

devices are in their last phases of bench-testing, with clinical trials expected to begin in October 2013. In contrast to older adults, for whom these devices may be definitive therapy, these devices are used in children as bridges to transplantation. The shortage of appropriate hearts for transplantation into children requires that better devices be available to support patients until a donor heart is available.

NHLBI also funds a number of grants that address common issues faced by children and adults with congenital heart disease, such as exercise capacity, problems with neurological function and learning, and overall quality of life. These investments are aimed to ensure a brighter future for people of all ages with congenital heart disease.

CHILDREN'S HOSPITALS GRADUATE MEDICAL EDUCATION

Question. The administration proposes cutting the Children's Hospitals Graduate Medical Education (CHGME) program by two-thirds to \$88 million in fiscal year 2013. As you know, this program supports training of pediatric providers at two freestanding children's hospitals in Illinois—Children's Memorial and La Rabida Children's Hospital—and approximately 50 others around the country. The CHGME recipient hospitals train more than 5,600 full-time equivalent residents annually.

I am concerned by the proposed cut to CHGME funding. Through Medicaid and the Children's Health Insurance Program, we've expanded the number of children with insurance coverage in the United States. I view this as a great success, however we must ensure we have an adequate supply of physicians to care for these children.

Already, there are significant shortages in several pediatric subspecialties, including neurology, developmental-behavioral medicine, general surgery, and pulmonology, that are affecting patient care. A survey last year by the National Association of Children's Hospitals and Related Institutions found wait times of more than 10 weeks to see a pediatric endocrinologist, and 9 weeks for a pediatric neurologist.

Is the administration concerned that reducing CHGME funding will worsen the shortage of pediatric subspecialists and affect children's access to care by general pediatricians?

Answer. We recognize the vital role that children's hospitals and pediatric providers play in providing quality healthcare to our Nation's children. The fiscal year 2013 CHGME funding level continues to support direct costs for training pediatric residents at independent children's hospitals. This payment provides support for resident salaries, expenditures related to stipends and fringe benefits for residents, salaries and fringe benefits of supervising faculty, cost associated with providing the GME training program, and allocated institutional overhead costs.

The fiscal year 2013 budget retains the incentive to maintain total resident levels. The administration recognizes that research has indicated that there is a significant shortage of pediatric subspecialists, resulting in children with serious illnesses being forced to travel long distances—or wait long periods—to see a pediatric specialist. In response to these shortages, the fiscal year 2013 President's budget includes \$5 million to implement the Pediatric Specialty Loan Repayment (PSLR) program that was authorized in the Affordable Care Act (ACA). Under this program, loan repayment agreements will be authorized for pediatric specialists who agree to work in underserved areas.

While both the CHGME Payment and the PSLR programs support the pediatric medical workforce, the focus of each is different. The CHGME Payment Program serves the purpose of providing residency training in Children's Hospitals through the payments made to Children's Hospitals, while the PSLR program is designed to assist pediatric specialists more directly and increase the number of pediatric specialists in underserved areas.

SECTION 317 IMMUNIZATION PROGRAM

Question. The Section 317 Immunization Program helps to ensure high immunization coverage levels and low incidence of vaccine preventable diseases by supporting state and local immunization programs in planning, developing, and maintaining a public health infrastructure. The administration's budget proposes a \$58 million cut to the section 317 program. Will this reduction impact the agency's ability to purchase grants or operational support for health departments? How do you see the role the section 317 program evolving with the implementation of ACA? The President's budget proposes transferring \$72 million from the Prevention and Public Health Fund to the section 317 program. How would those funds be used?

Answer. The fiscal year 2013 budget request includes funds for vaccine purchase to continue outreach to the hardest-to-serve populations, and critical immunization

operations and infrastructure that supports national, State, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs \$25 million toward continuation of the billables project, which allows public health departments to vaccinate and bill for fully insured individuals in order to maintain section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The fiscal year 2013 budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The budget does not continue funding for one-time enhancements planned for fiscal year 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan.

ACA requires new health plans to cover routinely recommended vaccines without cost-sharing when provided by an in-network provider. As these health insurance reforms expand prevention services to more Americans, the size of the population currently served by section 317 vaccine is expected to decrease in size, specifically underinsured children. The Section 317 Immunization Program will continue to have a critical role in:

- providing vaccines to meet the needs of uninsured adults and responding to urgent vaccine needs such as outbreak response; and
- ensuring the necessary infrastructure is in place to support the Nation's immunization system for both routine vaccination as well as managing vaccine shortages and other emergency response.

This critical infrastructure serves both the public (e.g., Vaccines For Children Program and Section 317) and private sectors. Insurance coverage alone will not provide the immunization infrastructure necessary to ensure a strong evidence base for national vaccine programs and policy, quality assurance for immunization services, and high-vaccination coverage rates across the lifespan.

QUESTIONS SUBMITTED BY SENATOR JACK REED

SECTION 317 IMMUNIZATIONS

Question. The Centers for Disease Control (CDC), in its fiscal year 2011 report to the Congress on the Section 317 Immunization Program estimated that approximately \$1.72 billion is necessary to fulfill the goals of adequately immunizing uninsured and underinsured children, adolescents, and adults. Indeed, vaccination programs have been proven to be one of the most cost-effective approaches to reducing disease and future healthcare costs, a critical goal of the Congress. However, the fiscal year 2013 budget proposal contains a nearly 10-percent cut to this program. While millions more uninsured and underinsured individuals will receive free vaccinations beginning in 2014, how does this funding level ensure the cost-effective immunization programs currently in place are maintained during the intervening years?

Answer. The fiscal year 2013 budget request includes funds for vaccine purchase to continue outreach to the hardest-to-serve populations, and critical immunization operations and infrastructure that supports national, State, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs \$25 million toward continuation of the billables project, which allows public health departments to vaccinate and bill for fully insured individuals in order to maintain section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The fiscal year 2013 budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The budget does not continue funding for one-time enhancements planned for fiscal year 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan.

LEAD POISONING PREVENTION

Question. The Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recently recommended reducing the blood lead level in children from 10ug/dL to 5 ug/dL when greater medical monitoring is necessary, along with en-

hanced lead education for family members and more comprehensive investigations of the child's environment. What is CDC's plan for implementing this recommendation?

Answer. The ACCLPP recommendations are currently being reviewed and evaluated by U.S. Department of Health and Human Services (HHS). The process of carefully reviewing ACCLPP's recommendations and deciding whether or not to concur with them may take several months to complete.

Question. In fiscal year 2012, the Congress requested the CDC and Health Resources and Services Administration (HRSA) work together to expand healthy housing activities as part of its Home Visiting Programs and provide greater incentives for States to implement programs that already include these activities. What action has been taken to respond to this request?

Answer. CDC and HRSA are working to identify possible solutions for integrating childhood lead poisoning prevention activities into routine services of HRSA's early childhood Home Visiting Program.

HEALTHY HOME AND COMMUNITY ENVIRONMENTS

Question. The fiscal year 2013 budget proposes a consolidation of the CDC Healthy Homes and Lead Poisoning Prevention Program and the Asthma Control Program even though the two programs are distinctly different in their mission and activities. Grantees of the Healthy Homes and Lead Poisoning Prevention Program reduce injuries at home, make aging in place a real option for our seniors, prevent radon-caused lung cancer and carbon monoxide poisoning, and sustain efforts to prevent and treat childhood lead poisoning. The Asthma Control Program provides grantees with resources to offer workforce and professional development for asthma prevention and care and self-management, and help improve asthma management in schools, child care centers, and homes. Given the distinctions in these activities, how does CDC plan to consolidate these programs into one while ensuring we don't lose any ground on our lead poisoning prevention and asthma care efforts?

Answer. The fiscal year 2013 budget proposes a new program—Healthy Home and Community Environments—that will incorporate the National Asthma Control Program (NACP) and the Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The fiscal year 2013 request for the Healthy Homes and Community Environments program is \$27.3 million.

The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors.

TITLE VII HEALTH PROFESSIONS

Question. The administration's fiscal year 2013 request proposes eliminating the Title VII Health Careers Opportunity Program (HCOP), and suggests that "other federally funded health workforce development programs will continue to promote training of individuals from disadvantaged backgrounds." Can you please provide specific examples of Federal programs other than HCOP that prepare underrepresented minorities to become more competitive applicants to health professions schools? If the program is eliminated, where could aspiring health professionals find the HCOP-offered academic, financial, and mentorship opportunities designed to build a more diverse healthcare workforce commensurate with the Nation's needs?

Answer. The President's budget prioritizes funding activities that have a more direct impact on expanding the primary care workforce by supporting students who have committed to and are training as health professionals. Investments initiated in the fiscal year 2013 budget will train an additional 2,800 primary care providers over the next 5 years.

Other federally funded health workforce development workforce programs will continue to promote training of individuals from disadvantaged backgrounds and increase the likelihood that disadvantaged students are able to attend health professions programs through recruitment activities and scholarship opportunities. For example, the fiscal year 2013 budget includes \$22.9 million for the Centers of Excellence program to recruit, train, and retain underrepresented minority students and faculty in healthcare fields to increase the supply and quality of underrepresented minorities in the health professions. In addition, the fiscal year 2013 budget in-

cludes \$47.5 million for the Scholarships for Disadvantaged Students Program which provides grants to health professions and nursing schools for use in awarding scholarships to financially needy students from disadvantaged backgrounds. This program aims to increase the diversity of the health professions workforce as well as to increase the number of primary care providers working in medically underserved areas. The Affordable Care Act also provided \$85 million in funding for demonstration projects to address health profession workforce needs.

Increasing the diversity of the health professions workforce is an area of focus for HRSA's health professions programs and for the most recent academic year, 58 percent of the graduates from HRSA-funded programs were disadvantaged and/or underrepresented minorities (URM). Similarly, the proportion of NHSC Scholarship Program participants who are underrepresented minorities exceeds the average national enrollment rates for URMs in health professions disciplines. Other examples of programs that support diversity in the health professions workforce are the Primary Care Training and Enhancement and the Nursing Workforce Diversity programs. Grantees in the Primary Care Training and Enhancement program must put a plan in place to increase the number of diverse health professionals and must document their progress. Grantees under the Nursing Workforce Diversity program work to increase educational opportunities for disadvantaged individuals pursuing nursing degrees.

STATE CANCER REGISTRIES

Question. Given the fact that pediatric cancers are typically fast-growing and require prompt treatment, the Committee has provided funding to assist States with improving data collection and facilitating early case capture of pediatric cancers. This funding has enabled researchers in nine States to more rapidly report childhood cancer occurrences, reoccurrences, and treatments provided to State cancer registries, and 35 States with supplemental registry infrastructure funding. What is the range of technology that States have implemented designed to improve childhood cancer surveillance and facilitate early case capture?

Answer. Through CDC's National Program of Cancer Registries (NPCR), the Caroline Pryce Walker Conquer Childhood Cancer Act supports pediatric cancer research, including early case capture. Representing 96 percent of the population, data from NPCR are vital to understanding the Nation's cancer burden and are fundamental to cancer prevention and control efforts at the national, State, and local level.

CDC received funding to support pediatric cancer research in fiscal year 2010 and fiscal year 2011. Fiscal year 2010 resources were used to support supplemental grants to 35 cancer registries with existing electronic reporting activities to expand their work. During fiscal year 2011, CDC allocated funding to specific State projects, where resources could be concentrated to develop comprehensive approaches to pediatric cancer rapid reporting by healthcare providers. CDC awarded funding to seven States.

The seven States funded by CDC to facilitate early case capture of pediatric cancers are building upon existing cancer registry infrastructure and implementing a number of innovative technological approaches to rapid reporting. Some of these include:

- Electronic pathology reporting, which provides real-time, automated reporting to State central cancer registries from various sources, such as hospital pathology laboratories; in-State and out-of-State independent pathology laboratories; and large, out-of-State children's hospitals.
- Electronic reporting from State Health Information Exchanges.
- Using Electronic Health Record data.
- Using electronic reporting of diagnostic imaging to capture cancer cases that do not have a pathology report, such as clinically diagnosed brain tumors.
- Using web-based technology to capture hospital discharge data to ensure that reported information is complete.

As a result of these technological advancements to improve reporting speeds and facilitate data access, researchers will be able to use more timely cancer data—improving research on pediatric cancer trends, risk factors, and treatments. Finally, CDC is working to identify technological methods to streamline data access for researchers by facilitating data linkages and assisting researchers in managing the process to access cancer registry data.

QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

Question. I appreciate the tough decisions your Department has to make as we work to achieve a budget which begins to get our national debt under control. However, I am concerned about the cuts recommended to the Low-Income Home Energy Assistance Program (LIHEAP). The administration's recommendation of \$3 billion represents a 40-percent cut since fiscal year 2010. Since only \$400 million of this will go into the Tier 2/Tier 3 formulas, the low-income citizens of warm weather and growth States will see a marked decrease in their ability to get help.

Unfortunately, America's most vulnerable citizens are concentrated in warm weather States, where they face the growing danger of high summer temperatures. Arkansas's poverty rate of 18.8 percent is the third highest in the Nation. Under the fiscal year 2013 budget request for LIHEAP, it appears that one-third fewer households will be able to receive assistance from LIHEAP this year as compared to 2011.

At a time when LIHEAP is needed the most, I am concerned that this program is proposed to be cut again, and that Americans with little recourse should be denied access to LIHEAP. How can we work together to ensure that the needs of this segment of the population are met?

Answer. The Department of Health and Human Services (HHS) is committed to improving the Nation's health and well-being while simultaneously contributing to deficit reduction. To do this, HHS makes investments where they will have the greatest impact and lead to meaningful gains in health and opportunity for the American people.

Our fiscal year 2013 budget request includes a number of investments which support America's most vulnerable citizens. The budget supports critical reforms in Head Start and a Child Care Initiative that, when taken together with the Race to the Top Early Learning Challenge, are key elements of the administration's broader education reform agenda. The budget also includes additional funds to provide incentives to States to improve outcomes for children in foster care and for children at risk of foster care placement.

The request for LIHEAP is \$3.02 billion, \$452 million less than the fiscal year 2012 enacted level, but \$450 million (17 percent) above both fiscal year 2008 and the 2012 request. The fiscal year 2013 request targets \$2.8 billion in base grants using the State allocation the Congress enacted for fiscal year 2012. The request also includes \$200 million in contingency funds, which will be used to target energy or weather-related emergencies.

Questions. It has come to my attention that there are concerns that some high-cost, low-volume radiopharmaceuticals may not be receiving adequate reimbursement under Medicare in the outpatient setting. It is my understanding that today many of these diagnostic drugs are bundled into a payment that may only capture a fraction of their cost. Average Sales Price (ASP) data submitted on a voluntary basis by companies manufacturing radiopharmaceuticals indicates that current Medicare reimbursement for these radiopharmaceuticals is likely below hospital acquisition costs. Has Centers for Medicare & Medicaid Services (CMS) re-evaluated ambulatory payment classifications (APC) payment rates for nuclear medicine procedures or its mean cost data for the radiopharmaceuticals in relation to ASP data? If the new sales data is at odds with CMS calculated costs and the agency believes the discrepancy should be addressed in a fiscally responsible manner, does CMS have the authority to unbundle and pay separately for diagnostic radiopharmaceuticals?

Answer. The Medicare outpatient prospective payment system (OPPS), like other Medicare prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service or bundle of services for a particular patient, but with the exception of outlier cases, the payment is adequate to ensure access to appropriate care. Packaging payment for multiple interrelated services into a single payment creates incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment.

In the calendar year 2008 OPPS rule, CMS finalized a policy to treat diagnostic radiopharmaceuticals differently, for payment purposes, than therapeutic radiopharmaceuticals, as part of a broader packaging policy under the OPPS. For calendar year 2008 through calendar year 2012, we packaged payment for all diagnostic radiopharmaceuticals into the major procedure that it was performed with, most commonly nuclear medicine scan procedures. We finalized this policy because we view diagnostic radiopharmaceuticals as functioning effectively as supplies that

enable the provision of an independent service and are always ancillary and supportive to an independent service, rather than serving as a therapeutic modality.

While we package the cost of diagnostic radiopharmaceuticals into payment for the nuclear medicine scan as a single diagnostic modality, the OPSS makes separate payment for both therapeutic radiopharmaceuticals and brachytherapy sources as a distinct therapeutic modality.

For the calendar year 2012 OPSS, we continue to package payment for nonpass-through diagnostic radiopharmaceuticals into payment for their associated nuclear medicine procedures. We have established claims processing edits (called procedure-to-radiolabeled product edits) requiring the presence of a radiopharmaceutical or other radiolabeled product HCPCS code, including brachytherapy sources and therapeutic radiopharmaceuticals, when a separately payable nuclear medicine procedure is present on a claim. This enables hospital's reported charges for diagnostic radiopharmaceuticals to be incorporated into the annual APC payment rate setting calculations, and provides assurance that the claims information we use in rate setting are accurate and reflects the associated cost of the single diagnostic modality. We evaluate these claims processing edits every quarter to ensure that they are up to date.

We incorporate the line-item estimated cost for diagnostic radiopharmaceuticals in our claims data as a reasonable and accurate approximation of average acquisition and handling costs for diagnostic radiopharmaceuticals. We therefore use these estimated costs to establish payment rates for the separately payable product with which the diagnostic radiopharmaceutical is packaged. We evaluate and establish these APC payment rates on a yearly basis, to reflect changes in service costs as well as practice patterns.

We also note that, in the event that the diagnostic radiopharmaceuticals packaged into the primary procedure's payment are sufficiently costly, the separately payable major procedure would be eligible for an OPSS outlier payment, mitigating any impact from extreme costs associated with providing the major procedure.

While the statute allows us the authority to pay separately for these procedures, we believe that the APC payments associated with the primary procedures reflect the costs commonly associated with providing the procedures as well as support the right incentives in the OPSS system for efficiency. Unbundling these procedures would give providers no reason to exercise financial prudence when providing the primary procedure, along with any associated packaged items. Similarly, removing the incentive through packaging, of making cost-efficient decisions, could have an adverse effect on the beneficiary, since they would pay a 20-percent coinsurance for those items.

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

OBESITY FUNDING

Question. More than one-third of U.S. adults are obese. The Deep South has the highest obesity rate in the country, with 6 out of 7 States having an obese population higher than 30 percent. The two most obese States in the Nation, Alabama and Mississippi, both have obesity rates more than 32 percent, yet do not receive any obesity prevention funding from the Centers of Disease Control (CDC). Why do public health dollars not track with burden?

Answer. In 2008, CDC released a funding opportunity announcement for the State-Based Nutrition and Physical Activity Program to Prevent Obesity and Other Chronic Diseases. The purpose of this program is to improve healthful eating and physical activity to prevent and control obesity and other chronic diseases by building and sustaining statewide capacity and to implement population-based strategies and interventions. The program currently funds 25 States to address the problems of obesity and other chronic diseases through statewide efforts coordinated with multiple partners.

State-based nutrition and physical activity (obesity) grants were awarded using a competitive process. Applications were reviewed for responsiveness to the eligibility criteria in the Funding Opportunity Announcement (FOA) and underwent an objective review. Applications were scored against the criteria identified and not against one another. For each application, objective review comments were presented to a panel and a vote took place by the panel to determine if the application was approved, disapproved, or deferred. Approved applications were then rank ordered by score and funding decisions made based on the availability of funding, with preference given for States that had higher obesity prevalence rates, provided there

was adequate justification to fund out of rank order. Neither Alabama nor Mississippi met the criteria for funding out of rank order.

CDC is continuing work to improve the effectiveness of obesity related grant programs (nutrition, physical activity and obesity, diabetes, heart disease and stroke, cancer and arthritis) by strengthening coordination and collaboration across individual categorical programs; better defining the range of targeted science-based interventions and activities that will accelerate health improvements; and working with State grantees to identify efficiencies and improve the effectiveness of program investments.

Regardless of whether a State receives funding or not, CDC provides technical assistance to all States.

CDC continues to develop and disseminate tools and resources for funded and nonfunded entities to inform the development and implementation of State and local strategies to improve healthful eating and physical activity to prevent and control obesity.

CENTERS FOR MEDICARE & MEDICAID SERVICES DEMOS/CENTER FOR MEDICARE &
MEDICAID INNOVATION

Question. The Center for Medicare & Medicaid Innovation (CMMI) was established in the Affordable Care Act to “test payment and services delivery models to reduce program expenditures” under Medicare and Medicaid. The law appropriated \$10 billion to fund these new models. At a time when the Nation’s healthcare entitlement programs are facing severe financial strain, I am concerned that funds are being expended by CMMI with little to no value provided and further threaten the entitlement programs’ solvency. Have you received estimates from the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary that demonstrate that any program developed by CMMI is generating lower Medicare spending?

Answer. During the development of initiatives under the authority of section 1115A(f) of the Social Security Act (ACA section 3021), the Innovation Center works closely with the CMS Office of the Actuary to develop potential models, ensure the potential model will accurately test the changes in the delivery of care, and project the expected financial implications of the model. The Innovation Center prepares estimates of the financial impact of the proposed initiatives, as well as an analysis of their potential impact on the quality of health and healthcare among beneficiaries, an examination of current costs of the targeted healthcare service, an analysis of the potential savings, and a review of the prior research that supports testing the initiative. The Office of the Actuary has participated in reviewing these savings estimates and in some cases produced estimates.

Question. While the Innovation Center typically works closely with the Office of the Actuary during the development of models, the statutorily mandated certification of savings by the Chief Actuary does not occur in the design phase, but rather in the testing phase to determine whether modification or termination of the testing of a model is needed and after the conclusion of the demonstration to inform whether there should be expansion or wide-scale adoption of the initiative. To date, none of the Innovation Center models have been in the testing phase long enough to generate sufficient data for the Chief Actuary to make such determinations. We believe that the Innovation Center’s evidence-based approach to innovation will result in reducing healthcare costs while improving quality.

Secretary Sebelius, can you provide specific measures that are being used to evaluate the impact of the CMMI initiatives on reducing Medicare spending or improving the quality of care?

Answer. An evaluation of the model’s performance is planned for each model tested by the Innovation Center. The evaluation is intended to determine the model’s impact on spending, quality of care delivered, and patient health outcomes and experiences. The Innovation Center will align its relevant performance measures to those from the Department of Health and Human Services National Strategy for Quality Improvement in Health Care, as well as measures used for other CMS programs, such as those used for the Physician Quality Reporting System and the Medicare Shared Savings Program.

All participating providers will be required to work with an independent evaluator to track and provide agreed-upon data as needed for the evaluation. As applicable, these data will be merged with administrative claims data collected by CMS to allow assessment of performance on topics such as clinical quality performance, patient functional status, and financial outcomes. The Innovation Center anticipates using multiple cycles of data collection due to the changing nature of the approaches used by participants in response to rapid-cycle feedback. Particular care will be taken to identify the effect of each reform in the context of other interventions.

For example, when evaluating participants in the Comprehensive Primary Care initiative, the Innovation Center will review several types of quality and patient experience measures. These measures will include the following domains:

- patient and caregiver experience;
- care coordination and transitions;
- preventive health;
- practice transformation; and
- at-risk populations.

Question. The Congressional Budget Office (CBO) issued a report in January on the “Lessons from Medicare’s Demonstration Projects.” The report found that most programs have not reduced Medicare spending. In nearly every program, spending was either unchanged or increased relative to the spending that would have occurred in the absence of the program. In light of this track record, why should we continue to invest billions of dollars into CMMI?

Answer. We know that reforming our healthcare payment and delivery system won’t be easy. That doesn’t make it any less necessary.

Before the Innovation Center develops a new model for testing, it conducts a thorough review of similar programs’ past performance. This allows us to build on models that have been successful, while avoiding those that have not. When models are in their testing phase, the Innovation Center conducts continuous and rigorous evaluation, to determine the impact that models are having, both on health expenditures and on quality of care. Models that are working will be eligible for expansion, while those that are not will be either modified or terminated.

We note that CBO’s report also included lessons for the design of Medicare demonstrations that may increase a demonstration’s odds of success. These include the timely collection of clinical data, a focus on care transitions, the use of team-based care, and targeted low-cost interventions. Much of the Innovation Center’s work embodies these areas of focus, and all Innovation Center demonstrations emphasize rapid evaluation and ongoing data collection.

The Innovation Center is tasked with testing new and innovative payment and delivery models. By definition, such models are unproven. While we select models with high potential to improve quality and reduce costs, it is likely that some will prove successful, and others may not. The only way we can find out is by testing and rigorously evaluating them. However, the one thing we cannot afford is to choose not try new approaches, simply because they might fail. This would ensure that we are left with an outdated and unaffordable healthcare system, which misses opportunities to provide patients with high-quality, affordable care.

CENTERS FOR MEDICARE & MEDICAID SERVICES EXCHANGE

Question. Secretary Sebelius, some States, for example Alabama, have decided against setting up a new State-based exchange. If a State elects not to establish an exchange, under law, CMS must establish a federally facilitated exchange in that State. Is the Federal exchange on track to begin January 1, 2014, as advertised?

Answer. Yes. CMS is currently working to implement a federally facilitated Exchange, including important business functions such as eligibility and enrollment, plan management, and consumer outreach. In addition, contracts have been awarded to build the information technology systems essential to exchange operations.

Question. The budget proposes a significant 50-percent reduction in State High-Risk Pool funding with the expectation that States will transition to operational exchanges. In light of the fact that some States are not setting up an exchange, can you elaborate on how the transition from high-risk pools to exchanges is going?

Answer. The fiscal year 2013 President’s budget request provides sufficient funding to States as they begin scaling down activities in their existing State High-Risk Pools and enrollees are transitioned to Affordable Insurance Exchanges in 2014.

HHS is working diligently with our Federal and State partners to ensure exchanges are available to all Americans by January 2014. Much of the needed infrastructure work will occur in 2012, and beginning in 2013, major business processes will become operational in anticipation of open enrollment in the exchanges in October 2013. We continue to work with States to ensure that they are ready to begin exchange operations in 2014 to maintain coverage for State High-Risk Pool enrollees.

CHILDREN’S HOSPITAL GRADUATE MEDICAL EDUCATION

Question. The Children’s Hospitals Graduate Medical Education (CHGME) program supports the training of residents and fellows and increases the supply of primary care and pediatric medical and surgical subspecialties. Nationwide, free-standing children’s hospitals have trained 49 percent of all pediatric residents and

51 percent of all pediatric specialists. The President's budget proposes to decrease funding for training pediatric residency positions \$177 million less than fiscal year 2012. Meanwhile, the budget proposes to begin a new Pediatric Specialty Loan Repayment (PSLR) program to repay medical school loans. It seems illogical that we would allocate funding to repay loans of physicians but reduce the funding to train physicians. What is the rationale behind this decision?

Answer. We recognize the vital role that children's hospitals and pediatric providers play in providing quality healthcare to our Nation's children. The fiscal year 2013 CHGME funding level continues to support direct costs for training pediatric residents at independent children's hospitals. This payment provides support for resident salaries, expenditures related to stipends and fringe benefits for residents, salaries and fringe benefits of supervising faculty, cost associated with providing the GME training program, and allocated institutional overhead costs.

The fiscal year 2013 budget retains the incentive to maintain total resident levels. The administration recognizes that research has indicated that there is a significant shortage of pediatric subspecialists, resulting in children with serious illnesses being forced to travel long distances—or wait long periods—to see a pediatric specialist. In response to these shortages, the fiscal year 2013 President's budget includes \$5 million to implement the PSLR program that was authorized in the Affordable Care Act (ACA). Under this program, loan repayment agreements will be authorized for pediatric specialists who agree to work in underserved areas.

While both the CHGME payment and the PSLR programs support the pediatric medical workforce, the focus of each is different. The CHGME Payment Program serves the purpose of providing residency training in Children's Hospitals through the payments made to Children's Hospitals, while the PSLR program is designed to assist pediatric specialists more directly and increase the number of pediatric specialists in underserved areas.

LOBBYING RESTRICTIONS

Question. Secretary Sebelius, I am concerned about the Department's implementation of a longstanding Federal prohibition on lobbying with Federal tax dollars. Yesterday you testified before the House Labor, Health and Human Services, and Education, and Related Agencies Appropriations Subcommittee that you believe it is both legal and appropriate for grantees to lobby local governments.

I believe the interpretation is clear—Federal funds cannot be used to change policies at the Federal, State, or local level. However, I have several examples of Federal funds being used to secure bill sponsors, draft legislation, and lobby for tax increases. How will you clarify this misinterpretation by agencies within the Department, and what steps will you take to ensure a full investigation occurs regarding any Federal tax dollars that were misused for lobbying activities?

Answer. HHS is committed to ensuring the proper use of appropriated funds, and to ensuring awardees' compliance with all applicable regulations and statutes related to lobbying activities, including Office of Management and Budget (OMB) Circular A-122: Cost Principles for Non-Profit Organizations; OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Governments; and our own policy regarding lobbying activities.

HHS awardees are informed about the Federal laws relating to use of Federal funds, including applicable anti-lobbying provisions. Not only are the restrictions noted within HHS funding opportunity announcements, the lobbying prohibition is also included within the terms and conditions to which each awardee agrees prior to receiving Federal funds. In addition, HHS staff monitor the use of Federal funds by awardees using tools such as on-site review and risk mitigation plans.

Applicable lobbying restrictions do not prohibit awardees from all interactions with policymakers or the public. Federal law allows many activities that are not considered lobbying and that community awardees may decide to pursue. For example, awardees may use funds to disseminate information about public health programs and science-based solutions and to implement specific programs, such as evidence-based educational materials and media on the health effects of increasing physical activity or decreasing exposure to secondhand smoke.

At HHS, we are committed to fulfilling the mandates from the Congress to empower communities to pursue high-quality, science-based programs that make a real difference in the health of Americans. We take our responsibility as stewards of taxpayer dollars very seriously, and we are committed to enabling awardees' success and to ensuring that Federal funds are used efficiently and appropriately.

HEALTHCARE PREMIUMS

Question. Secretary Sebelius, we have repeatedly heard from this administration and the President that health insurance premiums will be lowered by the end of the President's first term. In February 2008 President Obama stated: "We're going to work with you to lower your premiums by \$2,500 per family per year. And we will not wait 20 years from now to do it or 10 years from now to do it. We will do it by the end of my first term as President." However, yesterday you testified before the House Labor, Health and Human Services, and Education, and Related Agencies Appropriations Subcommittee that health insurance premiums could not be lowered by \$2,500 until the exchanges come online in 2014. Madam Secretary, is it possible that premiums will be lowered by the end of this year or is this an abandoned campaign promise?

Answer. ACA contains market reforms that will reduce premium costs for the same level of benefits. Most of the market reforms that will impact premium costs, such as exchanges, will not be in place until 2014. Until the exchanges are implemented, consumers have limited ability to compare across options to get the best value for their premium dollars, and health insurance issuers have less incentive to compete. We may not realize premium decreases until such time as exchanges and other market reforms are fully operational.

DUPLICATION AND OVERLAP

Question. The Government Accountability Office (GAO) released a report in February that stated, "HHS is collaborating with Labor to conduct an evaluation to better understand policies, practices, and service delivery strategies that lead to better alignment of the Workforce Investment Act (WIA) and Temporary Assistance for Needy Families (TANF)." Can you provide further information on this collaboration, including examples of State and local practices that may be models for other areas to follow and how WIA-TANF duplication can be reduced?

Answer. The Administration for Children and Families (ACF) remains committed to bringing about better alignment of Federal investments in job training, improved models for delivering quality services across programs at lower costs, and providing relevant information to workforce and social service communities. In order to address GAO's recommendation for developing and disseminating information on State and local efforts and initiatives to increase administrative efficiencies, both Departments are exploring a variety of efforts aimed at addressing the challenges, strategies, incentives, and results for States and localities to undertake such initiatives, including developing joint administrative guidance, technical assistance and outreach, leveraging research resources and other collaborative efforts. Some examples of these efforts include:

- A partnership between ACF and the Employment and Training Administration (ETA) encouraged workforce and human service agencies to co-enroll youth in WIA and TANF programs and leverage TANF funds to cover subsidized wages for youth, thus promoting effective and efficient leveraging of Federal resources to expand summer employment opportunities for 2010.
- For program year 2012, ETA has consulted with multiple stakeholders, including ACF and other agencies, to redesign ETA's plan guidance related to WIA submissions.
- The Career Pathways Technical Assistance Initiative grants, led by an inter-agency work group consisting of staff from ACF, ETA and the Department of Education's Office for Vocational and Adult Education, leverages the latest research and best practices to help grantees in the workforce and human services agencies form partnerships to improve employment and training outcomes for low-skilled individuals.
- Ongoing monthly meetings of the Departments of Labor, Health and Human Services Research Working Group allows for sharing of current research, helps to identify gaps and to explore additional areas for potential collaboration.
- To gain a better understanding of the TANF-WIA integration that a number of States have implemented, ACF and ETA jointly plan to develop an approach to identify existing promising WIA and TANF linkages.

Question. In February, the Government Accountability Office (GAO) released a report on duplication, fragmentation, and cost-saving opportunities in the Federal Government. The report noted that there are several areas where the Department of Health and Human Services (HHS) may be duplicating work with other Federal agencies. In particular, GAO found that the National Institutes of Health (NIH), Department of Defense (DOD), and the Veterans Administration (VA) each lack comprehensive information on health research funded by other agencies, which means that duplication may sometimes go undetected. Secretary Sebelius, what are you

doing to ensure that HHS is improving the ability of agency officials to identify possibly duplication?

Answer. HHS continues to work with other Federal agencies and the Congress to address areas of duplication identified by GAO. To date, HHS has addressed or partially addressed a number of the actions recommended by GAO. For example, HHS has been working with the VA and HUD to better coordinate the collection, analysis, and reporting of homelessness data. HHS is also collaborating with the Department of Labor (DOL) to promote administrative efficiencies within employment and training programs. In addition, the fiscal year 2013 budget proposes to transfer the Senior Community Service Employment Program from DOL to HHS to further reduce duplication of efforts.

NIH efforts to address duplication include resources to examine details of existing funding when evaluating overlap such as access to an Electronic Research Administration (eRA) module called QVR (for Query/View/Report). QVR provides extensive data about funded grant and unfunded grant applications. NIH makes the QVR resource available to other Federal agencies, contingent upon acceptance of the formal data access agreement. In fact, the VA currently uses the NIH eRA system for some of their applications. DOD staff may request access to QVR and may also obtain training in the use of QVR.

NIH is also an acceptable grant processing site under the Grants Management Line of Business (GMLoB) Initiative and is available to DOD. HHS will continue to work with other Federal agencies and the Congress to address areas of duplication identified by GAO.

Question. GAO found the Federal investment in early learning and child care is fragmented, with overlapping goals and activities. For example, five programs within HHS and the Department of Education (ED) provide school readiness services to low-income children. These similar programs in different agencies create added administrative costs and confusion. What steps are you taking to identify and minimize unwarranted overlap in early learning and child care programs?

Answer. Cross-program coordination to ensure that children have access to high-quality early learning and child care programs has been a priority and key focus for the administration. Over the last 3 years, ACF has developed and implemented an integrated early childhood unit under the leadership of the Office of the Deputy Assistant Secretary for Early Childhood Development, which has become the focal point within HHS for early childhood activities at the Federal level. Within this structure, the administration has taken several steps to improve coordination between the Office of Child Care (OCC) and Office of Head Start (OHS), such as establishing the National Center on Child Care Professional Systems and Workforce Initiatives funded by both OCC and OHS, implementing the Early Head Start for Family Child Care Demonstration Project jointly coordinated by OCC and OHS, and issuing joint guidance on aligning eligibility policies across Head Start and child care programs.

The administration has many interagency and interdepartmental efforts to coordinate federally funded early care and education programs:

State Advisory Councils on Early Childhood Education and Care.—The Improving Head Start for School Readiness Act of 2007 required that the Governor of each participating State designate or establish a council to serve as the State Advisory Council on Early Childhood Education and Care for children from birth to school entry. The State Advisory Councils will lead the development or enhancement of a high-quality, comprehensive system of early childhood education and care that ensures statewide coordination and collaboration, while addressing how best to prevent duplicative services among the wide range of early childhood programs and services in the State, including child care, Head Start, Individuals with Disabilities Education Act preschool and infants and families programs, and pre-kindergarten programs and services. ACF awarded \$100 million of American Recovery and Reinvestment Act (ARRA) funding for State Advisory Councils to 45 States, the District of Columbia, Puerto Rico, Virgin Islands, and American Samoa.

Early Learning Interagency Policy Board.—The Secretaries of ED and HHS established the Early Learning Interagency Policy Board to improve the quality of early learning programs and outcomes for young children; increase the coordination of research, technical assistance and data systems; and advance the effectiveness of the early learning workforce among the major federally funded early learning programs across ED and HHS.

Administration for Children and Families/Child and Adult Care Food Program Workgroup.—Convened by OMB, the Administration for Children and Families (ACF)/Child and Adult Care Food Program (CACFP) Workgroup brings together staff from the Food and Nutrition Services, OCC, and OHS to discuss

possible collaboration around the CACFP. The workgroup has identified the following areas of collaboration:

- sharing the National Disqualified List;
- publishing joint information memorandums on collaboration at the State and local level; and
- improving tribal participation in CACFP.

In addition, the administration's Race to the Top—Early Learning Challenge grants, administered jointly by ED and HHS—are designed to foster innovation and integration within early education programs within a State. In 2011, nine States were awarded Early Learning Challenge Grants and in April 2012, the two departments announced that five additional States were eligible for such grants. While each State has its own areas of focus, all States are working to improve early education in all settings so that more high need children are receiving high-quality early education services. States are focusing on workforce training, early learning standards, developing data systems to track children's progress, and engaging families to promote academic success for children. And, all States are working on these areas across all types of early learning programs, including public pre-K, Head Start, privately funded preschool, and child care (such as child care centers and family day care homes).

Finally, several of the Child Care Development Fund (CCDF) principles for reauthorization included in the President's budget request would streamline Federal, State, and local early care and education programs. For example, the budget proposal supports promoting continuity of care for children and quality improvement for child care providers.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

ELIMINATION OF PREVENTIVE HEALTH BLOCK GRANT

Question. I am concerned about the elimination of the Preventive Health and Health Services Block Grant. The block grant gives States the autonomy and flexibility to solve State problems and address community level needs, while still being held accountable for demonstrating the local, State, and national impact of this investment. Eliminating this source of flexible funding would jeopardize important public health programs already strained by tightening budgets. I am concerned that states without capacity will be disproportionately affected by the elimination of this formula grant. Additionally, I am concerned that your budget proposes to fill the need for the block grant with competitive programs funded by the Affordable Care Act. Secretary Sebelius, how are you proposing States address community health needs to keep their citizens healthy and safe without the Prevent Block Grant?

Answer. Through Centers for Disease Control and Prevention's (CDC) existing and expanding activities, there is substantial funding to State health departments to address community health needs. The activities currently supported by the Preventive Health and Health Services Block Grant may be more effectively and efficiently implemented through the new Coordinated Chronic Disease Prevention and Health Promotion Grant. The budget includes \$379 million, an increase of \$129 million more than fiscal year 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition, and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self-management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. At the end of the 5-year program, CDC will report on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

TEEN PREGNANCY PREVENTION

Question. Teen and unplanned pregnancy costs taxpayers billions of dollars every year, and contributes to a cycle of poor outcomes that affect the long-term strength of our workforce. The Mississippi Economic Council released a report in January that the State's high teen childbearing rate was a hindrance to having an educated and competitive workforce. They recommend reducing teen pregnancy as a part of

improving economic development. Do you have the resources you need to spearhead a successful effort to reduce teen and unplanned pregnancy?

Answer. Teen mothers and their children are more likely to face a range of challenges and adverse conditions when it comes to the health and economic security of themselves and their children. That is why my strategic plan for the Department identifies reducing rates of teen pregnancy as a priority.¹ HHS is making investments in strategies that give children and youth a positive start in life and is committed to supporting both evidence-based programs and innovative approaches for children and youth in order to positively impact a range of important social outcomes, such as child maltreatment, school readiness, teen pregnancy prevention, sexually transmitted infections, and delinquency.

The budget proposes to use unobligated Abstinence Education funds from the Title V State Abstinence Education Grant Program for a new initiative to address pregnancy prevention among youth in foster care, who have an estimated 50-percent teen pregnancy rate. The new initiative will not reduce the amount available to States for Abstinence Education. Each year, some States choose not to draw down their allotment of Title V Abstinence Education funds. Instead of lapsing, these funds will be redirected to help youth in the foster care system avoid pregnancy.

Beginning in fiscal year 2010, under the Teen Pregnancy Prevention Program, the Office of Adolescent Health has provided \$75 million in grant funds to States, non-profit organizations, school districts, universities, and other organizations to replicate models that have been rigorously evaluated and shown to be effective at reducing teen pregnancies, sexually transmitted infections, or other associated sexual risk behaviors. An additional \$25 million in grant funding also supports research and demonstration projects to develop and test additional models and innovative strategies to prevent teen pregnancy, so that evidence base continues to expand and refine. This program supports 102 grant projects in 36 States and the District of Columbia.

Through the Personal Responsibility Education Program (PREP), authorized by the Affordable Care Act, the Administration for Children and Families provides \$55 million in formula grants to States to support evidence-based program models or to substantially incorporate elements of effective prevention programs while including three of six adult preparation subjects mandated by the Congress. To date, 45 States as well as DC, Puerto Rico, the Virgin Islands, and the Federated States of Micronesia had accepted PREP funds. In addition, 16 PREP grants were awarded to tribes and tribal organizations in the summer of 2011. The PREP program also includes \$10 million in competitive PREP Innovative Strategies cooperative agreement research and demonstration grants to develop and test additional models and innovative strategies. The PREP Innovative Strategies program awarded 13 grants through the joint funding announcement with OAH. Both programs target groups with high teen pregnancy rates. In addition, the Affordable Care Act gives States the option of expanding eligibility for Medicaid family planning services without having to go through the Federal waiver process. Despite these substantial investments much work remains in reaching adolescents given there are an estimated 47 million persons ages 10–19 of age in the United States. Increased training for the multiple professionals who touch the lives of young people, media campaigns, and well-coordinated care services at the community level can all help ensure healthy, productive and hopeful young persons.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

PATIENT PROTECTION AND AFFORDABLE CARE ACT REGULATIONS

Question. Please provide a schedule of when you expect upcoming healthcare regulations will be published. Senior administration staff previously indicated that many of the interim final rules will be reissued as final rules. Is this true? If so, please include the dates you expect the interim final rules will be reissued as final rules as part of the schedule mentioned above.

In December, the administration published a “bulletin” on essential health benefits—the mandates that all new health plans sold to individuals and small businesses will be required to provide in 2014 and beyond. The “bulletin” fails to answer basic questions from States and employers.

When will you provide the details regarding benefit mandates and the other new insurance rules, so that we can know how much premiums will be raised and how much Federal costs will increase?

¹ http://www.hhs.gov/secretary/about/priorities/youth_futures.html.

The “bulletin” tells States they must choose among four options before September 2012. Will a rule be finalized before the September 2012 deadline the “bulletin” places on States?

How can States be expected to implement a “bulletin” which has no force of law?

Answer. Centers for Medicare & Medicaid Services (CMS) issued a bulletin on December 16, 2011 and has gathered input. CMS will take public input into consideration and then issue a Notice of Proposed Rulemaking. The bulletin announced CMS’s intended regulatory approach for defining the essential health benefits, based on a State-selected benchmark plan. States will need to make their selection and submit their essential health benefits benchmark to U.S. Department of Health and Human Services (HHS) in the third quarter of 2012 for coverage year 2014.

PATIENT PROTECTION AND AFFORDABLE CARE ACT ACCOUNTING

Question. The new healthcare law appropriates “such sums as may be necessary” to implement the State-based health insurance exchanges. Your budget estimates spending \$1.087 billion in mandatory money for fiscal year 2013.

How much will the Department have spent on health insurance exchanges since the time the healthcare bill was signed into law until 2014 when the exchanges are supposed to be fully operational?

Answer. Our current baseline for Exchange Planning and Establishment Grants estimates that we will obligate approximately \$2.5 billion from when the law was enacted until fiscal year 2014 and that we will outlay \$2 billion during that time-frame.

Question. In addition to this mandatory money for State-based health insurance exchanges, the President’s 2013 budget requests an additional \$864 million for the Federal exchange and other exchange activities. How will this money specifically be spent and how will the Federal exchange differ in functionality from the web portal HHS has already implemented?

Answer. As with the State-based exchanges, fiscal year 2013 is the year many operations of the federally facilitated exchange begin, as CMS will need to be prepared for open enrollment on October 1, 2013, the first day of fiscal year 2014. The majority of the \$864 million request for CMS’s exchange work is related to operations and management of the federally facilitated exchange with some funding to support the Secretary’s duties on behalf of all exchanges. Specifically, \$574.5 million of the total will be used for exchange operations and management including eligibility and enrollment functions, certifying health insurance plans as qualified to be sold through the exchange, as well as oversight of plans and State-based exchanges. The additional \$289.5 million will be used for consumer education and outreach activities, such as a call center, to help consumers understand their new options under the Affordable Care Act (ACA) and to fund navigators and in-person enrollment assistance to facilitate the enrollment process.

Healthcare.gov is a useful tool for providing information on potential sources of insurance available to individuals today, and HHS can leverage its capabilities for presenting information to assist consumers in comparing across plans in exchanges. The federally facilitated exchange will go beyond what is available through Healthcare.gov by certifying that the plans offered meet certain standards of quality and benefits. The federally facilitated exchange will also perform eligibility determinations, enroll individuals into plans, and provide for in-person or call center support to answer questions about available coverage.

The healthcare law included a \$1 billion implementation fund. In order for the Congress to better evaluate the administration’s request for additional funds for implementation activities, please provide an accounting of how the monies provided pursuant to the new healthcare law have been expended. As part of your answer, please include a comprehensive breakdown of spending by department and subsidiary administrative units, as well as by function.

Answer. The following table displays the spending from the Health Insurance Reform Implementation Fund as of February 29, 2012, by agency:

Organization	Obligations	Outlays
Internal Revenue Service	\$213,264,945	\$154,181,697
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Department of Health and Human Services	251,742,492	134,917,483
Total, Health Reform Implementation Fund	471,001,389	293,500,162

HHS uses these funds to implement Medicare and Medicaid changes required in the ACA, including closing the Part D coverage gap and developing new value-based purchasing models for Medicare providers. HHS has also used these funds to plan and prepare for the establishment of State-based and federally facilitated exchanges as required in the ACA.

The Office of Personnel Management (OPM) uses funding to plan for implementing and overseeing the establishment of at least two Multi-State Plan Options to be offered on each State health insurance exchange beginning in 2014, and allowing tribes and tribal organizations to purchase Federal health and life insurance for their employees.

The Department of the Treasury uses funding to implement multiple tax changes from the ACA, including the Small Business Tax Credit, expanded adoption credit, excise tax on indoor tanning services, charitable hospital requirements, plan for exchanges, and a number of other revenue provisions.

The Department of Labor uses funds to conduct compliance assistance; modify or develop IT systems that support data collection, reporting, policy and research; and develop infrastructure for the newly required Multiple Entity Welfare Arrangements reporting and registration within ACA.

Of the \$251,742,492 obligated by HHS to date, approximately 13 percent has paid for personnel, 84 percent has supported contractual services, and 3 percent has been obligated for rent, supplies, or other miscellaneous services.

Question. The HHS budget calls for 76,341 employees in fiscal year 2013. This is an increase of nearly 1,400 employees over the fiscal year 2012 level. How many of these employees will be hired to implement the new healthcare law?

Answer. At the Centers for Medicare & Medicaid Service (CMS), the President's budget requests an increase of 136 full-time equivalents more than the fiscal year 2012 appropriated level to enable CMS to address the needs of a growing Medicare population, as well as oversee expanded responsibilities from legislation passed in recent years.

Question. How many staff members are currently working at the Center for Consumer Information and Insurance Oversight (CCIIO)? Please provide numbers for both full-time and part-time staff separately.

Answer. As of March 10, 2012, CCIIO has approximately 261 employees on-board. 258 employees are considered full-time, and 3 employees are considered part-time. This staff is supported by a combination of discretionary funds and mandatory ACA funding.

Question. How many staff do you expect will be working at CCIIO at the end of fiscal year 2012? How many staff do you expect will be working at CCIIO at the end of fiscal year 2013?

Answer. By the end of fiscal year 2012, CMS expects to use 450 FTEs on CCIIO-related activities. This staffing level will grow to a projected 710 FTEs by the end of fiscal year 2013 as CMS brings the exchanges online and implements consumer protections and other reforms.

CENTERS OF EXCELLENCE IN EARLY CHILDHOOD

Question. In the 2007, the Congress authorized the establishment of Centers of Excellence in Early Childhood for the purpose of evaluating the success of Head Start and other early childhood programs funded by the Federal Government. However, minimal funding has been allocated to support these Centers. At the same time, the Federal Government continues to fund more and more programs focused on early education. The President's fiscal year 2013 budget further requests additional funding, through Race to the Top, for an Early Learning Challenge Fund.

Rather than just adding to the duplicative list of funding silos for early education, wouldn't this money be better spent in support of the Head Start Centers of Excellence so that we can figure out what is working and what is not working?

Answer. The Departments of Health and Human Services and Education have been working collaboratively reduce and prevent silos and duplication of efforts between our two Departments, to develop the infrastructure and models to maximize the use of Federal dollars at the State, and local levels and to build accountability into all Federal funds. Both the Race to the Top—Early Learning Challenge and the Head Start Centers of Excellence in Early Childhood are examples of our efforts. However, these efforts have very different goals. There are 10 Head Start Centers of Excellence that serve as models for other individual programs. This funding has provided an excellent opportunity to showcase these Head Start programs so that other early childhood programs may benefit from their best practices. In contrast, the Race to the Top—Early Learning Challenge provides grants to States that target broad systems of reform across all early childhood programs, including building

the infrastructure in States to better manage funding and minimize duplication of efforts. The goal of Race to the Top and our other interagency work is to provide greater continuity between schools, child care programs, Head Start programs, and State-funded pre-kindergarten programs.

CONSUMER ORIENTED AND OPERATED PLANS

Question. The Department of Health and Human Services issued rules governing the grants for the Consumer Oriented and Operated Plan (CO-OP) program on July 20, 2010. On February 21, 2012, the Department released the identities of the first eight grants/loans recipients.¹ One of the grant recipients was the Common Ground Healthcare Cooperative of Wisconsin, which is an organization affiliated with the liberal activist group Industrial Areas Foundation. Common Ground was reportedly formed in August 2011, just 3 months prior to applying for the taxpayer money, and will receive \$56,416,000.

What criteria were used to select CO-OP grant recipients? Specifically what criteria were used to assess their experience in providing health insurance and benefits?

Answer. CO-OP loan applications are subject to rigorous review and vetting by CMS' independent contractors, and by a review committee in CMS, which is separate from the CMS group responsible for administering the CO-OP program. CMS and these experts evaluate applicants based on their financial models and business plan, the applicant's ability to meet the regulatory standards and milestones for development, the likely long-term sustainability of the plan, adherence to the health policy goal of consumer operation and orientation, and the likelihood of loan repayment. The awards are also subject to legal review. Each CO-OP must be licensed as a health insurance issuer in each State in which it offers a health insurance plan. In addition, CO-OPs must meet the same requirements that other health insurance issuers must meet in each State. All CO-OPs are selected based on their viability and potential for success, as evidenced in their detailed business plans, financial plans, and actuarial projections.

Question. Is it true that the HHS rules regarding CO-OPs projected a 35–40 percent default rate?

Answer. The regulatory impact analysis in the CO-OP proposed rule (76 FR 43237) included an estimate of a technical default rate but incorrectly described it as an estimate of a non-repayment rate.

The default rate is not an estimate of insolvencies. The rules did not estimate insolvencies.

Because of Federal accounting rules, the default estimate includes loan recipients that CMS expects will fully repay the loan and at all times will be compliant with their loan agreement and Federal law. For example, the Affordable Care Act, in section 1322, requires the repayment of loans, but repayment terms "must take into consideration any appropriate State reserve requirements, solvency regulations, and requisite surplus note arrangements." The statute envisions occasions, such as when a loan recipient must keep additional State-mandated insurance reserve requirements, when it is in the best interest of the consumer, loan recipient, and the State regulator for Department to change the loan repayment terms. This is one of many examples in which a loan recipient may be considered a default and included in the default rate estimated in the rules but is not in financial distress.

Given the high bar to receiving funds, the detailed monitoring and oversight by CMS, and the concurrent oversight by State insurance regulators, we expect a high percentage of CO-OP loans to be repaid in full.

All CO-OP loans must be repaid with interest and loans will only be made to private, nonprofit entities that demonstrate a high probability of becoming financially viable. In addition, as described in the Funding Opportunity Announcement, CMS has built in a strong monitoring process to ensure that CO-OPs are meeting development milestones according to prescribed timetables. Loan recipients are subject to strict monitoring, audits, and reporting requirements for the length of the loan repayment period plus 10 years. To ensure strong financial management, CO-OPs are required to submit quarterly financial statements, including cash flow data, receive site visits by CMS staff, and undergo annual external audits, in order to promote sustainability and capacity to repay loans. This monitoring is concurrent with ongoing financial and operational monitoring by State insurance regulators. In addition, CMS will use all remedies available in law or equity to collect unpaid loans.

¹ <http://www.jsonline.com/business/nonprofit-health-insurer-lands-Federal-loan-rm49ho7-139863553.html>.

EXCHANGE GRANTS

Question. Patient Protection and Affordable Care Act (PPACA) section 1311(a) enables the Secretary of HHS to make planning and establishment grants each year to the States. The law specifies that the Secretary shall determine the amount to be made available to States, but it does not specify how the Secretary should make the determination. So far HHS has spent nearly \$1 billion on exchange grants, but it is not clear how these monies are being used.

Please identify all recipients of the planning and establishment grants and explain the criteria you used to determine how much to award to each grantee. As part of your answer, please include the total amounts each grantee received and identify how each grantee has indicated they will spend these funds.

Answer. States are required to submit detailed budgets as part of their grant applications. These budgets must outline the costs for each of the exchange core areas on which they will be working under the grant (e.g., IT systems, outreach and education, etc.) including administrative and overhead costs. These budgets are carefully reviewed and negotiated with the State before each award is made to ensure they represent a valid cost estimate to perform activities required under the grant.

Question. In general, States used Planning Grant funding to perform such activities as insurance market analysis and stakeholder outreach to provide the information necessary to make initial policy decisions about how an exchange could best serve their residents. Many States are using Level I Establishment grants to begin work on their eligibility systems and other IT systems, to develop consumer assistance functions, and to implement the plan management infrastructure necessary to certify qualified health plans. The State of Rhode Island has a Level II Establishment Grant for work to establish all core functions of a State-based exchange. For a complete list of States that have been awarded Establishment Grants, the specific activities they are performing under those grants, and the amounts that have been awarded, please see: <http://www.healthcare.gov/news/factsheets/2011/05/exchanges05232011a.html>.

Please also describe the process for selecting grantees, identifying whether this was a competitive process, and if so, what criteria were used to evaluate grant applications.

Answer. The funding provided under section 1311 of the Affordable Care Act is available to fund activities of any State for activities necessary to establish an exchange. All grant applications are subject to objective review by programmatic experts to ensure that requirements outlined in the funding opportunity announcement are satisfied.

PREVENTION FUND

Question. Recently enacted legislation to extend unemployment insurance, payroll tax provisions and delay a scheduled reduction in Medicare payments to physicians was paid for in part by a \$5 billion reduction in the prevention fund. In addition, the President's budget also called for a \$5 billion reduction in this fund. In light of the bipartisan interest in reducing the monies allocated to this fund, we would request that you provide the following information to help us assess the effectiveness of the expenditures authorized under the fund.

Please describe how the programs funded under section 4002 of PPACA are being measured to determine their efficacy. As part of your answer, please indicate whether and how each program is evaluated to determine how it improves health outcomes for identified individuals and reduces healthcare expenditures.

Answer. HHS strives to ensure that programs funded by the Prevention and Public Health Fund (PPHF) are making the greatest health impacts. Within the programs, the Department assigns a trained project officer to monitor and advise each grantee. Project officers provide ongoing consultation and oversight to grantees regarding program performance.

Project officers also conduct site visits in order to objectively validate information and actively resolve challenges that a grantee is facing in order to ensure that the goals of the project are achieved.

Programmatic performance measures also have been developed for each PPHF funded program at three levels:

- performance milestones for start-up;
- short-term impact; and
- long-term objectives.

All PPHF funded programs report twice a year regarding the status of established milestones and measures.

HHS leaders regularly review these performance data to ensure that programs are on track and accountable for the outcomes associated with each investment.

CHRONIC DISEASE COORDINATION

Question. Less than 4 cents of every healthcare \$1 is spent on prevention, yet chronic diseases account for 70 percent of deaths and a huge healthcare cost burden. The CDC budget proposes the consolidation of several existing categorical programs into a single coordinated program. Can you explain what efficiencies you hope to gain from this proposal and what assurances you can give to those who are concerned about losing the identity of disease specific funding streams?

Answer. The budget includes \$379 million, an increase of \$129 million more than fiscal year 2012, for the Coordinated Chronic Disease Prevention and Health Promotion Program. This program consolidates disease-specific chronic disease funding into a comprehensive program to address the leading chronic disease causes of death and disability, including heart disease and stroke, obesity, diabetes, arthritis and the primary preventable causes of cancer, tobacco use, poor nutrition, and physical inactivity. Because many inter-related chronic diseases and conditions share common risk factors, this program will improve health outcomes by coordinating interventions that benefit multiple chronic diseases. As a result, the program will gain efficiencies in cross-cutting areas such as epidemiology and surveillance, supporting healthful behaviors and chronic disease self-management, and improving effective delivery of clinical and other preventive services. At the end of the fiscal year, CDC will report on the funding spent on prevention and control of specific diseases. CDC will also report annually on improvements in outcomes specific to each disease as well as cross-cutting outcomes.

ENVIRONMENTAL HEALTH/LEAD

Question. While CDC has prevented approximately 100,000 children from being poisoned by lead each year through the Healthy Homes and Lead Poisoning Prevention Program, in fiscal year 2012 funding was not included for the program. The Committee noted that \$350 million will be spent by HHS to conduct home visiting programs in fiscal year 2012 through the Maternal, Infant, and Early Childhood Home Visiting Program; this funding appropriated by the Patient Protection and Affordable Care Act, is \$100 million more than the fiscal year 2011 level. The subcommittee further stated that it intends the Health Resources and Services Administration and CDC to work together to ensure that activities previously funded through Healthy Homes will be fully incorporated into the Home Visiting Program. How has the Department worked to support this legislative intent?

In fiscal year 2013 again the Healthy Homes and Lead Poisoning Prevention Program was again consolidated and slated for potential elimination. How is the administration going to ensure that the Nation's most vulnerable children are tested for lead poisoning and ensure that if those children test positive that treatment and environmental remediation services are provided?

Answer. CDC and HRSA are working to identify possible solutions for incorporating childhood lead poisoning prevention activities into routine services of HRSA's early childhood Home Visiting Program.

The fiscal year 2013 President's budget proposes a new program—Healthy Home and Community Environments—that will incorporate CDC's National Asthma Control Program (NACP) and the Healthy Homes/Lead Poisoning Prevention Program (HHLPPP). The fiscal year 2013 request for the Healthy Home and Community Environments program is \$27.3 million.

The Healthy Home and Community Environments program is a new, multi-faceted approach to address healthy homes and community environments through surveillance, partnerships, and implementation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of disease through comprehensive asthma control. This integrated approach aims to control asthma and mitigate health hazards in homes and communities such as air pollution, lead poisoning hazards, second-hand smoke, asthma triggers, radon, mold, unsafe drinking water, and the absence of smoke and carbon monoxide detectors.

Question. Given the drastic cuts to CDC's Lead Poisoning Prevention Program that could essentially end all State cooperative agreements, what are your proposed strategies moving forward to ensure that the essential services (emergency response to children with lead poisoning, home inspections that include environmental health components, surveillance, etc.) provided by State and local health departments to vulnerable children are not lost?

Answer. With fiscal year 2012 funding, CDC's Healthy Homes and Lead Poisoning Prevention Program will continue to provide lead expertise and analysis at the national level and remain a valuable resource to State and local agencies by providing the following:

Surveillance Support.—Provide software and technical assistance to support the Healthy Homes and Lead Poisoning Surveillance System (HHLPSS), which gathers information related to lead and other health hazards in homes.

Epidemiological Support.—Maintain staff to provide expertise and epidemiological support in response to a lead poisoning outbreak.

Subject-Matter Expert Support.—Maintain the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The ACCLPP advises and guides the Secretary and Assistant Secretary of HHS and the Director of CDC regarding new scientific knowledge and technical developments and their practical implications for childhood lead poisoning prevention efforts.

SECTION 317

Question. CDC takes one of the largest hits in the budget request, and especially concerning is the proposed reduction in the section 317 immunization program. A report from CDC estimates that this program is underfunded by hundreds of millions of dollars. Vaccination programs have been proven to be some of the most cost-effective approaches to preventing disease and reducing healthcare costs, and the children's vaccine programs are estimated to be a 10:1 savings as one example. The section 317 program provides the infrastructure for the Vaccines for Children program, which has been a huge success.

What is the rationale for cutting this program by \$58 million or close to 10 percent when we are still 1 to 2 years away from expanded coverage? Will this reduction cut purchase grants or operational support for health departments?

Answer. The fiscal year 2013 budget includes funds for vaccine purchase to continue outreach to the hardest-to-serve populations, and critical immunization operations and infrastructure that supports national, State, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs \$25 million toward continuation of the billables project, which allows public health departments to vaccinate and bill for fully insured individuals in order to maintain section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The fiscal year 2013 budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The budget does not continue funding for one-time enhancements planned for fiscal year 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan.

Question. How do you see the role of the section 317 program evolving along with implementation of the Affordable Care Act?

Answer. The Affordable Care Act requires new health plans to cover routinely-recommended vaccines without cost-sharing when provided by an in-network provider. As these health insurance reforms expand prevention services to more Americans, the size of the population currently served by section 317 vaccine is expected to decrease in size, specifically underinsured children. The Section 317 Immunization Program will continue to have a critical role in providing vaccines to meet the needs of uninsured adults and responding to urgent vaccine needs such as outbreak response, and ensuring the necessary infrastructure is in place to support the Nation's immunization system for both routine vaccination as well as managing vaccine shortages and other emergency response. This critical infrastructure serves both the public (e.g., Vaccines For Children Program and Section 317) and private sectors. Insurance coverage alone will not provide the immunization infrastructure necessary to ensure a strong evidence base for national vaccine programs and policy, quality assurance for immunization services, and high vaccination coverage rates across the lifespan.

Question. In 2012, \$190 million from the Prevention and Public Health Fund will be transferred to the section 317 immunization program. How will these funds be used and will those activities continue in 2013 at the same level of support?

Answer. In fiscal year 2012, PPHF will meet the needs of the Section 317 Immunization Program, as well as provide one-time resources for infrastructure enhancements in health IT, planning and implementation of public health billing systems, adult vaccination, and capacity for vaccinating school-age children. The fiscal year 2013 budget directs \$25 million toward continued progress in the billables project, but eliminates these other one-time enhancements.

QUESTIONS SUBMITTED BY SENATOR RON JOHNSON

Question. In the Massachusetts Health Insurance Exchange, I understand there is a 6-month period between when an employer drops coverage and when an employee is eligible for participation in the exchange. Is there any similar provision in Obamacare?

Answer. In Massachusetts, an individual is not eligible for subsidized coverage if offered employer-sponsored insurance within the last 6 months. The employer offer must meet certain benchmarks and the Board can waive the 6-month requirement (956 CMR 3.05). There is no similar 6-month waiting period in the Affordable Care Act.

Question. In the various analyses conducted by the Department of Health and Human Services (HHS) or the Centers for Medicare & Medicaid Services on employer behavior related to employer sponsored insurance, is this significant difference in policy taken into account?

Answer. The Affordable Care Act does not include the same requirements as the Massachusetts law, and the Department has not examined the differences. Congressional Budget Office (CBO) and the Joint Committee on Taxation recently released updated estimates of the potential impact of the Affordable Care Act on coverage. The report shows that the Affordable Care Act is estimated to reduce the number of nonelderly people without health insurance by 30 million to 33 million in 2016 and subsequent years.

Question. Are other differences in the Massachusetts model taken into account? If so, which ones. If not, why not?

Answer. HHS is charged with implementing the Affordable Care Act and not a State law. Estimates of the impact reflect analysis of the Federal law only.

Question. How much will HHS spend on health insurance exchanges, in total, from the time the healthcare bill was signed into law until 2014 when the exchanges are supposed to be fully operational?

Answer. Our current baseline for Exchange Planning and Establishment Grants estimates that we will obligate approximately \$2.5 billion from when the law was enacted until fiscal year 2014 and that we will outlay \$2 billion during that timeframe.

Through the end of fiscal year 2011, HHS had obligated approximately \$100 million to implement the federally facilitated exchange as well as carry out the Secretary's responsibilities on behalf of all exchanges. The fiscal year 2013 President's budget requests an additional \$864 million for the Department's exchange-related responsibilities to prepare for the opening of exchanges in January 2014.

Question. Please describe a realistic timeline for HHS to establish Essential Health Benefits, Health Information Exchanges, and State and Federal Insurance Exchanges?

Answer. The establishment of the exchanges is a complex and resource-intensive process. We believe it is realistic to have an exchange operating in every State in time for open enrollment beginning on October 1, 2013, for plan year 2014. The Department is currently working to provide additional information on Essential Health Benefits in the coming months, so that States and health insurance issuers have information available to prepare for plan year 2014.

The State Health Information Exchange (HIE) program promotes innovative approaches to the secure exchange of health information within and across States and ensures that healthcare providers and hospitals meet national standards and meaningful use requirements. Fifty-six States, eligible territories, and qualified State Designated Entities received awards under this program. In fiscal year 2011, all recipients received approval of their implementation plans for achieving statewide health information exchange. Recipients are currently continuing to execute these plans and improve health information exchange in their localities.

Question. How does HHS plan on addressing the low income individuals who will frequently alternate between insurance through an exchange and Medicaid?

Answer. HHS recognizes the potential for movement of individuals between the exchange and Medicaid. Our goal is to ensure the accuracy of eligibility determinations to achieve a seamless transition experience for individuals with changes in circumstances that cause their program eligibility to change between the exchange and Medicaid. To this end, the verification and eligibility determination processes for exchanges will be designed to parallel and integrate with those in Medicaid and Children's Health Insurance Program (CHIP). The exchange will coordinate with Medicaid and CHIP to ensure that an applicant experiences a seamless eligibility and enrollment process regardless of where he or she submits an application.

To the extent that individual's circumstances change, section 155.330 of the exchange proposed rule establishes standards for eligibility redeterminations during a

benefit year. Exchanges must redetermine eligibility if they receive and verify information either reported by an enrollee or through electronic data matching. In an effort to identify changes quickly, this section proposes to require enrollees to report changes in circumstances that affect eligibility within 30 days of such a change.

Question. If HHS does not have a plan for these individuals, why not?

Answer. HHS recognizes the potential for movement of individuals between the exchange and Medicaid. Our goal is to ensure the accuracy of eligibility determinations to achieve a seamless transition experience for individuals with changes in circumstances that cause their program eligibility to change between the exchange and Medicaid. To this end, the verification and eligibility determination processes for exchanges will be designed to parallel and integrate with those in Medicaid and CHIP. The exchange will coordinate with Medicaid and CHIP to ensure that an applicant experiences a seamless eligibility and enrollment process regardless of where he or she submits an application.

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Question. What funding does HHS plan on using to establish State-level exchanges for the States that refuse to establish their own exchange?

Answer. In fiscal year 2012, CMS will use a combination of administrative funding and the Implementation Fund for Exchanges. In fiscal year 2013, the President's budget requests additional funding in the CMS Program Management account for programmatic and administrative activities necessary to prepare for exchange open enrollment beginning October 1, 2013. CMS anticipates collecting user fees in fiscal year 2014 to begin offsetting some of the operational costs of the federally facilitated exchange.

Question. Please describe the HHS Federal exchange model, also describe how will it be different from an inter-State exchange?

Answer. Specific details about the federally facilitated exchange will be released through guidance to States and other stakeholders in the coming months. Although there are opportunities for States to participate in the federally facilitated exchange, such as through a Partnership Exchange, the ultimate responsibility for operations will remain with the Federal Government. An inter-State exchange would share functions, such as a call center and financial management, across states in a manner similar to the federally facilitated exchange, but in this case the States involved are responsible for the exchange operations.

Question. In addition to this mandatory money for State-based health insurance exchanges, the President's 2013 budget requests an additional \$864 million for the Federal exchange and other exchange activities. How will this money specifically be spent and how will the Federal exchange differ in functionality from the web portal HHS has already implemented?

Answer. As with the State-based exchanges, fiscal year 2013 is the year many operations of the federally facilitated exchange begin, as CMS will need to be prepared for open enrollment on October 1, 2013, the first day of fiscal year 2014. The majority of the \$864 million request for CMS' exchange work is related to operations and management of the federally facilitated exchange with some funding to support the Secretary's duties on behalf of all exchanges. Specifically, \$574.5 million of the total will be used for exchange operations and management including eligibility and enrollment functions, certifying health insurance plans as qualified to be sold through the exchange, as well as oversight of plans and State-based exchanges. The additional \$289.5 million will be used for consumer education and outreach activities, such as a call center, to help consumers understand their new options under the Affordable Care Act and to fund navigators and in-person enrollment assistance to facilitate the enrollment process.

Healthcare.gov is a useful tool for providing information on potential sources of insurance available to individuals today, and HHS can leverage its capabilities for presenting information to assist consumers in comparing across plans in exchanges. The federally facilitated exchange will go beyond what is available through Healthcare.gov by certifying that the plans offered meet certain standards of quality and benefits. The federally facilitated exchange will also perform eligibility determinations, enroll individuals into plans, and provide for in-person or call center support to answer questions about available coverage.

Question. How does HHS plan on integrating the necessary private information needed from the Internal Revenue Service (IRS), HHS, Department of Homeland Se-

curity (DHS), Social Security, and patient medical records while ensuring that the data is up-to-date and remains private?

Answer. Protecting the privacy and confidentiality of personal health information is among our highest priorities. The Department has a long and successful history of doing so in the Medicare program. The minimum functions that an exchange must perform do not require or necessitate the collection of medical records of individuals who purchase coverage through the exchange. In response to concerns regarding privacy of personal health information of individuals enrolling in exchanges and Medicaid, the final exchange rule will address privacy and security standards for personally identifiable information that exchanges must establish and follow in more depth than previously discussed.

Section 1413 of the Affordable Care Act outlines a series of data exchanges through secure interfaces that will facilitate eligibility determinations for enrollment in a qualified health plan (QHP) in the exchange and insurance affordability programs in a timely manner. To assist in these operations HHS has contracted for support in building a data services hub that will provide critical IT functions to every exchange. The hub will act as a single interface point for exchanges to Federal agency partners, minimizing the burden on states in exchanging information with Federal agencies. The hub will enable a streamlined, secure, and interactive customer experience that will maximize automation and real-time adjudication to the extent possible while protecting privacy and personally identifiable information.

Question. What database will be established to handle this data?

Answer. HHS is not establishing a database to facilitate eligibility determinations. Data will not be held by HHS. Instead, as described above HHS, through the data services hub will facilitate the exchange of data between Federal agencies and exchanges necessary to determine eligibility for enrollment in a QHP through the exchange and for insurance affordability programs.

Question. What progress has been made and what portion of the budget has been allocated to ensure this integration and confidential data are protected?

Answer. Protecting the privacy and confidentiality of data is among our highest priorities. In response to concerns regarding privacy of personal health information of individuals enrolling in exchanges and Medicaid, the final exchange rule will address privacy and security standards for personally identifiable information that exchanges must establish and follow in more depth than previously discussed.

As we implement exchanges working with our State partners we will use the provisions of the final regulation along with other applicable statutes to ensure the privacy and confidentiality of data.

Question. The healthcare law included a \$1 billion implementation fund. In order for the Congress to better evaluate the administration's request for additional funds for implementation activities, please provide an accounting of how the monies provided pursuant to the new healthcare law have been expended. As part of your answer, please include a comprehensive breakdown of spending by department and subsidiary administrative units, as well as by function.

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HHS uses these funds to implement Medicare and Medicaid changes required in the ACA, including closing the Part D coverage gap and developing new value-based purchasing models for Medicare providers. HHS has also used these funds to plan and prepare for the establishment of State-based and federally facilitated exchanges as required in the ACA.

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adoption credit, W-2 changes for loan forgiveness, excise tax on indoor tanning services, charitable hospital requirements, and plan for exchanges.

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Question. The Department of Health and Human Services Budget (HHS budget) calls for 76,341 employees in fiscal year 2013. This is an increase of nearly 1,400 employees over the fiscal year 2012 level. How many of these employees will have responsibilities covered under the new healthcare law?

Answer. The fiscal year 2013 President's budget requests an increase of 136 FTEs more than the fiscal year 2012 appropriated level for ACA related activities.

Question. How many staff members are currently working at the Center for Consumer Information and Insurance Oversight (CCIIO)? Please provide numbers for both full-time and part-time staff separately. How many staff do you expect will be working at CCIIO at the end of fiscal year 2012? How many staff do you expect will be working at CCIIO at the end of fiscal year 2013?

Answer. As of March 10, 2012, CCIIO has approximately 261 employees on-board. 258 employees are considered full-time, and 3 employees are considered part-time. This staff is supported by a combination of discretionary funds and mandatory ACA funding. By the end of fiscal year 2012, CMS expects to consume 450 FTEs on CCIIO-related activities. This staffing level will grow to a projected 710 FTEs by the end of fiscal year 2013 as we bring the exchanges online.

Question. How does HHS account for the \$111 billion increase in mandatory spending for health insurance exchange tax credit between fiscal year 2014–2021? Please provide a full itemized breakdown.

Answer. Premium tax credits for individuals enrolled in qualified health plans are under the jurisdiction of the Department of the Treasury, so HHS did not provide the estimates of the tax credits in the President's budget referenced in the question.

HHS understands from the Department of the Treasury that approximately one-half of the \$111 billion increase for premium tax credits related to exchanges results from legislative changes enacted in 2011, primarily Public Law 112–56, which changed the definition of modified-adjusted gross income to include certain Social Security income. This legislative change resulted in shifting individuals previously eligible for Medicaid into the exchange premium tax credits. The remaining difference is attributable to technical changes to Treasury's revenue estimating model that are designed to improve its overall accuracy. Those changes impact all income tax modeling and were not implemented just for purposes of calculating the cost of the premium tax credit. One example of the technical changes involves the projection of the distribution of income, which resulted in the composition of families projected to claim premium tax credits being somewhat older and lower-income than previously projected. These changes do not reflect fundamental changes in assumptions regarding utilization of premium tax credits or the cost of providing coverage for a given person in the exchanges.

Question. Please describe how the programs funded under section 4002 of PPACA are being measured to determine their efficacy. As part of your answer, please indicate whether and how each program is evaluated to determine how it improves health outcomes for identified individuals and reduces healthcare expenditures.

Answer. HHS strives to ensure that programs funded by PPHF are making the greatest health impacts. Within the programs, the Department assigns a trained project officer to monitor and advise each grantee. Project officers provide ongoing consultation and oversight to grantees regarding program performance.

Project officers also conduct site visits in order to objectively validate information and actively resolve challenges that a grantee is facing in order to ensure that the goals of the project are achieved.

Programmatic performance measures also have been developed for each PPHF funded program at three levels:

- performance milestones for start-up;
- short-term impact; and
- long-term objectives.

All PPHF-funded programs report twice a year regarding the status of established milestones and measures.

HHS leaders regularly review these performance data to ensure that programs are on track and accountable for the outcomes associated with each investment.

QUESTION SUBMITTED BY SENATOR JERRY MORAN

MEDICARE PART D PREFERRED NETWORK PHARMACY PLANS

Question. Last year, Centers for Medicare & Medicaid Services (CMS) allowed insurers to partner with large chain drug retailers to launch a preferred network Part D pharmacy plan. Similar plans were rolled out at the end of 2011. These plans can offer prescription drugs to Medicare beneficiaries at significantly reduced prices compared to other Part D plans.

It is important that these preferred network plans, and all Part D plans, are accurately marketed to Medicare beneficiaries so they are able to fully understand the features of the various plans and the benefits and drawbacks of signing up for one plan compared to another.

Many seniors get their medications and related counsel from a trusted pharmacist in their community. The preferred pharmacies in the preferred network plans, Part D agents and brokers, and representatives of the Senior Health Insurance Information Program should disclose to Medicare beneficiaries that the beneficiaries may have to go to a specific preferred pharmacy provider to access the most reduced drug costs advertised by such plans.

If Part D plans are not accurately marketed, pharmacy access for rural Americans could be jeopardized. If a Part D plan limits Medicare beneficiaries to only a small number of pharmacy providers to get the most reduced drug prices, it is important that this information be clearly disclosed to them. Additionally, it is important that the Medicare Plan Finder contain obvious information for beneficiaries regarding such pharmacy provider options as well as costs.

What actions is CMS taking to ensure accurate marketing and full disclosure of Part D preferred network plans for the 2013 plan year?

Answer. An increasing number of Part D plans offer cost-sharing differentials between preferred and nonpreferred network pharmacies. It is important to ensure that beneficiaries understand whether preferred cost sharing is available at individual pharmacies. Specifically, confusion may arise if beneficiaries do not select a pharmacy when they compare Part D plans using the Medicare Plan Finder. Therefore, we are currently working to change the Plan Finder to require each beneficiary to select a pharmacy in his/her plan's network for purposes of providing cost estimates that reflect the selected pharmacy's preferred or nonpreferred status in the plan's network. We believe this change will eliminate the possibility that a beneficiary will obtain cost estimates and plan selections based on preferred pharmacy cost sharing when that beneficiary does not intend to use pharmacies in the preferred pharmacy network. The selection of a particular pharmacy in Plan Finder for this purpose has no bearing on the beneficiary's ability to fill prescriptions at any network pharmacy.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you, Madam Secretary.

The record will stay open for 1 week for additional input from members of this subcommittee.

The subcommittee will stand in recess.

[Whereupon, at 11:45 a.m., Wednesday, March 7, the subcommittee was recessed, to reconvene at 10:30 a.m., Wednesday, March 14.]

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2013**

WEDNESDAY, MARCH 14, 2012

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:30 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Brown, Shelby, Cochran, Alexander, Graham, and Moran.

DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

STATEMENT OF HON. HILDA L. SOLIS, SECRETARY

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

Welcome back to the subcommittee, Madam Secretary. You are joining us today at a critical time for our Nation's workforce.

The economy is moving in the right direction. U.S. employers added 227,000 jobs in February, marking 3 months in a row of job gains of more than 200,000. In the private sector, we have had 24 straight months of job growth. The outlook for manufacturing is particularly encouraging, with 429,000 jobs added in the past 2 years.

But too many people still remain unemployed or underemployed. More must be done to ensure that all Americans benefit from economic growth, not just the wealthy in our country.

And so I applaud the efforts that you and your Department are making to get more Americans back to work, and to keep our workers safe, especially in times of budget constraints.

FISCAL YEAR 2013 PRESIDENT'S BUDGET

Under the President's request, funding for the Department in fiscal year 2013 would drop slightly below the level for fiscal year 2012. Obviously, we are going to ask you to do more with less. I am pleased, however, that within the President's total, he has pro-

posed increases for efforts to prevent the misclassification of workers, to protect whistleblowers, and to enhance oversight of the sub-minimum wage program for workers with disabilities.

The President's budget would also continue the disability employment initiative that we started in the fiscal year 2010 appropriations bill. While the overall unemployment rate in February was 8.3 percent, the rate for people with disabilities was 15.8 percent—almost double. So we must do a better job of removing employment barriers for people with disabilities. Your Department's disability employment initiative will surely help.

JOB CORPS CENTER CLOSURES

One reduction proposed by the President is to cut funding for operating Job Corps centers by \$23 million. His plan is to close a small number of centers that are chronically low performing.

As you know, I have always been a strong supporter of Job Corps. These centers play a crucial role in giving young people the training they need to enter the workforce, the military, or postsecondary education. And my experience with their work in Iowa has been very positive. The center in Denison, Iowa, is 1 of only 3 in the country to be named a Job Corps Center for Excellence by the Department of Labor (DOL).

A new center in Ottumwa, Iowa, for which you were present during the groundbreaking, opened its doors this past October, and is taking an innovative approach to training its students. The center has a partnership with a nearby community college, Indian Hills Community College, that will give its students access to higher education at the same time they are enrolled in the Job Corps center.

So I think the Congress should continue to strongly support the Job Corps program. But, then again, we also have a responsibility to hold centers accountable for their performance. If there are centers that fail to serve their students year after year, then no one is helped by continuing to provide them with taxpayer funding.

PREPARED STATEMENTS

What I will want to understand better is how the Department plans to define "chronically low-performing", and what criteria will be used to determine whether a center should be closed. And that is something for an ongoing discussion.

So, Madam Secretary, I will leave the record open at this point for an opening statement by Senator Shelby and Chairman Inouye. [The statements follow:]

PREPARED STATEMENT OF SENATOR RICHARD C. SHELBY

Madam Secretary, our Nation continues to face an unemployment rate more than 8 percent, the longest stretch of high unemployment in this Nation since the Great Depression.

Moreover, the official unemployment rate of 8.3 percent does not adequately illustrate the current employment turmoil. The official rate excludes "discouraged" workers—those who want to work, but have not searched for a job in the last month and those working part-time but who would prefer a full-time job.

If these groups were counted, the real unemployment rate would be 14.9 percent. As more and more Americans are unemployed or underemployed, they are looking toward the Department of Labor (DOL) to provide job training and employment

placement. We need to ensure that DOL is using its funds effectively and efficiently and that Americans are receiving the training they need to re-enter the labor force.

DOL's fiscal year 2013 request is for \$12 billion. DOL claims that the 2013 request reduces spending by \$1.2 billion. This is misleading.

With the transfer of the community service employment for older Americans program to another agency and the decrease in the unemployment insurance workload, DOL's request is not a decrease of \$1.2 billion, but less than one-half that amount.

In this difficult economic environment, limited funding should be targeted to programs that are most effective. I have repeatedly expressed concern about the Job Corps program. While Job Corps has a noble goal and a difficult challenge, it is an expensive program per enrollee, it has a number of historically low-performing centers in the system, and there are concerns that the program's outcomes may not justify the program's costs.

I appreciate you taking my concerns into consideration and proposing a fiscal year 2013 budget that streamlines the program and strengthens its accountability.

However, I do remain concerned that other job training programs have not received the rigorous evaluations necessary to determine whether their costs are justified by their outcomes. Many of the Workforce Investment Act (WIA) programs have not been evaluated since 2005, and we do not have current data to assess whether they are working.

In this time of record unemployment, I believe DOL should target worker training programs to ensure unemployed Americans can return to work. Unfortunately, there are several unnecessary initiatives that cost hundreds of millions of dollars, such as the Workforce Innovation Fund and the One-Stop Rebranding proposal, that will not train a single worker.

The budget submission for the Workforce Innovation Fund requests \$125 million this year while the Fund has \$175 million in the bank. I think everyone would agree that we should not add a third year of funding to a program that has not awarded a single grant and has unknown results.

In addition, the One-Stop Rebranding initiative allocates \$50 million for a publicity campaign. How will either of these proposals help Americans return to work?

In difficult budgetary times, we need to make tough choices and prioritize spending. I look forward to working with the chairman and DOL to target funding that puts Americans back to work.

PREPARED STATEMENT OF SENATOR DANIEL K. INOUE

Mr. Chairman, thank you for chairing this hearing to review the President's fiscal year 2013 budget for the Department of Labor.

I would like to extend a warm aloha to Secretary of Labor, Hilda Solis. Madam Secretary, I will continue to do all I can to support your vision of good jobs for everyone, because a strong economy depends on a strong middle class.

Senator HARKIN. And in the interest of time, since we have a series of votes starting at 11:30 a.m., Madam Secretary, I have your statement. It will be made a part of the record in its entirety.

Again, welcome back. I will, for the record, say that Secretary Hilda L. Solis was sworn in as the 25th Secretary of Labor on February 24, 2009. Prior to her confirmation, she was one of us, as a Representative of the 32d Congressional District in California, holding that position from 2001 to 2009.

The Secretary is a graduate of California State Polytechnic University, and earned her master of public administration from the University of Southern California.

So, Madam Secretary, again, welcome, and please proceed as you so desire.

SUMMARY STATEMENT OF HILDA L. SOLIS

Secretary SOLIS. Thank you so much, Mr. Chairman, and also to the subcommittee members. Senator Brown, it is good to see you and other members that I know will be joining us shortly.

I want to thank you for the invitation to testify before you today. And I provided, as you stated, my written testimony for the record, but wanted to review a few highlights with you. I also want to thank you for all that you did over the past year to assure that the Congress adopted an appropriations bill that balanced the need of deficit reduction with the real needs of American workers.

DOL's budget request reflects the approach the President has taken to make priority investments in areas that we know are essential to helping America get back to work. And some of the most significant of these proposals are not before this subcommittee, but are essential to securing the position as the most competitive economy in the world, such as proposals to include access to education and job training.

I am going to concentrate on those items before the subcommittee which address the need to invest in our workforce, protect workers on the job, and secure Americans' incomes and benefits. In some cases, we have made tough decisions on finding reductions, as you well stated, Mr. Chairman, in order to put America on a more sustainable fiscal course. This is part of the administration-wide effort to improve efficiency and find savings. My testimony lists these items, which can provide you with information to justify the specific actions.

INVESTING IN A COMPETITIVE WORKFORCE

But I want to concentrate on two particular areas this morning, first, the need to invest in a competitive workforce. And as the President has said, for an economy that is built to last, we must get all of our dislocated and low-income workers back to work.

The budget request continues the Department's commitment to those who are most vulnerable to the economic distress by maintaining and, in some cases, restoring funding for our employment and training programs. To support innovation in our workforce investment system we are asking for an increase in the Workforce Investment Fund that will allow us to test new ideas and replicate proven strategies for delivering better employment and training results. I like to call the Workforce Innovation Fund a reform effort, because we are really looking at and testing new types of techniques and coordination that actually help to enhance our programs.

We also know that returning veterans can contribute greatly to our economy. This has been a big discussion item with the Congress as well as the President. That is why the unemployment rate for recent veterans is so troubling to many of us. We will bolster our support for newly separated veterans by expanding the Transition Assistance Program, known as TAP, and employment workshops that are advanced through our State grants for veterans' employment services, by other investments necessary to implement the recently enacted Veterans Opportunity to Work (VOW) to Hire Heroes Act. I want to publicly thank Senator Murray, who is not here but has been a champion in particular, for her leadership with respect to veterans.

RE-EMPLOYMENT SERVICES FOR UNEMPLOYMENT INSURANCE
CLAIMANTS

I also would like to state that to help workers continue to receive Unemployment Insurance (UI) benefits, they also need assistance. And we are proposing a \$30 million investment for employment service grants to States to fund re-employment services for UI claimants, as well as an increase of \$15 million for re-employment and eligibility assessment.

Eligibility assessment and re-employment services have been found to be highly effective at helping UI claimants find higher-paying jobs sooner, while at the same time saving money for the UI system. You might recall that in the last few years people typically get on the phone and call in when they are having to register for their employment benefits. We have to do a bit more to actually bring the individual in so we can do an assessment, get them a program and the assistance that they need, diagnostic testing, whatever it takes, to make sure that they are successful. And those routes tell us that they are more effective, and it is more cost effective.

ONE-STOP CAREER CENTERS

As you know, the system of the one-stop career centers is the core delivery mechanism for employment and training services. To strengthen our community-based system, the budget includes a \$50 million allocation to create a uniform and recognizable brand for the system. What we are talking about is really coordination, and making very clear that the workforce systems can be easily identified by users as well as employers. As you know, even in your State, you may have a different name that doesn't relate directly to the one-stop center, and most people are confused about what that means. So we are trying to re-brand, and also create more mechanisms to use online tools, better technology. Whether you are in rural America or in an inner-city, you ought to be able to access same kinds of services. So, we are attempting to coordinate that effort.

WORKER PROTECTION PROGRAMS

We are also maintaining our efforts to ensure that persons with disabilities have the opportunity to use the system in a better way. And we also need to support the worker protection programs that are not only there to protect American workers, but are crucial to ensuring that all firms are playing by the same set of rules. Because, as you know, when wages are not provided to employees, as well as into our tax system, overall consumers and the public lose. So we think that there is more that we can do in that area.

As we continue to recover from one of the worst economic crises in three generations, it is especially important that we invest in the enforcement of key laws to protect our workers through their wages and benefits. Thus, the budget requests for funding for Wage and Hour Division (WHD), including additional funds for the enforcement of the Fair Labor Standards Act and the Family Medical Leave Act, along with an investment both in wage and hour and in unemployment insurance to address the practice of em-

ployee misclassification, as you stated earlier, Mr. Chairman. I know that that is of particular interest to you. I also want to thank you for the increase that we were able to provide to WHD, looking at the targeted enforcement program of 14c, one that you have been very involved in.

MINE SAFETY AND HEALTH ADMINISTRATION MINE INSPECTIONS

The budget also includes funding to allow for our Mine Safety and Health Administration (MSHA) to meet its statutorily mandated inspections, while maintaining our efforts within both MSHA and our Office of the Solicitor to continue the progress that we have seen already being made to reduce the backlog of contested citations. We must continue our efforts in this area to ensure that we are holding mine operators accountable if they fail to meet their legal and moral responsibility to operate safe mines.

FISCAL YEAR 2013 REQUEST SUMMARY

In conclusion, I wish to summarize: DOL's fiscal year 2013 budget request provides investments to prepare Americans with the skills they need, to assist businesses who are looking for employable individuals, and to help workers and employers find each other in a more efficient manner so that we can enhance our workforce system.

This proposal also ensures that we have fair and safe workplaces for our workers. We must continue to foster safe workplaces with respect to workers' rights, provide a level playing field for businesses, help American workers provide for their families and keep the pay and benefits that they earn. We will focus on our shared long-term goal of reducing the Federal deficit, and I believe it is possible to do so in a way that meets these goals and also helps achieve a better and efficient system.

PREPARED STATEMENT

I look forward to working with you and this subcommittee in the future on this particular area.

Again, thank you, Mr. Chairman, for inviting me here to this hearing. I appreciate that.

[The statement follows:]

PREPARED STATEMENT OF HILDA L. SOLIS

Chairman Harkin, Ranking Member Shelby and members of the subcommittee, thank you for the invitation to testify today. I appreciate the opportunity to appear before you to discuss the fiscal year 2013 budget request for the Department of Labor (DOL).

To build an economy that is built to last, we have to do more to live within our means and restore fiscal accountability and responsibility. The President has put forward a plan to make priority investments in areas essential to helping America win the race for the jobs and industries of the future, while making difficult choices to identify cuts and savings that ask for shared sacrifices across the board. The budget proposes specific steps to boost growth and secure the United States' position as the most competitive economy in the world, such as improving access to education and job training, so that our workers are the best prepared in the world for the jobs of the 21st century.

The DOL fiscal year 2013 budget request reflects this direction. To build on the economic gains we have experienced under this administration, we must create good jobs and make investments that will boost economic growth. The request makes targeted investments and introduces significant reforms to give workers a fair shot to

gain skills that make them more employable, regain their footing after a job loss, find new employment opportunities, maintain workplace safety and health, exercise their voice in the workplace, and enjoy critical wage and hour protections.

TARGETED INVESTMENTS THROUGH DIFFICULT CHOICES

As the President said in the State of the Union Address, we must renew our commitment to revitalizing our Nation's economy and to building an America that is built to last—where everyone gets a fair shot, does their fair share, and plays by the same set of rules.

DOL's 2013 budget request focuses on how we can help accomplish this goal in innovative and cost-effective ways, to ensure we are delivering critical services for American workers in everything from job training to workplace protection. However, in light of current economic realities, and like many families across the country, we had to make some tough choices to ensure we are able to:

- Invest in a competitive workforce;
- Protect American Workers; and
- Secure Americans' incomes and benefits.

In some cases, that meant making tough decisions on funding reductions that will put America on a more sustainable fiscal course. Consistent with administration-wide efforts to improve efficiency and find savings, DOL's budget proposes to streamline operations by:

Eliminating Overlapping Training Programs.—The missions of the Women in Apprenticeship in Non-Traditional Operations and Veterans Workforce Investment program will continue to be advanced through other Departmental training offices and programs.

Re-proposing the fiscal year 2012 request to transfer the Community Service Employment for Older Americans program to the Department of Health and Human Services' Administration on Aging in recognition of the dual purpose of the program to support the economic well-being of seniors, while improving coordination with other senior-serving programs with similar purposes.

Closing a Small Number of Chronically Low-Performing Job Corps Centers.—While most centers meet program standards, some centers have been persistently low-performing based on their educational and employment outcomes, and have remained in the bottom cohort of center performance rankings for many years. Especially in a constrained budget environment, and given the resource intensiveness of the Job Corps model, it is neither possible nor prudent to continue to invest in centers that have historically not served students well. The populations previously served by these Job Corps centers will be eligible to attend higher-performing centers. Job Corps will also make changes to its strategies and approaches based on the findings of program evaluations, strengthen the performance measurement system, and report center-level performance in a more transparent way.

Reforming the Regional Office Structure of Five Offices Within the Department of Labor.—The Occupational Safety and Health Administration (OSHA); the Employee Benefits Security Administration (EBSA); the Office of the Solicitor (SOL); and the Women's Bureau, where the savings are reinvested dollar-for-dollar in the Wage and Hour Division (WHD), and the Office of Public Affairs. By consolidating or streamlining offices we will minimize administrative costs while ensuring that offices are strategically placed to perform DOL's functions across the country.

Curbing Nonessential Administrative Spending.—In support of the President's message on fiscal discipline and spending restraint, DOL has established a plan to reduce the combined costs of certain administrative expenses by more than 20 percent from fiscal year 2010 levels by the end of fiscal year 2013. Reduction efforts focus on travel, printing, supplies, advisory contracts, the executive fleet, extraneous promotional items, and employee information technology devices.

Improving Program Effectiveness and Efficiency.—DOL's fiscal year 2013 budget request continues past efforts to enhance program effectiveness and improve efficiency. We will invest in program evaluations to be overseen by the Chief Evaluation Officer and request expanded authority to set aside funds from major program accounts for an increased number of evaluations. These investments will provide DOL with valuable information about strategies and approaches that work and ensure that our resources are invested strategically in proven tactics.

INVESTING IN A COMPETITIVE WORKFORCE

Particularly during this time of high unemployment, we believe it is imperative to provide both a helping hand and a viable path back to employment. To get America back to work, DOL will continue critical investments in job training and resources for job seekers. Not only do these investments provide a lifeline for those who still need critical help, but they will also save resources of the Unemployment Insurance (UI) system and other programs at DOL by helping people get back to work. The budget documents have been provided to the subcommittee and are available on our Web site, but for now, I want to share some key investments included in our budget request before your subcommittee:

Training and Employment Services.—For an economy built to last, we must get our dislocated and low-income workers back to work. The budget request continues DOL's commitment to those who are most vulnerable to economic distress by maintaining funding for our core training programs while also restoring funding to programs that serve some of the most vulnerable populations. This includes continued requests for the joint Employment and Training Administration and the Office of Disability Employment Policy Disability Employment initiative, and our policy work aimed at increasing the employment opportunities for persons with disabilities, including integrated employment for people with severe disabilities.

Workforce Innovation Fund.—The public workforce investment system is more important now than ever, but we need to make it more efficient, streamlined, and targeted to serve our growing customer base. To ensure that our investments in employment and training are focused on reform, DOL will invest \$100 million in the interagency Workforce Innovation Fund, which will test new ideas and replicate proven strategies for delivering better employment and training results at a lower cost to service providers, allowing for more participants to be served at static funding levels. This investment will be combined with \$25 million from the Department of Education for a total fund of \$125 million in fiscal year 2013. Within the Fund, \$10 million is dedicated to building knowledge of what strategies are most effective with disconnected youth.

Veterans' Employment and Training Service.—We know returning veterans can contribute greatly to our economy and that recent veterans have particularly high unemployment rates. The Department will bolster its support for newly separated veterans by delivering effective education, employment, and other transition services that enable them to move successfully into civilian careers. The recently enacted Veterans Opportunity to Work to Hire Heroes Act expands tax credits to encourage the hiring of veterans and expands access to the Transition Assistance Program (TAP) employment workshops that are offered to separating servicemembers. The budget builds on these efforts by boosting funding for TAP and grants for employment services to veterans by \$8 million more than 2012 levels.

Employment Service.—The Nation continues to struggle with high levels of unemployment and the acute needs of employers seeking qualified workers. The employment service fills a critical role in helping connect workers with jobs, and serves more than 17 million participants annually. To help workers receiving UI get the assistance they need to find work, the budget proposes an additional \$30 million for the employment service grants to States to fund re-employment services for UI beneficiaries. These types of intensive re-employment services and job search assistance have been found to be one of the least costly and most effective ways to get the unemployed back to work.

One-Stop Career Centers.—The system of One-Stop Career Centers is the core delivery system for employment and training services. To strengthen this system, the budget includes \$50 million to create a recognizable and uniform brand for the career center system, improve access to workforce services, and create on-line tools to reach individuals sooner and more frequently while offering personalized services.

The President's budget request includes additional legislative proposals for job training and education resources that we are requesting other congressional committees to act upon. These proposals include:

Community College to Career Fund.—An educated and skilled workforce is critical for the United States to compete in the global economy. To help forge new partnerships between community colleges and businesses to train 2 million workers for good-paying jobs in high-growth and high-demand industries, the Departments of Labor and Education will invest \$8 billion more than 3 years in this Fund. These investments will give more community colleges the resources they need to become community career centers where people learn cru-

cial skills that local businesses are looking for right now, ensuring that employers have the skilled workforce they need and workers are gaining industry-recognized credentials and receiving training relevant to the local needs of employers to build strong careers.

Pathways Back to Work Fund.—Many Americans of all ages need better access to job opportunities and employment-based training in order to succeed in today's economy. Building on successful American Recovery and Reinvestment Act programs that provided employment opportunities for low-income adults and youths, the budget also includes a \$12.5 billion Pathways Back to Work Fund to make it easier for the long-term unemployed and low-income workers to remain connected to the workforce and gain new skills for long-term employment.

PROTECTING AMERICAN WORKERS

Worker protection programs are crucial to ensure all firms are playing by the same set of rules to keep workers safe. The fiscal year 2013 budget preserves this administration's recent investments in worker protection. Some of the highlights of our worker protection request include:

Mine Safety and Health.—The Mine Safety and Health Administration (MSHA) provides miners across the Nation with safer and more healthful workplaces through enforcement of mine safety and health laws, as well as through technical assistance, training, and outreach. The budget request for MSHA of \$372 million provides funding to allow MSHA to carry out its mission, while achieving efficiencies and reallocating resources into its highest-priority activities, including statutorily mandated inspections in the coal and metal/nonmetal enforcement programs.

Case Backlog Before the Federal Mine Safety and Health Review Commission.—The budget includes \$16.9 million for MSHA and SOL to continue ongoing work to address the backlog of contested citations at Federal Mine Safety and Health Review Commission (FMSHRC). We must continue our efforts in this area to ensure that we are holding mine operators accountable if they fail to meet their legal and moral responsibility to operate safe mines. If we do not reduce the backlog, some mine operators will continue to contest violations as a way of “gaming the system” to delay payment of civil penalties and avoid scrutiny under MSHA's existing pattern of violation regulations. This will lead to even higher contest rates and potentially unsafe mines.

Occupational Safety and Health Administration.—Occupational Safety and Health Administration (OSHA) uses enforcement and compliance assistance activities to ensure that this Nation's employees are able to return home safely from work every day. The request of \$565 million for OSHA includes an additional \$5 million to support OSHA's enforcement of the 21 whistleblower protection programs it administers that protect workers and others who are retaliated against for reporting unsafe and unscrupulous practices.

International Labor.—DOL must ensure American workers are given a fair shot to compete on a level playing field with their overseas counterparts. The budget requests \$95 million for the Bureau of International Labor Affairs (ILAB) to strengthen workers' rights and protections in our trading partner countries, including an increase of \$2.5 million for enhanced trade agreement monitoring and enforcement.

SECURING AMERICANS' INCOMES AND BENEFITS

It is essential that we take steps to ensure that America's workers are not permanently affected by economic distress. To that end, DOL's budget includes resources to help those who have been affected stay afloat while they struggle to get back on their feet. Some key investments we propose in the fiscal year 2013 budget to ensure Americans' income and benefits security are:

Wage and Hour.—As we continue to recover from one of the worst economic crises in three generations, it is especially important that we invest in the enforcement of key laws that protect our workers' wages and benefits. In fiscal year 2013, DOL will continue to protect workers and level the playing field for businesses by providing WHD with \$238 million, including an additional \$6.4 million for increased enforcement of the Fair Labor Standards Act and the Family and Medical Leave Act (FMLA), which ensure that workers receive appropriate wages, overtime pay, and the right to take job-protected leave for family and medical purposes.

Employee Misclassification.—When workers are misclassified as independent contractors, they are deprived of benefits and protections to which they are le-

gally entitled, such as overtime and unemployment benefits. At the same time, those businesses that play by the rules are placed at a disadvantage against employers who violate the law. The fiscal year 2013 budget proposes \$14 million to combat misclassification, including \$10 million for grants to States to identify misclassification and recover unpaid taxes within the unemployment insurance system and \$3.8 million for the WHD to detect and deter the misclassification of employees as independent contractors and strengthen and coordinate Federal and State efforts to enforce labor violations arising from misclassification.

Unemployment Insurance.—This administration is committed to protecting the financial integrity of the UI system and helping unemployed workers return to work as swiftly as possible. The budget provides full funding for State administration of the UI program, as well as an increase of \$15 million for re-employment and eligibility assessments. Eligibility assessments and re-employment services have been found to be highly effective at helping UI claimants find higher paying jobs sooner, while at the same time saving money for the UI system. To help those who have lost their jobs, the President's budget also seeks to strengthen the UI safety net. While not before this subcommittee, the budget request incorporates the Reemployment NOW program originally included as part of the American Jobs Act, which includes resources and reforms to help UI claimants get back to work quickly. The Reemployment NOW program provides funds to introduce programs that allow the flexible use of unemployment benefits for short-term employment and for individuals who want to start their own businesses, some of the elements of which were adopted as part of the recently enacted Extended Benefits, Reemployment, and Program Integrity Improvement Act (Public Law 112–96). The budget also proposes to put the UI system back on the path to solvency and financial integrity by providing immediate relief to employers to encourage job creation now, reestablishing State fiscal responsibility going forward, and working closely with States to eliminate improper payments.

Employee Benefits Security.—To protect health and retirement benefits, DOL is requesting \$183 million for EBSA for the protection of more than 140 million workers, retirees, and their dependents who are covered by more than 700,000 private retirement plans, 2.5 million health plans, and similar numbers of other welfare benefit plans which together hold estimated assets of \$6 trillion.

Pension Benefits.—The budget proposes to strengthen the defined benefit pension system for the millions of Americans who rely on it by giving the board of the Pension Benefit Guaranty Corporation (PBGC) authority to adjust premiums and directing the board to consider a number of factors, including a plan's risk of losses to the PBGC. This action will both encourage companies to fully fund their pension benefits and ensure the continued financial soundness of the PBGC. It is estimated that this proposal will save \$16 billion more than the next decade.

State Paid Leave.—Too many American workers must make the painful choice between the care of their families and a paycheck they desperately need. While the FMLA allows workers to take job-protected, unpaid time off, millions of families cannot afford to take advantage of this unpaid leave. DOL's budget request includes a \$5 million proposal for a State Paid Leave Fund to provide technical assistance and support to States that are considering paid-leave programs to help workers who must take time off to care for a seriously ill family member.

CONCLUSION

To summarize, DOL's fiscal year 2013 budget request provides investments to help better connect workers and employers and prepare Americans with the skills they need—and that businesses are looking for—for the jobs of today and the jobs of the future. It also ensures that we have fair and safe workplaces for our workers. An economy built to last will require good jobs that pay well and provide security for the middle class, and this entails undertaking actions now to support and strengthen economic growth and reallocate resources to allow targeted investments where they are needed. Our efforts will help to get America back to work, foster safe workplaces that respect workers' rights, provide a level-playing field for all businesses, and help American workers provide for their families and keep the pay and benefits they earn. I am committed to achieving my goal of good jobs for everyone while the administration focuses on our shared long-term goal of reducing the Federal deficit. I believe it is possible to do both and stand ready to work with you in the weeks and months ahead on a responsible way forward.

Mr. Chairman, thank you for inviting me today. I am happy to respond to any questions that you may have.

Senator HARKIN. Thank you, Madam Secretary.

We will begin a round of 5-minute questions here, as soon as I figure out who has control of my clock here. Here we go. And then I will recognize Ranking Member Shelby.

Madam Secretary, first of all, I just want to say that last evening, I have looked over your entire statement and noted the sections where you are bumping up some funding. I absolutely cannot find anything that I really disagree with. I think you have got the right priorities. I think where you are focusing some additional monies is where they ought to be focused, and you have my full support in that.

Again, we will have to see how the whole appropriations process works out this year, but I do believe that you have done a great job, and your staff has done a great job in making sure we have the right priorities funded, and bumped up a little bit in those areas that are needed.

SEQUESTRATION UNDER THE BUDGET CONTROL ACT OF 2011

One question I just want to ask for the record, and I ask it of all the Secretaries that appear before this subcommittee, and that is the impact of sequestration. Under the Budget Control Act of 2011, funding for almost all programs face a possible across-the-board cut in January 2013 if the Congress does not enact a plan before then to reduce the national debt by \$1.2 trillion. In other words, the Congress could approve the Departments of Labor, Health and Human Services, and Education, and related agencies appropriations bill later this year, but find that every budget item is going to be cut by sequestration.

Now, this responsibility rests with the Office of Management and Budget (OMB). They have not announced how they are going to carry out the process. However the Congressional Budget Office (CBO), that is who we rely on, estimated that most nondefense discretionary programs would face a cut of up to 7.8 percent. Some, such as the Center on Budget and Policy Priorities, think the cut could be even larger, about 9.1 percent. But for the sake of discussion, we will go with CBO.

I just wonder, have you looked at this question? What would the impact be of a 7.8-percent cut to the services and activities of your Department? Again, I am particularly interested in what that would mean for job training programs and worker protection.

Secretary SOLIS. Thank you, Mr. Chairman.

I know that our effort, with the administration, is to work with the Congress to see that we can enact a balanced approach to deficit reduction. So that is our first priority. We still stand very committed to finding some resolution there.

With respect to the details of sequestration, I cannot get into the procedures and how that will be conducted, because I know OMB and the administration would like to avoid sequestration to begin with. Nevertheless, that is something that they will also have to help guide us on.

PROGRAMMATIC IMPACTS OF A 7.8-PERCENT CUT

But I will tell you that, based on overall, your question about a reduction of 7.8 percent, in terms of job-training programs, we are looking at a hit of about \$500 million to our workforce system, and also the inability, to reach 1.7 additional participants. And, of course, you and I know how important this 1.7 million individuals that would be cut short of our services, and in a time of high unemployment. That is not a good sign.

With respect to veterans, which I know this subcommittee is very focused on as well, we are looking at a reduction of about \$13 million overall in the efforts to try to find employment services and provide help for veterans.

With respect to the Job Corps program—and, in fact, I have some students that are visiting us from the Potomac center here that have chosen to come and attend this hearing—we are looking at a Job Corps program cut, that would be about \$122 million reduction overall. That would mean 3,100 or 3,145 to be exact, fewer slots that we would not be able to offer around the country. And in a time of high unemployment for youth, which is at 16 percent, that obviously would have a devastating effect.

In worker protection, in terms of safety, monitoring, and being able to provide technical assistance to businesses, we are looking at a worker protection reduction in our agencies of \$136 million. Again, that would also hurt the safety, well-being, and protection of workers in the workforce.

That is about as best as I can gauge right now, Mr. Chairman. But, certainly, we want to work with you and the Congress to avoid sequestration.

Senator HARKIN. Well, thank you, I appreciate that. And I might be asking for further clarification in written correspondence, because I just think people have to know that it is not just the defense industry that would be hit. They have, of course, been very vocal in their opposition to the sequestration, about what it would mean for cuts in aircraft and warfighting equipment. But we also have to look at what it is going to do to our human infrastructure in this country, if we had the sequestration. And a lot of that falls in your Department.

So I think it is important for us to note what is going to happen if we have the 7.8-percent sequestration. So I thank you very much for outlining them.

I would yield now to our ranking member.

Senator Shelby.

Senator SHELBY. Thank you, Mr. Chairman.

Madam Secretary, we welcome you again here.

JOB CORPS: DEFINING CHRONICALLY LOW-PERFORMING CENTERS

In the area of the Job Corps, I have several concerns about the cost per student, program performance evaluations, and employment outcomes over the life of a Job Corps participant. I am pleased to see, however, that the fiscal year 2013 budget includes reforms to improve the outcomes and strengthen accountability. But we have not seen a lot of the details in your request.

The budget includes, as I understand it, a proposal to close chronically low-performing centers. That sounds good. But it does not define a chronically low-performing center.

Can you discuss aspects of your proposal, specifically the approximate number of centers that you intend to close, what classifies the center as low performing, and how will you use those savings from the closure? I think you are going down the right road, but I want to hear some specifics, if you can discuss them.

Secretary SOLIS. Thank you, Senator Shelby. I know that this is of concern of other members on the subcommittee. And while I strongly believe that the Job Corps program is one of our premier programs, I have had the ability to work with many of them and probably have a record now as one of the secretaries that has visited most of the Job Corps centers in the country. And I can tell you that our goal remains to continue to try to have at least one Job Corps in each State, and we hopefully are continuing to achieve that, which is very important with the addition of the New Hampshire site and Wyoming site.

But we need to look at performance, and looking at how well we are doing and how well we are not doing. And I certainly care about that.

Senator SHELBY. Well, that goes to the durability and the reputation of the program, doesn't it?

Secretary SOLIS. Exactly. And it is very important that we are training individuals for good certificates, and that we don't evaluate these Job Corps centers by criteria that they have not been introduced to before. So that is one thing that we want to make sure of.

I cannot give you a list right now of the job centers that we are looking at, but we will be looking at criteria that we have used in the past to look at low-performing centers to see what improvements they have made—

Senator SHELBY. Is that how you would define a "low-performing center?"

Secretary SOLIS. There would be other aspects, as well, but nothing that I think would be out of the ordinary would be entirely new. So we would use the best criteria, and also what kind of attempt they have made over the past 3 years to correct themselves. Since I have been there, we have tried to institute better evaluation and technical assistance.

I think the message is very clear. It isn't just with Job Corps but our other programs as well. We think that there should be higher standards. In my opinion, I would love to see more of our students while obtaining their high school or GED, also enrolled at a community college. And some of our centers do that, and I want to be able to set a marker so that we can enhance the growth and ability so those young people have more choices. That is the direction that the Department will take.

Senator SHELBY. But the bottom line is, and you know this well, is you have to measure what we are spending money for, what is working and what is not working, what centers are efficient and which ones aren't. Otherwise, we are just throwing money away, aren't we?

Secretary SOLIS. And, Senator, I would tell you that before anything is made public, we will converse with you——

Senator SHELBY. Will you consult with——

Secretary SOLIS. Coordinate——

Senator SHELBY [continuing]. The chairman of the subcommittee?

Secretary SOLIS. Yes, and we will also make sure that the public is fully aware, so we give ample opportunity for communities to come forward and also make comments. We will go through the Federal Register process.

Senator SHELBY. Sure. Thank you.

UPDATES TO H-2B RULES

I have another area, the H-2B rules. Many industries, as you well know, including the seafood and timber industries rely on DOL's H-2B visa program to find temporary seasonal workers. The seasonal nature of these industries means that these businesses routinely face shortages of local workers during their peak season.

The H-2B program not only keeps these businesses open, but also contributes to the creation of additional year-round jobs for local workers by being open.

For the second year in a row, it is my understanding that the Department has proposed an H-2B rule that would add regulatory burdens and costs to American businesses. In particular, an H-2B worker would be required to receive a minimum of three-quarters of their wages for each 12-week period they are employed, even if they do not work three-quarters of the time due to weather or other unforeseen circumstances. Further, the rule would require, as I understand it, employers to pay transportation and subsistence costs to and from the workplace for those workers hired under the program.

Many small businesses that use the H-2B program are, you know, just simply cannot afford these regulations, and will ultimately close, costing us jobs, be more job losses. These rules, I believe, are clearly not meant to reform the program but, some people believe, to shutter it.

Do you understand that these rules, as we understand it, and they are being implemented, will kill American jobs, not create them? And what can we do about this? What is the real thrust here?

What we want to do is create jobs, sustain jobs, isn't it?

Secretary SOLIS. The Department has a responsibility, as you know, to ensure that the H-2B program works for American workers. Yet, one of our priorities is to make sure that we strengthen the recruitment requirements for employers, and establish an on-line national job registry because of the high rate of unemployment.

So we also understand that there is a need to at least give American workers a chance to apply for these jobs. And what we have actually done here is try to minimize abuses that we have heard that have occurred.

Senator SHELBY. Sure.

Secretary SOLIS. With respect to recruiters that have been somewhat unscrupulous——

Senator SHELBY. Sure.

Secretary SOLIS. In terms of enticing individuals to come through the program.

Senator SHELBY. And you aim to get rid of those people, sure.

Secretary SOLIS. What we are attempting to do is to hear from the employers, and we have heard from those folks that you did mention. We did meet with them, and talked about how to look at enhancing and improving upon the system as it works now. And I know we still have a ways to go. In fact, as a result of an appropriations rider, the effective date of the wage rule has changed from October 1, 2012.

The rule changes and the methodology of how H-2B wages are calculated will be looked at. And what our attempt here is trying to make sure that people are paid adequate wages, that foreign workers aren't just drawn here with the belief that they are going to have good wages. And then we are shortchanging other competitors, businesses that are playing by the rules. So we always look to ensure that we can provide fairness in those wages.

Senator SHELBY. Well, there should be fairness, and people ought to go by the law. And you have to root out fraud and everything else.

But on the other hand, if you put such a burden on these small businesses, look at the jobs, the unemployment rate. You know, look at the rate of people who have quit looking for a job, is 15 percent.

We shouldn't try to kill and tighten up and over-regulate these businesses, should we? I think a lot of the employers think that is what you are doing.

Secretary SOLIS. Well, we are going to work hard with business and try to see how we can better inform them of how these programs fully operate. Because the job market has changed, and the dynamics of our unemployment situation has caused us to look at things a little differently.

And we will be conducting more outreach, such as, national webinars, and making sure that the employer community is engaged with us and we are engaged with them. But we have met with several Senators on this particular issue, and we are very much aware of their comments and concerns.

Senator SHELBY. Don't forget a balanced approach.

Secretary SOLIS. Absolutely.

Senator SHELBY. What you do with regulations if you overdo it.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you.

Senator Brown.

Senator BROWN. Thank you, Mr. Chairman. And welcome, Madam Secretary, nice to see you.

WORKER TRAINING PROGRAMS AND THE SECTORS ACT

Early in my term, in 2007, I conducted dozens of roundtables around Ohio where I would meet with sort of cross-sections of communities, and what was clear to me was that even as the economy worsened in 2008, is that employers oftentimes, and a wide cross-section of employers, had difficulty finding qualified workers. And what we sort of came up with, and I have introduced this legislation in three different Congresses now, is the Sectors Act, which,

as you know, and as you and I have talked, Madam Secretary, pretty much empowers local businesses, community colleges, workforce investment boards, unions when applicable, to right, sort of from the bottom up, to construct, well, worker training programs.

We saw something similar to that, and that the Labor Department helped to fund. Just a few weeks ago I was at Cincinnati State in southwest Ohio with a group of, in the biosciences school, in the school of biosciences, if you will, with employers. And they had, in part with this Labor Department grant, were seeing a number of people connected that way, and employers who need pretty highly skilled workers coming out of Cincinnati State finding them.

The President included \$8 million for the Community College to Career Fund. I think we have seen quantitative evidence that this kind of worker training works.

And I would like your thoughts on how the Department is currently supporting sector partnerships, how does the administration plan to move the fiscal year 2013 proposal forward? How does, what role does the Labor Department play in this?

Secretary SOLIS. I want to commend you for having the foresight to put forward legislation when you did, because it is exactly where we need to go. And we are not going to wait for reauthorization of Workforce Investment Act (WIA), because we have been in gridlock, even though I know the Senate has been very much more forward-thinking about working together.

We have identified programs that we have funded already that are looking at sectors. And we have partnered with other agencies like Departments of Energy and Commerce so that we can help to fund and provide new initiatives, and support in innovation for sectors.

So, just like Silicon Valley, you see a section of California that has taken off with IT over the years, and that has been changing. We want to continue to fund those kinds of regional sectors that are looking at broad growth in the next decade or so, and also looking at places like North Carolina and even Florida, where we know that the National Aeronautics and Space Administration (NASA) effort is going to be changing there. But we should not allow for that brain trust to leave by somehow incentivizing businesses and others to come forward.

And we see it best done with community colleges. We are requiring them to do much more. And while this funding has been a great opportunity, there is still much more work that we have to do because community colleges typically don't always, how can I say, go out onto the assembly line and floor and really engage with some of the businesses to get the best curriculum, and find out exactly what employers want. Some are doing a better job than others—but we need to do more. And that is why, through the Workforce Innovation Fund, we are continuing to fund those efforts.

Also, through the community college and the Trade Adjustment Assistance (TAA) program has just been phenomenal. We are already seeing some of the benefits from that. I just came off a bus tour with Dr. Jill Biden, and we visited your State of Ohio, Columbus State University, and heard from many of those businesses that have taken advantage of these programs that are now actually thrusting us into new areas of renewable energy, manufacturing,

and creating a need for businesses to be attracted to a particular area because they know they are going to have better skilled individuals, and that the communities themselves are even offering up tax credit incentives to make that happen.

So I think this is a very good thing that is going on. And it is a win-win for all of us, particularly these training programs that are finally, I think, reaching the type of folks that have been out of work for long periods, and helping to get dislocated workers into a new train of thought where if, they were doing something for 25 years and their job is no longer there, they can now receive upgraded skill certificates. So I think certificates, and making it more measurable in that way, we are having better results.

And we are using the dollars more efficiently.

Senator BROWN. Thank you. Let me shift in my last question.

YOUTH UNEMPLOYMENT AND JOB TRAINING

Ohio's unemployment rate is much too high. It is below the national average, but still much too high. Even more troubling is the unemployment rate among young people, as you know. And in Ohio, people aged 16 to 19 have, last year their unemployment rate was 19.5 percent.

I have worked on the Youth Corps Act of 2012, which would help to address the need to provide young adults, especially those who are in some sense disconnected with more employment opportunities. Talk to me about what the Labor Department is doing with employment opportunities, especially for young adults, especially as summer nears, when the mayors don't have the opportunity to put as many young people to work teaching them skills, and teaching them work habits, and giving them some financial help.

What are we doing?

Secretary SOLIS. Well, Senator, as you know, in the Recovery Act we did receive funding to help push out summer youth employment around the country. We had close to 400,000 student participants, which was good because that helped to provide them with good work experience and a pay check.

We continue to work with our youth field programs to assure that we are continuing to train individuals. And you can see in the audience here today we also have some young students from Potomac Job Corps that are entering into areas like pharmaceutical assistance and security. We are seeing that we are changing our curriculum to make it more amenable and cost effective, and really listening to what employers want we can make that bridge a lot sooner.

We also are making investments with students and young people that have had trouble with the law, through our reintegration of ex-offenders programs. That continues to be a high priority, and we are working with the Department of Justice to help alleviate some of those issues and barriers that continue to be major impediments for people to reintegrate into society.

The President also has now taken up this initiative to create summer jobs but on a volunteer basis. Since there is no funding for this initiative, we are asking for corporations to step forward. We have about 170,000 corporations that have now said that they will work with us, set up mentoring programs, internship programs,

and paid positions. But we need more corporations, and more small businesses, and even nonprofits to participate. So that is something that the President has strongly gotten behind.

I remain very committed to not only Summer Youth, but to all of our youth programs, because I think that we have too many young people that are out of work; there is a 16-percent under-employment rate and in some areas, as you know, depending on the particular ethnic backgrounds, it is much higher. And that is unacceptable at a time when we need everybody to be working.

I look forward to working with you on ideas that you might have on how we can make our programs a more efficient, and hopefully get more of the private sector involved in joining in our partnerships.

Senator BROWN. Thank you.

Senator HARKIN. Thank you, Senator Brown.

Senator Moran.

Senator MORAN. Mr. Chairman, thank you.

Madam Secretary, I am pleased to have the opportunity finally to visit with you this morning. I want to follow up on at least the topic that was just raised in your conversation with the Senator from Ohio and, in fact, in response to the question from the Senator from Alabama about youth. And I noticed that you said that we have high unemployment especially with youth. And in regard to Senator Brown, you were talking about mentoring programs and internships.

CHILD LABOR IN AGRICULTURE

And I am very concerned about the DOL's proposed regulations as they deal with youth labor in regard to farms. And disappointed—you and I know each other from our days of serving in the House of Representatives—and disappointed in the Department's effort at outreach and understanding of what I think is a very unique way of life. The Department, on its own volition, decided to alter, at least propose altering, the regulations related to young people working on farms, including young people working on their own families' farms. And this is an issue that fundamentally alters a historic and familiar relationship so important to America, and particularly important to rural America.

And so I am here to engage in a conversation, but to criticize not only the process but, at least to date, the result that your Department is pursuing in regard to these regulations.

I have asked—again, from our experience in the House I consider you to be a conscientious, well-intentioned, open-minded person. But I do want you to know that we have reached out to you, invited you to meet with me, which was declined, invited you to come to Kansas, which was declined. Not to necessarily spend time with me, but to be on family farms, to meet with Future Farmers of America (FFA) students, see what a 4-H program is like, to get an experience of something that is a pretty common way of life in many places across the country.

Also, 30 Senators wrote you, the DOL, a letter expressing concerns and raising questions. We were told—it was a bipartisan letter, we were told that the Department would not respond to that

letter, but that it would be considered just like other comments made by citizens in regard to those rules.

And so I have the sense that there are those who have the ability and desire to have a conversation with you at the DOL so that you are fully aware of the consequences of the proposed changes that you are making.

The rules that you are proposing deal, at least in my view, in three broad areas. One is a parental exemption, the question of whether or not children could work on their own family's farm. And the idea that you would even—and I understand that you are re-proposing that portion of the rule, and I am worried that that sends a message that things are okay. We don't know what that re-proposed rule is going to look like, but the fact that you would suggest rules that relate to whether a farmer's own child at age 15 can work on their own farm suggests that input is needed, that this is a major change in the way that we live our lives.

And as you talked about the need for youth employment, it is one of the few remaining opportunities for many rural youth in small towns across Kansas and around the country to find employment in the summer and throughout the school year.

In addition to that, you want to intrude upon what is currently working, in my view, well, related to student learner exemptions, and replace 4-H and FFA and county extension programs with a DOL program. And you indicate in the proposed rules that you believe 4-H and FFA and county extension are, quote, too locally driven and lacking Federal direction.

In my view, those kinds of programs that are locally driven by people who have experience, knowledge and a desire to see children in their own communities succeed is exactly the kind of programs we need.

And finally, the third component of your proposed rules deals with hazardous occupations. And in that regard, the regulation is so overly broad, regulations prohibiting a young person from working 6 feet off the ground mean that no child, no young person is going to be in the cab of a tractor or a combine. And, in fact, your rules suggest that a young person could not even use a power-driven screwdriver. The language of the legislation prohibits anything for a young person to use that is not driven by their own power. And so, based upon the broad language of this "hazardous occupation", do you believe that you are prohibiting the use of a power, a battery-powered screwdriver?

The consequences of the things that you put in your regulations lack common sense. And, in my view, if the Federal Government can regulate the kind of relationship between parents and their children on their own family's farm, there is almost nothing off limit in which we see the Federal Government intruding in a way of life.

ADMINISTRATIVE PROCEDURE ACT

Senator HARKIN. Madam Secretary, before you answer that, I just want to interject something here.

I understand the Senator has concerns about this proposal. I think we probably all do, those of us from rural areas. I still live

in my hometown of 150 people. Not too many people can say that. And we are all farm-based, and so we all have concerns about it.

However, I just want to state that I and my colleagues need to recognize that the DOL must be careful to adhere to the Administrative Procedures Act (APA) while it is engaged in this rule-making. Under the APA, the Department is limited in the way it is able to discuss a proposed rule, either in meetings or in correspondence with interested parties.

So, you know, this goes back—I've been here a long time. Sometimes we all get frustrated with rulemakings. But I recognize that whether it is a Democratic or Republican administration it doesn't make any difference, they still have to adhere to the APA. And so they are limited in what they can say, and how they can approach it.

All the indications I have is that the Secretary takes the views and concerns of the agriculture community seriously. They are carefully reviewing the more than 10,000 comments it has received on this rulemaking. They are consulting with the U.S. Department of Agriculture (USDA). And any letters that I write, or anybody else writes, will be considered as part of those, as part of those comments.

So I just wanted to state that for the record, under the APA.

Please proceed.

Secretary SOLIS. Thank you, Mr. Chairman. And also, Senator Moran, I understand your concern, and have taken note of comments by other Members of Congress and Senators that have communicated with us on this rule. I take very seriously the comments that you have made. And I realize that you sent a letter to us, but it was at a point where I couldn't respond because we were already entering into that gray area where I am not allowed to publicly put anything in writing because of the comment period.

But I will tell you that other letters that we received, 10,000 in fact, had similar subject matters. So it is noted.

I also want to let you know that, while I wasn't able to visit with your local farmers or you in your district, or your State, that doesn't mean that my staff isn't available to work with you and your subcommittee staff. We have had meetings with your staff when you were unable to be there. And we have tried to mitigate and at least explain, where there are issues. Some of the comments that you make about the use of powered screwdrivers and what have you, are taken out of context, and they are not what we are proposing. So we do need to do a better job of communicating it that is what is being said out there.

I do want to make very clear that it is important for us to allow for young people to have the ability to go through education programs such as 4-H programs. I don't think this rule in any way will hinder that involvement. We are concerned when there are fatalities, when we still see the second-largest rate of fatalities occurring on farms.

And while I don't have a problem with children working on their parents' or relatives' farms, that is a question that we are going to seek comment on. Personally I agree that, those are things that should be allowable, quite frankly. But I do know that we have to

protect and prevent any further injuries from young people that are working in settings that are not protected.

We have seen serious fatalities, a record of more than, 21.3 percent per 100,000. And I just received a report that was issued yesterday by the Journal of Pediatrics that also states very clearly that we have seen an increase in injury and cost to businesses because of fatalities of young people in agriculture. Not all of them have been through direct work on farms, but many of them in the agricultural industry. So I think there is a compelling reason to look at this. We haven't upgraded the rule for 40 years. And the way business is done on farms has changed a bit.

We just want to make sure that we get it right, that we get the most abundant comments from people that are out in the field, that are running these operations, and to do our best to try to inform farmers and business owners that we want to work with them and provide as much technical assistance and help as we can. Certainly we want to clarify those areas that you pointed out, that I believe are misinterpreted.

And we will do what we can to work with you on that. Personally, I will see to it that we do that.

Senator MORAN. Madam Secretary, I just would indicate that the outreach that, in my view, should have occurred before the proposed rules were proposed, was short, fell short. And I am troubled by the fact that where you start is so contrary to a way of life, to common sense, and to the way that things are done.

I am hopeful that the comment period that you are now in will result in significant changes, if not withdrawal, of the proposed rule. In fact, we have had pages of folks who have contacted us with additional comments, but the comment period has expired.

And it does highlight how the Department's initial announcement of proposed rules is so out of touch with farm families and youth in rural communities.

I look forward to the degree that the chairman will allow the rules, to have you respond, I would be glad to continue the conversation.

Senator HARKIN. Okay, we will start another 5-minute round. Thank you.

As I stated in my letter on this issue, I noted, that experts have learned a lot in the 40 years since child labor rules in agriculture were first issued. On Monday, the Journal of Pediatrics said that more than 26,000 kids and adolescents get injured on farms and ranches in the United States every year, 26,000. I would just say, Madam Secretary, I would hope that you would, in your looking at this, make contact with an organization called Farm Safety 4 Just Kids. It was started by Marilyn Adams in 1987. It is a wonderful organization. It started in Iowa, I am very proud of that. The Web site is www.fs4jk.org.

They have worked with farm families all over the country on how to establish safe parameters for kids working on farms, working on farms under their parents supervision. I think they have really come up with ingenious ways of protecting kids on farms and so they could be a great source of information for you. My staff could get hold of the staff there for you.

EMPLOYMENT OPPORTUNITIES FOR DISABLED INDIVIDUALS

I had one last question, then, and that was dealing with the issue of disability. As you know, individuals with disabilities have left the workforce at twice the rate of people without disabilities, about 7 out of 10.

Because so many people with disabilities in the recession have been laid off, as we begin to re-employ people, I hope that we are going to really be looking at, again, not one-for-one, but almost two-for-one. For every one person without a disability, we have got to hire back two with a disability just so we get back to where we were prior to the recession.

I just, again, would ask you about your disability employment initiative. We started that in the fiscal year 2010 bill from this subcommittee. I know your commitment to finalizing section 503 rule-making by October of this year. I appreciate that.

So, I just wonder if you could just tell us about the disability employment initiative. Are there other proposals in this budget that I haven't seen to address workforce issues related to individuals with disabilities?

Secretary SOLIS. Thank you, Mr. Chairman. I know you have been a tireless leader on this issue, and something that you care and many of us care very deeply about. I do want to say that we appreciate your support that you have given us at the Department. We have also looked at increasing, through a proposed rule, Federal contractors' employment opportunities for disabled individuals, which we think is moving in the right direction.

With respect to the disability employment initiative that you helped to champion, ETA and our ODEP office, that is the Assistant Secretary for ETA, and our Director, Kathy Martinez, who you know very well, are working to increase access to training, and creating new initiatives. One is the Add Us In Initiative. And I think you may be somewhat familiar with that. The Add Us In's goal is to get small businesses to better understand what the expectations are, and perceptions are, with people with disabilities to help create and foster more positive outcomes, so that people won't be frightened or afraid to hire folks with disabilities, and understand what all that means. We are also working with employer associations and other sectors to expand that field.

Senator HARKIN. A year ago I met downtown with the U.S. Chamber of Commerce, under Mr. Donahue, Tom Donahue. They have set as a goal to employ 1—is it 1 million? One million more people with disabilities by 2015. I think it is 1 million, it may be a little bit more than 1 million. But it is a very aggressive goal, and here is someplace where the DOL could work with the chamber of commerce in making that happen.

Secretary SOLIS. We are attempting to do that with some of the various business associations. Kathy Martinez, and our Assistant Secretary for ETA who is here, Jane Oates, have been working on this, and we know how serious it is. We do have to try to level the playing field. So we look forward to working with you.

Senator HARKIN. Kathy Martinez does a great job for you.

Secretary SOLIS. Thank you.

Senator HARKIN. Senator Alexander.

Senator ALEXANDER. Thanks, Mr. Chairman. And welcome, Madam Secretary.
Secretary SOLIS. Thank you.

COMPANIONSHIP RULE

Senator ALEXANDER. I would like to discuss the so-called “companionship exemption” under the Fair Labor Standards Act (FLSA), and the proposed rule of the Department, that I believe the comment period may end tonight. So I would like to make a comment about it. And then I would like to ask you three questions, all of which I believe you could answer yes or no without offending anything in the APA.

Here is my comment. I understand it has not—my worry is about changing the way overtime is considered, with the companionship exemption. Here we are talking about a situation when mostly seniors would hire someone, or some small business, to provide a nurse or a helper to live in with that person, or to come to that house every day to help someone. And the proposals that the proposed rule would seem to have concerning overtime suggests to me that the rule would mean that seniors in America would have less care, because it would be more expensive. There would be fewer jobs for those who are helping, and it would likely force a large number of people who are now cared for in homes into more expensive institutional settings, which would drive up healthcare costs in States which are already struggling with healthcare costs, and are about to be hit with the new costs that come with the Medicaid mandates on the healthcare law.

So I am concerned that the Department hasn’t sufficiently evaluated the impact of the rule on what it will do to seniors who need care, on people who want jobs, and on Medicaid costs to the States.

The Office of Advocacy at the Small Business Administration (SBA) recently sent a letter to you stating the Department’s economic analysis doesn’t fully reflect the fact the majority of the in-home companionship services are provided by small businesses, and are paid for through the private market. These small businesses will have to pass on the higher costs of this new overtime to seniors, most of whom are single and living on fixed incomes.

So here are my three questions. One, will the Department follow SBA’s recommendation to conduct a more thorough economic analysis before moving forward with this proposed rule? That is number 1.

Number 2, my office was told by your staff that the Department didn’t consult with a single Medicaid director when developing the rule. Is that true? I am especially interested in that because Medicaid is 24 percent of State budgets.

And, number 3, is the Department willing to withdraw the rule to conduct a more comprehensive analysis of the impact on State Medicaid and budgets?

Secretary SOLIS. Well, Senator, I would first of all tell you that in looking at the companionship exemption through FLSA that was established back in 1974, it was intended at that time to look at other kinds of occupations, like babysitting. It didn’t really encompass this whole new arena of healthcare, in-home healthcare providers. And so it has changed because of changing times.

Senator ALEXANDER. Well, but the change is that we have a lot more older people in America who don't have money, who are often single. They need help, and they can't a big overtime bill.

Secretary SOLIS. Senator, I don't disagree, but I also know that there is more professionalism that has come about in this industry. You have different providers who would like to keep people not achieving, say, a better footing, in terms of the economy, through these jobs. So they do not want to pay them. Many of them have already commented that they are very concerned about the overtime pay. But we are looking at an industry of about 2 million women, mostly women in this area, that are already trying to make ends meet, and are paid very, very low wages—

Senator ALEXANDER. Well, if you put them out of work with higher costs caused by your overtime rule, they will really have a hard time making ends meet.

Secretary SOLIS. Well, I think one of the things that we are attempting to do here is also level the playing field. Because you do have some good providers, some good folks that are playing by the rules.

Senator ALEXANDER. There is no rule that requires overtime pay.

Secretary SOLIS. Well, what we are looking at, Sir—

Senator ALEXANDER. So what you are doing is talking about raising the cost of home healthcare to people who can't really afford it, and putting people out of work who can't get the job. That is what you are really talking about.

Secretary SOLIS. Well, we are still taking comments. And I know that we have, because of the enormous amount of comment—

Senator ALEXANDER. Well, what about the answer to my three questions? Will you get an SBA report before you move ahead? Will you—did you consult with any Medicaid director in any State? And, if you didn't, will you before you do the rule?

Secretary SOLIS. Well, certainly we have a responsibility to always look at economic impact.

Senator ALEXANDER. Well, the answer can be "Yes" or "No", Madam. Did you, or will you, follow the SBA's recommendation? Yes or no?

Secretary SOLIS. I will get back to you on that.

[CLERK'S NOTE.—Additional information is available in questions submitted by Senator Alexander under heading "Proposed Companionship Exemption Rule".]

Senator ALEXANDER. That is not a "Yes" or a "No". Did you consult with any Medicaid director in any State about the increased healthcare costs?

Secretary SOLIS. We have consulted with a broad variety of appropriate groups.

Senator ALEXANDER. Did you consult with any Medicaid director, which is 24 percent of the costs of a State budget about the impact on their healthcare costs?

Secretary SOLIS. My staff met with several stakeholder groups, yes.

Senator ALEXANDER. Did you meet with any Medicaid director?

Secretary SOLIS. I did not directly.

Senator ALEXANDER. Did your staff? They told me they didn't.

Secretary SOLIS. I have to ask my—

Senator ALEXANDER. So you don't know.

Secretary SOLIS [continuing]. Wage and Hour deputy.

Senator ALEXANDER. You don't know? Whether you met with—

Secretary SOLIS. Not offhand. But I know that I have been informed fully that they have met with various stakeholder groups.

Senator ALEXANDER. Well, I didn't ask that. I asked whether you met with a Medicaid director about this—

Secretary SOLIS. I did not personally, Senator.

Senator ALEXANDER. And if you didn't—well, whether you did or not—

Secretary SOLIS. No, I did not.

Senator ALEXANDER. Are you willing to consult with Medicaid directors about—

Secretary SOLIS. Certainly. Certainly.

Senator ALEXANDER [continuing]. The effects of the proposed rule?

Secretary SOLIS. Certainly. Certainly. Certainly.

Senator ALEXANDER. Thank you.

Senator HARKIN. Senator Graham.

Senator GRAHAM. Thank you, Mr. Chairman. Thank you, Madam Secretary.

H-2B VISA PROGRAM

I want to talk about the H-2B program. And, one, I appreciate your staff coming over to meet with several Senators that were concerned about this. I thought it was a productive meeting. And Senator Mikulski from Maryland was deeply involved, so this is a bipartisan issue.

I think most Americans would be surprised to know, would you agree, that apparently there is a labor shortage in America, even though we have 8.3-percent unemployment in certain areas of our economy?

Secretary SOLIS. I know that in certain sectors there is that issue does exist.

Senator GRAHAM. Yes. How can that be?

Secretary SOLIS. How can that be?

Senator GRAHAM. People ask me that. I mean, I just wonder, I mean, if we have 8.3 percent unemployment, and maybe 15 percent of underemployed, and people have stopped working, how can it be that we need visa programs for the seafood industry, the landscaping industry, and H-1B, the high-tech industry?

I mean, have you got any ideas on how that happened?

Secretary SOLIS. Well, all I can tell you is that for our purposes at the DOL, we are trying to assist in providing information to American workers about these employment opportunities, these openings—

Senator GRAHAM. And I think you are doing a—

Secretary SOLIS. That are available.

Senator GRAHAM. I think you are doing a good job.

But, I mean, let me talk about the Kiawah Island Resort, they're hosting the PGA, and please come, everybody, in August 2011. They are having to expand their workforce. That is good news. They need some workers, seasonal workers all the time, but a plus-up here.

And they were advertising for service workers, you know, maids and other folks to help with the increased capacity there, increased business. And they advertised, they needed 150 workers, and I think we got nine people from the region that basically applied. And I can't give you the exact number, but about one-third of them couldn't make it because of the drug test. So now they have to go to Jamaica and try to bring in 140-something folks who work hard and do a good job, and that was astounding to me. But when you go—have you ever been in a chicken processing plant? You know, I know a lot of people from the South, it is not a real surprise that American workers have moved on from these jobs. It is not because we are lazy, it is just because I think the American workforce has higher aspirations. And a lot of these jobs that are manual labor jobs, like landscaping, and chicken processing, and meat processing, employers just cannot find people here at home.

And I don't think it is an advertising problem. You are doing a good job trying to advertise more. And the pay scale, because of the rule, is dramatically higher than the minimum wage. And the concerns we had is that you were calculating a pay scale increase not based on the local community like work requirements, but a broader geographic area. You were requiring more transportation cost in and out that was making it harder for people to afford to get these workers.

So what I worry about is that we need to give employers access to labor, and the first person they should try to hire is an American, paying a decent wage. But if you can't hire an American, do you agree with me we should have a visa program that works for American employers?

Secretary SOLIS. Well, I would agree that our purpose is to, try to entice American workers to these jobs.

Senator GRAHAM. Right.

Secretary SOLIS. And if they are not able to find them after they have gone through a thorough advertisement, beyond just the local community paper.

Senator GRAHAM. Now, we all agree with that.

Secretary SOLIS. Because we have abused this program in the past.

Senator GRAHAM. No, we all agree with that. Let us say we do it the way that we all agree on, and you just can't find the workforce for whatever reason, we want a visa program on the high-tech and low-tech end that actually meets employers' needs, is that correct?

Secretary SOLIS. I would agree with that. And I also would think that our priority is to make sure that we don't also drive down wages in the past there have been unscrupulous employers that have not paid, say, the going rate in certain areas.

Senator GRAHAM. But, in—

Secretary SOLIS. And so they have abused the program. We are finding that out, and we are trying to clean it up.

Senator GRAHAM. But the visa program has always had a wage calculation requirement. The push-back you got from a lot of people from the seafood industry and the landscaping is that the cost of this program was getting to be exorbitantly high, and it was just

not paying what people in South Carolina make. You had a broader view of things. The transportation costs increased dramatically.

And as the law, as I understand the law, you can't pay an American worker any less than you pay an H-2B visa worker, is that correct?

Secretary SOLIS. Yes.

Senator GRAHAM. So you are driving up wages even for the local workforce.

And so I just want to end with this thought: Let us keep working together to work on a visa program that meets the needs of employers, so they will stay in business, and that American workers can go to find a decent paying job, and that the visa program doesn't put American workers at risk because we are driving up the cost unnecessarily here.

So, I just want to keep working with you on this. This is a big deal to people in my State and, I think, just throughout the country. And this is not a Republican issue, this is a bipartisan issue. So I look forward to working with you on reforming the visa program.

Secretary SOLIS. Senator, I agree, and look forward to working with you. I agree that we need to work with those industries that are growing, the high-tech area in particular, and making sure that everyone is using the same reference, in terms of bringing individuals here, and they are fully aware of what that means—but always giving preference to American workers here, that they have first dibs on those jobs. And that has been a big game change, I think, in the last few years, because of the fiscal crisis that we are in. So we do want to do our best.

And we have worked with Senators, yourself, and we thank you for your leadership on this issue and look forward to working with.

Thank you.

Senator HARKIN. Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you.

GULFPORT, MISSISSIPPI JOB CORPS CENTER

Madam Secretary, in 2005, the year 2005, Hurricane Katrina struck the Mississippi gulf coast, resulting in huge damages to property and businesses and homes all throughout the region.

Since that time, the Congress has appropriated \$14 million specifically for the reconstruction of our Gulfport Job Corps Center in Gulfport, Mississippi. And I hate to mention this, but the center has not been rebuilt yet, and I don't know why.

But I hope you can help us figure out a way to move forward with allocation of previously appropriated funds, or the use of funds that we may now appropriate, that can be used under your authorities for the construction of facilities for worker training and other activities that are appropriate under the law for a Job Corps center replacement facility.

Do you have any plans, specifically, for dealing with this need of the Department? Is it considered something that is a priority in the DOL?

Secretary SOLIS. Senator, I think the last time I was here before the subcommittee we had a conversation about this. And I do remain committed to continuing to build out that particular facility.

But I know since that time there have been some local issues with respect to the construction of that facility, because there are some buildings that are historic in nature, that were brought to our attention by the local community there. So I know that that has been a challenge for us, in terms of figuring out exactly how we go about building and starting the construction.

So I am mindful of that, and want to see how quickly that can be resolved, working with you and, of course, taking in public comment.

But while we are waiting, I am responsible for using the monies that had been set aside to facilitate other construction of other facilities. So I will do that, but I will remain committed to working with you, and hopefully see that we can get some resolution on a site there that would be amenable to the community, as well as to the folks that are involved in this process. But we have to do it legitimately. As you know, I have to follow procedures, rules, that have been laid down long before I arrived as Secretary of Labor.

Senator COCHRAN. Well, I appreciate that you have to operate under the restraints of law and currently existing regulations. But the local community in the Gulfport area, and those who would benefit from the training to obtain good-paying jobs is still a very serious need in that region.

PROPOSED H-2B RULES

One other question that I have relates to the gulf coast, as well. And it involves the seafood community. There have been a lot of problems in the Gulf of Mexico that have been identified. Many of these are challenging, to say the least.

But the Department has proposed two H-2B rules that will make the process of hiring workers even more cumbersome and more challenging to deal with in a positive way.

Now, I don't know all of the specifics about this, but I am told by my staff members in the Gulfport office that we have a lot of workers available for H-2B worker's permits. And I wonder what is your reaction to the challenge of putting together a seasonal workforce under new recruitment timeframes? What can we expect?

Secretary SOLIS. Senator, we are obviously very concerned about this, as well. We have received numerous comments regarding this proposal, and know that we are trying, to address this as best we can. We want to make sure that we do our best to make sure that American workers, have access to those jobs, as well—I totally agree with you, because of the fact that we have seen such great impacts in the gulf, and want to work with you.

I want to minimize abuses that have occurred in the past. I believe that there is more opportunity to have a better, robust program that actually helps to give those individuals that are engaged in that particular visa program a good quality of life.

But we want to minimize those unscrupulous businesses that take advantage, and drive down costs, and do that deliberately because they don't want to pay good wages. So many have been able to do that in the past that we are trying to clarify and upgrade our rules.

Our intention is to be very clear and transparent about it. But I know that there are folks out in the field that may not feel that way, and we want to work with them. That is why we are doing more outreach, we are doing more webinars. We are consulting with more business, and will do whatever we need to, in particular in the gulf. I would love to have my regional staff, work with you and your staff, and those appropriate individuals, you deem appropriate that we need to work with.

Senator COCHRAN. Well, I appreciate the fact that this has your personal attention and we thank you for your efforts.

Secretary SOLIS. Thank you. Thank you, Senator.

Senator HARKIN. Thank you, Senator.

Senator Shelby.

Senator SHELBY. Mr. Chairman, Senator Kirk is unable to be here. And, Madam Secretary, he has a number of questions, and I would submit them to you for the record to answer, if you would please.

Thank you very much.

Senator HARKIN. It looks like our votes are about ready to start.

I just wanted to comment about referring to what Senator Alexander was talking about, home care workers and the proposed regulation.

It seems to me that as society has changed, more and more people want to receive care in their homes, but we have learned some things about this. We know that it is cheaper for society as a whole for the elderly to be taken care of in their homes, rather than to go to an assisted living place, an institution or a nursing home. And, in most cases the quality of life is much better for the elderly. They are in their homes, they are in their neighborhoods.

And so this whole thing has built up over the last 30 or 40 years as we are living longer in our society, I think as Senator Alexander alluded to. But it just seems to me that the answer to this is not to say that if you are low-income elderly, then we need a whole bastion of low-income workers to take care of you, who are paid sub-minimum, poverty wages. That doesn't seem to help society much, and it doesn't help the elderly.

Some States have already moved ahead. Twenty-one States currently offer some protection to home care workers. Sixteen States now require overtime for home care workers. So I think we are basically moving in the right direction.

Home care workers need to be better qualified. We know instances, case after case, of an elderly person being taken care of by someone that is not being paid very well. They are not really qualified. The elderly person doesn't take his or her medicine. They may fall because they are not supervised properly, and maybe don't have the proper barriers in the house. They break a hip, they go to the hospital, and the costs go up for society because they are covered by Medicare, or Medicaid as the case may be. Maybe they are dual-eligible.

So I think, the time has come to address this issue of home care workers, their qualifications and how they are trained, to make sure that they are paid to do a job that I think is one of the most important jobs in our society. That is to make sure that elderly have a good quality of life, that they can maintain themselves in

their own homes and their own communities without being forced to go to an institution.

So we have to come up with the wherewithal to make sure they are paid adequately. As I said, the answer is not to have a whole bastion of workers out there that are paid poverty wages to take care of the elderly.

Last, we tried to get a Community Living Assistance Services and Supports (CLASS) act into ACA, where people could put some money aside for contingencies like this later in life. Well, a CLASS Act has got some problems, I know that. But it seems to me that we need to have some source of revenues for people when they get older to make sure that they can get that kind of home care if they so desire.

The problem, as I have said many times, I have said it forthrightly, the only problem with the CLASS Act, it was voluntarily. And young people never think they are going to get old. They are never going to need that, so they're not going to put any money into it.

But we have seen the value of Social Security, we have seen the value of Medicare. We have seen the value of disability insurance, all the three components of Social Security, which are mandatory, upheld by the Supreme Court numerous times. It seems to me we need one more tranche. Because of the longevity of people living now, we need another tranche in there, and that is a mandatory part that would go toward home care for the elderly, and so that we can have a good workforce out there that is qualified, trained, paid well, to take care of elderly in their own homes.

So I would just state that for the record, if anybody wanted me to go on and on about this!

Do you have anything else you wanted to add?

Senator MORAN. Mr. Chairman, thank you. I just want to follow up.

I just want the Secretary to know that folks in rural America, farm families, care greatly about their kids and their safety. Every parent wants to make certain that their child has the opportunity to grow up in a safe environment, and have the opportunity to earn a living, and learn a trade and a profession and pursue the American dream.

I just want to make certain, absolute certain, that in this need to find this safe environment by the Department of Labor, that you don't overreact, that you don't overreach, and that we don't fundamentally alter the way that rural Americans have lived their lives.

I think teaching, for example, is a noble profession. And how do we find good teachers? How does somebody decide they want to be a teacher? Well, they experience a great teacher in their life, and so they grow up thinking, when I grow up, I want to do what this teacher has done for me.

And your rules as proposed change the way in which we are going to have the opportunity for a young person to experience working on a farm, their own family's or their neighbor's. And we are going to lose that opportunity for that young person to say, when I grow up I want to be a farmer, I want to be a rancher.

This is a huge and significant issue for those of us who care about rural America. And the rules as proposed are overly broad, and overreach, and an involvement in ways that, in my view, destroy that opportunity, alter for generations to come the chance we have to have farm kids experience that and grow up with a dream to farm and ranch in this country.

We need your help, we need your attention to this proposed rule, and would ask again that you alter the plan that you are on.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you.

Madam Secretary, again, thanks for your appearance here. Thanks for your response.

Secretary SOLIS. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. We may have some further written questions, and we will leave the record open for 10 days for such questions.

[The following questions were not submitted at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

SEQUESTRATION IMPACT

Question. Please elaborate on your response to my question about sequestration. I'd like more specific information on the impact of a 7.8-percent cut on agencies of the Department of Labor (DOL), their missions and individuals served by their programs.

Answer. As I mentioned in the hearing, our effort, with the administration, is to work with the Congress to enact a balanced approach to deficit reduction. That is our first priority; we remain very committed to finding some resolution. By design, the sequester is bad policy, bringing about deep cuts in defense and non-defense spending and threatening continued economic growth and prosperity. The President's 2013 budget presents a balanced plan that contains sufficient deficit reduction to avoid a sequester. The budget also preserves the Department's core functions and makes important investments in areas such as job training and worker protection. Although the administration is continuing to analyze the potential impact of the sequester, I will tell you that it would be very difficult for us to manage cuts of 7.8 percent to our programs and still achieve our fundamental mission to prepare and protect American workers.

For example, a 7.8-percent decrease in funding in our employment and training programs would result in a reduction of more than \$500 million for our workforce system, meaning that more than 1.7 million fewer participants could be trained, retrained, or be helped to find a job. For the Workforce Investment Act (WIA) formula grant programs, this would mean a reduction of more than \$60.1 million for adults, resulting in approximately 483,000 fewer job-seekers receiving needed services to find sustainable employment; a decrease of \$78.6 million for dislocated workers, resulting in approximately 63,000 fewer workers served; and a reduction of \$64.3 million for youth, resulting in 18,600 fewer disadvantaged youth served. In addition, the Dislocated Workers National Reserve would be decreased by \$17.5 million, and Community Service Employment for Older Americans would be reduced by nearly \$35 million, resulting in approximately 5,500 fewer job-seeking older Americans served should this program remain in the Employment and Training Administration (ETA) of DOL.

For the statewide activities funds in each of the three formula-funded streams, some States may face a funding deficit to administer WIA in program year 2013 if the policy of reducing statewide activities funds from 15 percent to 5 percent is continued. If funded at a level that is 7.8-percent less than the fiscal year 2012 enacted level, approximately eight States (likely Wyoming, North Dakota, South Dakota, Vermont, Alaska, Nebraska, New Hampshire, and Delaware given program year 2012 formula allotments) would have less than \$300,000 available to administer their Workforce Investment Act programs.

In the Job Corps program, a 7.8-percent cut to our current level of operations funding would result in a decrease of close to \$122.4 million and would translate into approximately 5,000 fewer student enrollments. Funding at this level would also delay the opening of the new center in New Hampshire and require us to accelerate plans to close Job Corps Centers far beyond the chronically low-performing centers that we are committed to addressing, impacting not only the students who would not be served, but the communities where centers are located. Funding for Construction would be reduced by approximately \$8.2 million, delaying construction and center renovation projects and deteriorating center facility conditions, and a reduction of nearly \$2.3 million to Job Corps Administration would require a cut of 22 full-time equivalent (FTE) employees, achieved either through attrition or a reduction-in-force (RIF).

For the State Unemployment Insurance and Employment Service Operations (SUIESO) appropriation, a reduction of 7.8 percent to the fiscal year 2012 funding level translates to a decrease of nearly \$56.3 million for the employment service, resulting in approximately 1,735,000 fewer job-seekers served. Funding for the One-Stop Career Centers would be reduced by nearly \$5 million, which would result in one or two fewer Disability Employment Initiative grant to States, a small reduction in labor market information grants to States, and postponement of enhancements to electronic tools.

A decrease of this magnitude would also require ETA to reduce Federal staff by about 51 full-time positions, with severe impacts on the oversight, accountability, and efficacy of ETA programs.

For our worker protection agencies, a 7.8-percent reduction in funding would mean a decrease of approximately \$136 million. This would have a significant impact on our efforts to ensure safe and healthful workplaces, and to ensure that workers get the wages and benefits to which they are entitled. These reductions would likely impact our most vulnerable workers just as we are emerging from an economic recession.

At this decreased funding level, the Employee Benefits Security Administration (EBSA) would be reduced by approximately \$14.3 million and 100 FTE. This would force EBSA to eliminate nearly 10 percent of its workforce and constrain spending in its enforcement, participant assistance, and regulatory programs. As a result, EBSA would conduct fewer civil and criminal investigations. In addition, effectiveness would decline as each Benefit Advisor would have to handle a greater percentage of call volume, resulting in less time to analyze and resolve participant disputes and inquiries and reducing benefit recoveries by an estimated \$16 million.

For the Wage and Hour Division (WHD), a 7.8-percent decrease would result in a cut of \$17.7 million and 122 FTE, of which 80 would likely be investigators. Such a reduction would substantially hamper the agency's efforts to level the playing field for all businesses and ensure basic fairness in the workplace, particularly affecting the most vulnerable low-wage workers in the Nation. A decline of this magnitude in WHD investigator staff would result in fewer investigations and less money in the hands of workers who purchase basic goods and services in this country. More than \$17.8 million in back wages would go uncollected and more than 21,000 workers would not receive the compensation to which they are entitled. In addition, fewer investigations could well mean that more children are exposed to threatening or hazardous workplace conditions that would otherwise be prevented by investigator site visits.

At a reduced funding level for the Office of Federal Contract Compliance Programs (OFCCP), the agency would face a decrease of \$8.2 million and 68 FTE. Any reduction in funding would significantly impact the agency's ability to protect workers from discrimination. Specifically, OFCCP would reduce the number of supply and service investigations, construction evaluations, and Functional Affirmative Action Plan (FAAP) reviews such that more than 95,000 employees will be affected.

Reducing funding for the Occupational Safety and Health Administration (OSHA) by more than \$44 million would put our Nation's workers at unnecessary risk by reducing enforcement staffing by 81 FTE, 60 of which would be Compliance Safety and Health Officers, resulting in a decrease of 2,100 inspections. With 2,100 fewer programmed inspections targeted to the most dangerous workplaces, fatality and injury and illness rates would likely increase. OSHA's whistleblower protection program would also be cut by 20 investigator FTE, leading to an increase in the already-growing backlog of cases, and making the agency unprepared to administer recent whistleblower statutes, such as for finance reform and food and safety reform.

In addition, OSHA's State Plans would be cut by almost \$8 million at a time when many States are already in difficult financial situations due to reductions in funding at the State level. This would result in the unemployment of State Plan inspectors,

and would lead to 4,000 fewer inspections of hazardous workplaces. On-site consultation programs for small businesses would be reduced by \$4.4 million, which would lead to the unemployment of staff in these State-based programs and an estimated 2,200 fewer consultation visits provided to small businesses. Finally, OSHA would be forced to eliminate almost all compliance assistance specialists by cutting an additional 31 FTE. The agency would be forced to all but eliminate compliance assistance efforts for high-demand areas such as residential fall protection and severely cut its Voluntary Protection Program.

For the Mine Safety and Health Administration (MSHA), decreasing the agency's funding by more than \$29 million could result in delays of resolving potentially unsafe conditions and lessen MSHA's ability to maintain readiness in the event of a mine emergency. The recent MSHA internal review on the Upper Big Branch mine disaster documented the effects of imposing resource constraints deep enough to affect MSHA's enforcement efforts. At this level, MSHA's ability to maintain staffing levels would be impaired. Delays in hiring and training new personnel could lead to the staffing and experience shortcoming identified in the internal review. A 7.8-percent decrease would also adversely impact the ability of the Coal Mine Safety and Health (CMSH) and the Metal and Nonmetal Safety and Health programs to conduct all of their required inspections and impact MSHA's enhanced enforcement efforts targeting the most egregious and persistent violators through the Pattern of Violations program and the Special Emphasis dust inspections. It will also affect MSHA's ability to support the mine safety and health backlog project, and to conduct impact inspections, part 50 audits, accountability reviews.

Additionally, MSHA would have to reduce engineering support to enforcement personnel as they encounter difficulties during their inspection functions, as well as administrative support for the approval of plans, such as dust, ventilation, and roof control. This would lengthen the time necessary to review the various plans submitted by operators and test equipment destined for use in mines to ensure it is intrinsically safe.

A 7.8-percent reduction would impact MSHA's ability to ensure that miners are aware of their rights and responsibilities, impeding MSHA's efforts to conduct prompt investigations of miner discrimination complaints and investigations of knowing and willful violations of the Mine Act, including civil and potential criminal violations. Likewise, at the decreased level, MSHA would be forced to reduce efforts such as the Small Mine Consultation program and production and distribution of training materials to the mining industry, impacting MSHA's ability to provide mine operators effective compliance assistance. Many of these materials are the primary vehicle for providing safety and health awareness to miners. All of these actions have the potential to place miners' safety at risk.

Funding at 7.8-percent less than the fiscal year 2012 enacted level for the Office of the Solicitor (SOL) equates to a reduction of \$9.8 million. Because SOL funding largely supports FTE who provide litigation and other legal services to the Department in all of its enforcement and program areas, a decrease of this magnitude would require a reduction of approximately 50 FTE. Based on SOL's major areas of work, this would result in approximately 1,100 fewer litigation matters opened and concluded compared to SOL's actual litigation workload completed in fiscal year 2010 of 14,630 litigation matters opened and 14,204 litigation matters concluded. Likewise, SOL would have a diminished ability to provide legal opinion and advice, with an estimated reduction of 700 fewer opinion matters opened and 400 fewer opinion matters concluded, compared to the fiscal year 2010 actual results of 8,678 opinion matters opened and 6,198 opinions matter concluded.

For the Bureau of Labor Statistics (BLS), a reduction of 7.8 percent, or \$47.5 million, in fiscal year 2013 would force the Bureau to eliminate approximately eight of its survey programs. While the administration would have to determine which programs would specifically have to be eliminated, this reduction would likely lead to cuts in widely used data used to determine the state of the economy and for other key purposes.

At the reduced funding level, the Bureau of International Labor Affairs (ILAB) would be cut by nearly \$7.2 million. Some key impacts of reductions on this scale would be diminishing ILAB's capacity to combat child labor and to support projects abroad to ensure that United States workers do not suffer unfair competition in today's global labor market; reducing ILAB's capacity to monitor and enforce the labor commitments of trade partners under Free Trade Agreements, and labor obligations under Trade Preference Programs; hampering ILAB's capacity to engage in oversight and auditing of projects abroad funded by appropriations for specified purposes; and reducing policy engagements on job creation and worker protection with key economies such as China, India, Brazil, Russia, South Africa, and other G-20 members.

A 7.8-percent decrease to the Veterans' Employment and Training Service (VETS) would reduce funding to this agency by more than \$20.6 million. This includes a reduction of about \$13 million to Jobs for Veterans State Grants, which would reduce State Disabled Veterans Outreach Program and Local Veterans Employment Representative staff by approximately 165 positions. This reduction in personnel would result in approximately 53,000 fewer veterans receiving specialized services, including 7,100 veterans with significant barriers to employment who would not receive intensive services and thus continue to have issues with obtaining employment.

With a reduction of \$3 million to the Homeless Veterans Reintegration Program, VETS projects that approximately 1,500 homeless veterans with significant barriers to employment would not receive critically needed employment services. Since there are no other Federal programs reaching out to homeless veterans with employment services, and based on historical placement rates, approximately 889 homeless veterans would not be placed into employment and reintegrated back into the workforce. With these reductions, the administration's commitment to eliminate homelessness amongst veterans by 2015 will not be met.

At a 7.8-percent funding reduction for the Transition Assistance Program, VETS would only be able to provide the mandated Employment Workshop to 150,904 transitioning servicemembers and would not be able to fulfill the legislative mandates in the VOW Act. This funding level would grossly underfund a statutory requirement of the Agency and leave approximately 155,084 transitioning servicemembers unserved.

As you can see through the examples given above, a 7.8-percent across-the-board reduction to our programs would have a devastating impact on the Department. At a time when we are just starting to see strong signs of renewed economic growth, it makes no sense to undermine this progress with harmful automatic cuts to Federal discretionary spending.

WAGE EQUALITY FOR INDIVIDUALS WITH DISABILITIES

Question. The fiscal year 2013 budget request for WHD includes additional resources and staff for oversight related to the Fair Labor Standards Act 14(c) program. How will the WHD and other DOL agencies not only improve compliance with the law but also work to improve integrated and competitive wage outcomes for individuals with disabilities under the budget request?

Answer. DOL's WHD is working to enhance its investigation actions, technical assistance, and certification process on behalf of workers with disabilities. In addition, WHD and the Office of Disability Employment Policy (ODEP) are working collaboratively to ensure outreach efforts include relevant up-to-date information about available resources to ensure employers are aware of their obligations and how to comply with the law and that workers who have disabilities know and understand their rights. For example, WHD is collaborating with ODEP to include information about available resources and best practices at regional educational events in fiscal years 2012 and 2013 for Community Rehabilitation Programs that employ individuals with the most significant disabilities. WHD will also examine the Fair Labor Standards Act section 14(c) certification program to develop subregulatory processes that strengthen safeguards against noncompliance and maximize use of adaptive technology to provide frontline training to certification seekers. WHD will also collaborate with ODEP and other stakeholders to further develop existing programs and to identify new avenues of outreach to people with disabilities, caregivers, family members, and employers to ensure all stakeholders have equal access to information about effective, full employment of workers with disabilities. Among other methods, the agency will explore how the certification process may be used as a vehicle for disseminating new, state-of-the-art employment information and resources to affected employers and employees. The Department takes very seriously its role in ensuring that the Nation's workers receive the full protections afforded under the provisions of the law and will provide additional specific training to agency staff to ensure investigations and outreach efforts are timely and effective and maximize positive impact for workers with disabilities.

REGIONAL OFFICE CONSOLIDATION

Question. Please provide more information on the Department's proposed consolidation of regional offices, including how the involved agencies will continue to meet their goals and objectives under the regional reorganization and the specific factors that went into identifying the regions proposed for consolidation for each involved agency.

Answer. The budget proposes adopting a leaner, more efficient approach for five offices within the DOL:

- OSHA;
- SOL;
- Office of Public Affairs (OPA);
- the Women’s Bureau (WB); and
- the EBSA.

In fiscal year 2013, each of these bureaus will consolidate their regional offices to ensure that they are strategically placed to perform DOL’s key functions across the country while eliminating unnecessary administrative costs.

In an effort to streamline agency operations, OSHA proposes to reorganize its regional structure and jurisdictional authority from its current operation of 10 Regional Offices (ROs) to 7. The reorganization will involve the consolidation of OSHA’s Regions 1 (Boston) and 2 (New York); Regions 7 (Kansas City) and 8 (Denver); and Regions 9 (San Francisco) and 10 (Seattle). The estimated savings would come largely from the saved compensation from three Regional Administrator positions and related benefits. Additional savings would be achieved through reduced rent needs and travel expenditures.

SOL is working on regional office consolidation to better align legal offices with the Department’s component agency structures, with eventual reduction from eight to six SOL regions. As an initial step, SOL is planning to reduce one region (Kansas City) in fiscal year 2012.

OPA consolidation of regional offices includes the closure of offices in Denver, Colorado and Seattle, Washington. These offices have been essentially closed since fiscal year 2011 due to attrition of Federal staff. OPA will continue to meet agency goals and objectives continuing to have the workload of the Denver and Seattle locations processed and managed by the remaining regional offices in Chicago, Dallas, and San Francisco.

For the WB, the consolidation of regional offices will refocus the agency to its policy responsibilities as it works through other DOL agencies for its outreach functions. The Department strongly supports the work of the WB and believes that increased collaboration with other regional DOL agencies will allow the Bureau to more effectively and efficiently carry out its mission.

The WB is developing objective criteria to guide the process for consolidation of its regional offices. The goal is to continue to meet the Bureau’s mission in the most coordinated and efficient manner. We anticipate that we will be able to achieve this goal by maintaining those WB regional offices in geographical locations where other DOL regional offices exist and opportunities for sister agency collaboration will be maximized.

The Department remains committed to the advancement and rights of working women, particularly those who are the most vulnerable. Consolidating the Bureau’s regional offices will result in savings that are reinvested, dollar-for-dollar, in the enforcement of the Family and Medical Leave Act and Fair Standards Labor Standards Act—two laws that have a direct and tangible benefit for women in the workforce.

As with the WB, EBSA is still developing the details of its effort to consolidate regional offices. The objective of EBSA’s consolidation is to increase the efficiency and effectiveness of the enforcement and worker assistance operations. Similar to OSHA’s approach, a primary guiding principle in the EBSA effort is to not allow a reduction in front-line enforcement or other services for the public because of consolidation. Some of the specific factors that EBSA is considering in identifying the regions proposed for consolidation options include the closer alignment of regional offices with financial centers, number of plans, participants and beneficiaries, and total plan assets; a better alignment of regional workload; the elimination of some split state responsibility in regional jurisdictions; and taking advantage of the regional locations of other DOL offices such as SOL and the Office of Assistant Secretary for Administration and Management.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION ENFORCEMENT

Question. The President’s fiscal year 2013 budget request includes \$207 million for Federal OSHA enforcement and \$104.2 million for State OSHA enforcement. At this funding level, Federal OSHA has approximately 1,000 workplace inspectors and can inspect workplaces under its jurisdiction once every 129 years. This is similar to the number of inspectors in fiscal year 2001 and compares to nearly 1,500 Federal OSHA inspectors onboard in fiscal year 1980—a time when the workforce was significantly smaller.

With so few inspectors responsible for the safety and health of 140 million workers, what is the Obama administration's strategy for ensuring that there is a strong effective enforcement program to ensure that workers safety and health is protected on the job?

Answer. The agency attempts to shape and focus enforcement activities to have an impact on as many workplaces as possible, rather than just the workplace which was the target of the inspection. To achieve its goal of reducing workplace injuries, illnesses, and fatalities through Federal enforcement, OSHA uses strategies that make the most-effective use of its limited resources and powers. The agency also is working closely with Labor's Chief Evaluation Officer to assess its strategies—through current studies involving Site-Specific Targeting (SST) and On-site Consultation—and using data and evidence to make program changes when needed. OSHA uses the following enforcement strategies.

TARGETING THE MOST HAZARDOUS WORKSITES FOR INSPECTION

In addition to inspections that OSHA is required to perform or prioritizes, such as imminent danger, fatalities, catastrophes, complaints and referrals, OSHA targets inspections through a variety of means, including:

- SST is based on the OSHA Data Initiative and targets establishments in general industry with high injury/illness rates.
- Local and National Emphasis Programs (LEPs/NEPs) target high-hazard industries (e.g., shipbreaking), hazards that may lead to severe illnesses (e.g., lead and silica), and hazards that may lead to severe injuries (e.g., amputations).
- The Construction Targeting Program (C-Target) is based on a random selection of construction projects from a data file provided by F.W. Dodge and incorporates a modeling system to predict level of activity at a given construction site.

LEVERAGING ENFORCEMENT ACTIONS TO MAXIMIZE HAZARD ELIMINATION

The agency has two enforcement strategies designed to leverage enforcement action to maximize the elimination of workplace hazards that lead to injuries, illnesses, and death:

- The Severe Violators Enforcement Program (SVEP), which is intended to focus enforcement efforts on significant hazards and violations by concentrating inspection resources on employers who have demonstrated recalcitrance or indifference to their OSH Act obligations by committing willful, repeat, or failure-to-abate violations in certain circumstances. SVEP actions include mandatory follow-up inspections, nationwide inspections of related workplaces/worksites, increased company awareness of OSHA enforcement, enhanced settlement provisions, and Federal court enforcement under section 11(b) of the OSH Act.
- Corporate or Enterprise Wide Settlement Agreements (CSAs) are made with employers that have workplace hazards at multiple sites. Through a CSA, OSHA broadens its effect on employers' compliance and abatement efforts from one establishment at a time to hundreds or even thousands of workplaces at a time.

GETTING THE MOST DETERRENCE FROM PENALTIES

Actual and potential penalties deter employers from maintaining hazardous workplaces that do not comply with the requirements of the OSH Act. However, OSHA's statutory penalty limits are low, compared to other Federal agencies. As a result, OSHA must use leveraging strategies in order to get the most deterrence from the penalties OSHA imposes.

OSHA implemented a revised penalty system in fiscal year 2011, with the goals of increasing deterrence, decreasing noncompliance, and reducing workplace injuries, illnesses, and fatalities. Since that time, OSHA has been monitoring the effect of the new penalty system and has recently adjusted the penalty policy to allow a 60-percent reduction in penalty for employers that have between 1 and 25 employees. These monitoring efforts will continue and the agency will modify the system as necessary.

FOCUSING ENFORCEMENT ON A BROADER RANGE OF HAZARDS

Under the General Duty Clause (section 5(a)(1) of the OSH Act, employers must provide a workplace "free from recognized hazards that are causing or are likely to cause death or serious physical harm." OSHA is actively using the General Duty Clause to address hazardous conditions in areas where there are currently no standards, such as heat exposure, workplace violence and combustible dust.

INCREASED PUBLICITY AND DIRECT OUTREACH

OSHA uses increased publicity and direct outreach to reach many more workplaces, supporting its goal of reducing workplace injuries, illnesses, and deaths.

The fear of public disapproval, as a result of being identified as a violator of OSHA regulations, motivates employers to abate workplace hazards. OSHA has received reports that some employers have abated hazards in their workplaces, without any OSHA action directly aimed at them, after learning from the media about other employers who have received OSHA citations, sizable fines, and public notoriety for unsafe workplaces.

In addition, OSHA continues direct outreach to employers about hazards that OSHA believes put workers at particular risk of injury, illness, or death. For example, OSHA has continued its campaign on distracted driving and will actively work with NIOSH in support of its "Construction Fall Protection Campaign". OSHA applied this strategy in the grain storage industry in fiscal year 2011, following several grain entrapment deaths and a study by Purdue University showing that the number of grain entrapments in the United States was increasing annually. OSHA sent a strong warning letter to more than 1,900 grain storage employers in States covered by Federal OSHA and to 350 employers in State Plan States. Several months later, OSHA sent another letter to approximately 10,170 establishments, 6,200 of which were covered by Federal OSHA.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION STATE PROGRAMS

OSHA State Plans are responsible for workplace safety and health for 40 percent of U.S. workers. Although State Plans develop and enforce their own standards, section 18(c)(2) of the OSH Act requires these programs to be at least as effective in providing safe and healthful employment and places of employment as Federal OSHA programs.

Federal OSHA conducts annual on-site monitoring visits in each State plan to ensure that their standards and enforcement program are at least as effective as the Federal program. Federal OSHA is currently in the process of concluding an agreement with the state plans concerning new effectiveness measures that are scheduled to go into effect at the beginning of fiscal year 2013.

IMPROVING THE WHISTLEBLOWER PROTECTION PROGRAM

Question. Recently OSHA has reorganized their Whistleblower Protection Office to make the program more effective and to respond to criticism found by the Government Accountability Office (GAO) in several reviews. Could you describe what steps DOL/OSHA is taking to improve the effectiveness of its Whistleblower Program and how DOL intends to use the additional funds and personnel that have been requested for this program?

Answer. In addition to reorganizing and raising the status of the Whistleblower Protection office within OSHA, the agency is currently undertaking numerous internal improvement efforts in order to improve the efficacy of its whistleblower program.

Due to an increase in the number of whistleblower complaints filed with the agency over the past decade, OSHA has steadily accumulated a sizeable backlog of whistleblower complaints awaiting investigation. To address this issue, the Agency conducted a re-evaluation of its investigative processes and is developing numerous strategies for streamlining the process, including simplified paperwork requirements, new priority-based intake procedures, and a new approach for sharing information between parties of a case. Once implemented, these strategies will allow OSHA to better manage its whistleblower caseload, resulting in higher-quality investigations and better customer service.

The agency is also developing an alternative dispute resolution (ADR) program for whistleblower cases, which will serve as a valuable conflict resolution alternative to the resource-intensive and time-consuming investigative process. OSHA's ADR program will encourage early and fair resolution of whistleblower complaints by providing parties with an opportunity to explore resolution options with a neutral, third-party mediator.

OSHA is expanding its audit activities of the whistleblower program to promote accountability and ultimately improve the quality of whistleblower investigations. Newly developed audits will evaluate how closely regional investigators are following the Whistleblower Investigations Manual and applicable whistleblower regulations in their casework. Planned audit activities include a comprehensive audit of regional practices to be performed every 4 years by the National Office, as well as

self-administered audits for the regions to perform during the years that they are not audited by the National Office.

STEPS TO IMPROVE EFFECTIVENESS OF WHISTLEBLOWER PROGRAM

Additional OSHA projects aimed at improving the effectiveness of the whistleblower program include:

- Drafting new chapters to the Whistleblower Investigations Manual to provide more comprehensive guidance to the investigators in the field, and to promote consistency in investigative procedures across the regions;
- Revising OSHA’s information database to include a more detailed internal control system, which will allow OSHA to identify impediments to efficient investigations and better manage investigative resources by tracking and monitoring the critical phases of on-going investigations;
- Reconfiguring current training courses for new whistleblower investigators to better prepare new hires, and expanding OSHA’s training offerings to include advanced courses for more senior investigators, as well as training for regional supervisors and whistleblower managers.
- Redesigning OSHA’s whistleblower program Web site (www.whistleblowers.gov) to improve user navigability, and developing an online complaint filing system to allow workers to initiate the complaint-filing process electronically.
- Drafting and publishing four Interim Final Rules and four Final Rules, and establishing the procedures for the handling of retaliation complaints under the whistleblower provisions of several statutes recently enacted or amended by the Congress.

PLANNED USE OF ADDITIONAL FUNDS AND PERSONNEL

The fiscal year 2013 budget provides an increase of \$4.8 million and 37 FTE for the whistleblower program. The additional funds and staff requested are essential if OSHA’s whistleblower program is to continue its improvements. Without additional investigator staff, OSHA is challenged in meeting the growing demands of its increased statutory responsibilities.

Over the past decade, large increases in the number of whistleblower complaints received by OSHA and assignment of new whistleblower statutes to OSHA by the Congress have not been matched with adequate investigator personnel to handle those complaints. A DOL Office of Inspector General (OIG) report (Number 22–12–014–10–105, issued January 20, 2012) determined that reducing the caseload to six per investigator would require an additional 58 investigators. OSHA’s fully trained whistleblower investigators currently carry around 30–40 cases at a time on average. Without more investigators, investigative quality and timeliness will continue to suffer. Additionally, investigator turnover will remain high as over-worked investigators leave OSHA for opportunities elsewhere, compromising training resources and depriving the program of experienced whistleblower investigators within its ranks.

REDUCING EMPLOYER BURDEN IN MEETING OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION STANDARDS

Question. Please describe specific actions the OSHA will take to meet “the agency’s expanded commitment to reduce the burden on employers to the extent possible while still fulfilling its mission.”

Answer. The increase provided in the fiscal year 2012 appropriations for the On-site Consultation Program will allow OSHA to increase its commitment to assisting small businesses with identifying workplace hazards, providing advice on compliance with OSHA standards and assisting in the establishment of safety and health management systems. The additional funding will provide resources for increasing awareness about the On-site Consultation Program’s services, training for consultants to ensure that their skills are maintained and expanded, and promoting and supporting OSHA initiatives through outreach, including the planned Fall Prevention Outreach Campaign, residential construction initiatives, safety and health in the healthcare sector, vulnerable workers and the Injury and Illness Prevention Program.

In addition, OSHA will provide resources to help employers comply with new or updated standards. For example, OSHA will issue additional compliance assistance resources for its updated Hazard Communication Standard. These compliance assistance resources will include small entity compliance guides for chemical producers and users and a model training program. OSHA will continue to provide employers with resources to help them comply with OSHA requirements and protect

workers from a variety of workplace hazards, including falls and working outdoors in the heat.

Finally, all of OSHA's regulatory activity includes vast opportunities for input by stakeholders, including small businesses, concerning measures OSHA can take to reduce burdens while providing the protection to workers that the OSH Act mandates.

STATE INVOLVEMENT IN OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION POLICY

Question. How has OSHA involved State plans in development of national policy, including national emphasis programs?

Answer. OSHA recognizes that since States with OSHA-approved State plans are expected to participate in OSHA's National Emphasis Programs (NEPs), they should have the opportunity to participate in the development of these programs. OSHA meets several times every year with the Occupational Safety and Health State Plan Association (OSHSPA), an organization that represents the 27 States with OSHA-approved safety and health programs. When prospective NEPs are discussed at an OSHSPA meeting, States are encouraged to raise any concerns or experiences that they have on the issue, either during or following the meeting.

To further improve communication, OSHA implemented a more formal system to give the State plans an expanded opportunity, beyond discussions at regular OSHSPA meetings, to provide input into the development of specific NEPs and other major OSHA policy documents. Directives and other policy documents that constitute changes to the Federal program which will impact State programs, including NEPs and other enforcement policies, are being shared in draft on a special limited access Web site for State review in draft and comment prior to issuance. Six documents, including five NEPs, have been shared with the States in this manner, and conference calls were held between the States and the OSHA technical staff involved in developing the policies. OSHA has made significant changes in the directives in response to written comments submitted by States. OSHA also welcomes any State suggestions for hazards or industries that rise to the level of a national problem.

VOLUNTARY PROTECTION PROGRAM

Question. For the past 5 years with closed data, under the fiscal year 2012 budget and fiscal year 2013 request please provide a history for the approval of new Voluntary Protection Program (VPP) sites, renewal of VPP sites and total number of VPP sites.

Answer.

VPP DATA

Fiscal year	New	Reapprovals	Total active end of fiscal year
Fiscal year 2007 actual	256	203	1,902
Fiscal year 2008 actual	230	235	2,110
Fiscal year 2009 actual	172	239	2,284
Fiscal year 2010 actual	175	253	2,446
Fiscal year 2011 actual	101	298	2,445
Fiscal year 2012 operations plan	100	280
Fiscal year 2013 budget	60	280

Question. Also, what has the VPP Review Workgroup found in terms its review of VPP and recommendations for program improvement?

Answer. OSHA formed a VPP Review Workgroup in 2011 made up of representatives from OSHA's National and Regional Offices. The workgroup was responsible for conducting a comprehensive review of the VPP and submitting recommendations for improving the program. The recommendations of the workgroup are currently under review. OSHA has begun evaluating and prioritizing suggested recommendations for changes that are determined to be key and that will strengthen the program's effectiveness and integrity.

ONE-STOP CAREER CENTER SYSTEM REVIEW

Question. ODEP and ETA are conducting a separate independent survey of the physical, programmatic, and communications accessibility of the One-Stop Career Center system and review of Workforce Investment Board policies and procedures relative to the availability of intensive and training services for individuals with dis-

abilities. What are the findings from this work? What corrective actions are planned?

Answer. ODEP, ETA, and the Chief Evaluation Office (CEO) currently are planning the accessibility study and review of Workforce Investment Board policies and procedures. CEO will provide the funding for designing and conducting the accessibility study and currently is in the process of developing a Blanket Purchase Agreement (BPA) in order to competitively secure services to do so. The DOL's CEO has indicated that the BPA contract should be awarded this spring, at which time the Task Order for the accessibility study will be the first procurement action. The accessibility study is expected to begin in summer 2012, with findings projected to be available in late 2013.

UNIVERSAL DISLOCATED WORKER PROGRAM

Question. Earlier this month the Obama administration announced a proposal to create a Universal Dislocated Worker program. The proposal would consolidate the Trade Adjustment Assistance program with the Workforce Investment Act's Dislocated Worker program and provide the same benefits to all workers. Can you explain how National Emergency Grants (NEGs), which are funded through the National Reserve, fit into the Universal Dislocated Worker program proposal? Would NEGs continue to be funded with discretionary funding?

Answer. NEGs give the Secretary of Labor the ability to provide resources in situations where the workforce system is unable to meet an unanticipated need for re-employment services, such as a natural disaster or a large plant closure. These grants would work in conjunction with the Universal Dislocated Worker (UDW) program, as they do currently with the Workforce Investment Act's (WIA) Dislocated Worker formula program. Since NEGs are designed to respond to unanticipated events that yield unknown needs for workforce services, we believe it appropriate that they continue to be funded with discretionary funds out of the WIA appropriation, and accordingly NEGs would continue to be funded separately. It is important that the Secretary retain this flexibility to respond to events such as natural disasters, large plant closures, and other events which temporarily create more demand for services than the affected State and local workforce systems can address on their own, or which require a unique set of services, such as employing dislocated workers in jobs related to disaster recovery. We would work with the Congress to ensure that the benefits and services NEGs provide complement those provided under the UDW program.

FEDERAL REGULATION WAIVERS

Question. The President's budget requests legislative language that would allow the Secretaries of Labor and Education to waive statutes and regulations relating to the Workforce Investment Act of 1998, the Wagner-Peyser Act and title I of the Rehabilitation Act in instances when the Secretaries believe waivers would substantially improve education and employment outcomes. Additionally, in the Solicitation for Grants Announcement for the Workforce Innovation Fund (SGA/DFA PY-11-05) you encourage applicants to include information on how waivers of Federal laws or regulations, if waived, would enhance the proposed innovations. Can you provide examples of which laws and regulations you believe are prohibiting successful outcomes for workforce services delivery and information? Can you also describe how you would evaluate waiver requests? How would you define "substantial improvement of education and employment outcomes"?

Answer. Waiver authority can be one of the most effective tools the Federal Government has to spur experimentation and innovation. Particularly in the absence of significant funding to entice States and locals to come forward with new ideas, administrative flexibility is a powerful tool.

Because States and local areas are in the best position to identify statutory or regulatory barriers that may impede innovation and improvements in workforce service delivery, the President's budget requests expanded waiver authority for the Workforce Investment Act of 1998 (WIA), the Wagner-Peyser Act (W-P), and title I of the Rehabilitation Act to provide greater opportunity and flexibility to States in designing strategies that best fit their needs. Enhanced waiver authority would enable States to test innovative structural and service delivery approaches in a limited setting to improve participant outcomes and the cost-effective delivery of services.

The Department has exercised its authority under WIA to approve hundreds of waivers requested by States during the last decade, and has a well-established process for evaluating such requests. The Department believes this process can easily be adapted in the context of the Workforce Innovation Fund to incorporate a collaborative review of waiver requests with the Department of Education that affect pro-

grams administered by both agencies, including approval of such requests by both the Secretaries of Labor and Education or their designees. In reviewing applications, we would expect requesters to be able to demonstrate how their proposed approach would improve outcomes consistent with the purpose of the programs involved. As set forth in the fiscal year 2013 budget, waivers would only be provided to projects which include:

- A plan to effectively evaluate the impact of the strategies being tested on outcomes for program participants;
- A strong accountability system, including outcome measures which show outcomes for program participants and demonstrate that subpopulations with the greatest barriers to employment are being appropriately served by the workforce system; and
- Other required elements, as established by the Secretaries in regulation or grant solicitation.

DOL also requires States to report annually on outcomes achieved by waivers in the WIA annual performance report that States are statutorily required to submit to the Department, and would continue to do so.

NATIONAL APPRENTICESHIP ACT

Question. DOL is working on regulations for Equal Employment Opportunity in the National Apprenticeship Act, which should increase nontraditional job opportunities for women and underrepresented populations and accomplish the same goals of Women in Apprenticeship and Non-Traditional Occupations Act (WANTO). Can you provide an update on the timing of the regulations?

Answer. Since 2010, ETA has consulted stakeholders, including the Secretary's Advisory Committee on Apprenticeship, to gather input for development of this rule through a variety of methods, including virtual Webinars and in-person town hall meetings. The Department is in the process of drafting this Notice of Proposed Rule Making, and anticipates publishing it in 2012.

JOB CORPS CENTER CLOSURES

Question. Can you tell me more about how "chronically low-performing" Job Corps centers will be defined and the process the Department will undertake to close a center? Can you tell me more about how low-performing centers have been identified in the past and what opportunities they have been given to improve?

Answer. The Department has established a comprehensive performance management system to assess program effectiveness across multiple components of services and programs offered to Job Corps students. The performance management system serves three primary purposes, as follows, to:

- Meet accountability requirements for establishing performance measures (also known as metrics) and reporting student outcomes for the Job Corps system prescribed in the WIA legislation, Common Performance Measures for Federal youth training programs, and DOL priorities;
- Assess centers' and agencies' accomplishments in implementing program priorities and serving students effectively; and
- Have a management tool that provides useful and relevant feedback on performance, while encouraging continuous program improvement.

To assess center performance against established goals and priorities, the Office of Job Corps' Federal staff conduct on-site center assessments and monitoring trips, and electronic desk monitoring and contractor performance reporting. Underperforming centers may be placed on a corrective action plan or performance improvement plan. Such a plan may be targeted to a specific area of performance (e.g., academic attainment) or in cases of significant underperformance, may include overall center operations.

Chronically low-performing centers are those that have consistently failed to meet performance standards over the past several program years. The Department is using its existing performance measures as the key component for developing its methodology for identifying centers for closure that will be published in the Federal Register for the public and stakeholders to provide feedback, prior to its use in selecting centers for closure.

Further, the Department will ensure that it follows the legislatively mandated process for closing a Job Corps Center, per section 159 of the WIA, which includes the following:

- Advance announcement to the general public of the proposed decision to close the center, through publication in the Federal Register or other appropriate means;

- Establishment of a reasonable comment period, not to exceed 30 days, for interested individuals to submit written comments to the Secretary; and
- Notification of the Member of Congress who represents the district in which such center is located, within a reasonable period of time in advance of any final decision to close the center.

REBRANDING OF WORKFORCE CAREER CENTERS

Question. The President's budget includes a proposal to rebrand the workforce career centers. Can you provide additional information or examples of why the system needs rebranding? What barriers does the current branding pose to workers in need of services? And would States compete for funding or would the Department work with each State on the rebranding process?

Answer. A 2005 GAO report ("Employers Are Aware of, Using, and Satisfied with One-Stop Services, but More Data Could Help Labor Better Address Employers' Needs") found that only about one-half of employers are aware of the public workforce investment system. In addition, each year, 20 million individuals tap into our existing workforce system resources, but there are millions more who could benefit from being able to reliably find the services they need to succeed in today's economy. Currently, names for One-Stop Career Centers vary from State to State, or even from town to town, and online Federal, State, and local tools are spread across many Web sites with different names. Jobseekers may not understand that these resources are available to connect them to training and other supports. Veterans transitioning to civilian life might look for a One-Stop Career Center, but cannot find anything nearby with that name. Businesses that are well-connected to the workforce system in one State may not be aware that the same services are available to them elsewhere, under a different name.

The Department's initiative to establish the American Job Center Network is designed to give workers and businesses an easily identifiable source for the help and services our workforce system provides. While the Department will initiate this effort in fiscal year 2012, under the President's fiscal year 2013 budget proposal, the Department will:

- Use a significant portion of the funds (approximately 70 percent) to support collocation among partner programs, increase the number of American Job Centers and service points, and increase public awareness and accessibility of workforce services through nationwide outreach and education using the American Job Center brand. These funds would be distributed to States and locals, with a small national reserve for administration and technical assistance.
- To increase the number of service points, funds can be used to establish new service points for workforce services in local communities, such as computers at a library or community-based organization to access online services, or expanding access to workforce services within community colleges and schools, or even creating kiosks in major commercial chains.
- The recipients may also use these funds to expand workforce services during hours convenient for working adults and businesses, particularly small businesses. In addition, States will use the funds to fully implement the American Job Center brand, and funds could support Web site adjustments and outreach through multiple media. The Department will also seek to create a national outreach and education plan to increase awareness and usage of the public workforce investment system.
- The Department will use the remaining funds to expand current national electronic tools to provide more interactivity between the online customer and the virtual services currently available through www.CareerOneStop.org. The new electronic tools would include a jobseeker portfolio, an interactive resume analysis tool, an interactive knowledge and diagnostic database providing automated responses to common questions, and virtual chats with career counselors. For jobseekers who lack computer skills or Internet access, the Department will also expand its telephone contact centers to provide on the phone some of the personal interaction offered through staff-assisted services at brick and mortar One-Stop Career Centers.

RE-EMPLOYMENT SERVICES FOR UNEMPLOYMENT INSURANCE CLAIMANTS

Question. The President's budget includes increased funding for Employment Service Grants to States to carry out more intensive re-employment services for Unemployment Insurance (UI) claimants, among other activities. Can you provide information on the successful re-employment services that the Department will highlight and encourage States and local areas to implement?

Answer. Providing effective re-employment services to unemployed (including long-term unemployed) jobseekers and minimizing erroneous payments are high priorities for the Department and its partners, the State workforce agencies. Re-employment assistance can result in more rapid re-employment, shorter claim duration, and fewer erroneous payments of UI benefits. For example, in Nevada, a pilot program of Re-employment and Eligibility Assessments (REAs) coupled with re-employment services reduced weeks claimed by 2.96 weeks and benefits received by \$805. Further study revealed that REAs in Nevada increased re-employment by close to 20 percent initially and by close to 10 percent into the second year following participation in the program. REAs also increased earnings by 25 percent initially and close to 15 percent into the second year after participation in REAs. Thus, eligibility assessment and re-employment services not only shorten UI duration, but also persistently boost employment and earnings. Effective re-employment services for UI claimants include at the minimum the provision of labor market and career information, an assessment of the skills of the individual, and orientation to the services available through the One-Stop Centers established under title I of WIA. Some claimants benefit from additional services such as comprehensive and specialized assessments, job search counseling and the development or review of an individual re-employment plan, individual and group career counseling, and training services. The Department encourages States and local One-Stop Centers to consider the claimants' individual circumstances and adopt approaches that are most likely to effectively speed their return to work.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

COMPACT OF FREE ASSOCIATION

Question. In 1986, the United States entered into Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands. In 1994, the United States entered into a similar relationship with the Republic of Palau. The Compacts set forth the bilateral terms for government, economic, and security relations between the United States and the Freely Associated States (FAS), and the laws approving the Compact set forth the U.S. policy context and interpretation for the Compacts. Section 141 of the Compact provides that certain FAS citizens "may be admitted to, lawfully engage in occupations, and establish residence as a nonimmigrant in the United States and its territories." However, the Congress also stated, in section 104(e)(1), that "it is not the intent of Congress to cause any adverse consequences for an affected jurisdiction." It is estimated that affected areas of the United States are spending upward of \$200 million annually for healthcare, education, and other services for FAS migrants. Although the Compacts allow the FAS migrants to engage in work in the United States, employers find that there is a significant need for language and cultural education and job training. How best can the Department of Labor assist States and territories in preparing Compact migrants for employment opportunities?

Answer. Migrants from the Marshall Islands and Micronesia are eligible to receive labor exchange and employment services and Workforce Investment Act (WIA) authorized employment and job training programs in One-Stop Career Centers across mainland United States and outlying areas. There is a wide range of services available through the One-Stops that can be tailored to meet the employment and training needs of these individuals. Many outlying areas—Guam, American Samoa, the Virgin Islands, and Northern Mariana Island, including the Republic of Palau—receive annual WIA title I (WIA Adult, Dislocated Worker and Youth programs) formula allotments. The availability of WIA title I funding to Palau has also been extended through fiscal year 2012 in the Consolidated Appropriations Act of 2012 (in the Department of Education's General Provisions at section 306, title III, division F, Public Law 112-74).

In addition to the One-Stops, the Department's competitive grants to States and outlying areas, such as the recent Trade Adjustment Assistance Community College and Career Training Grant program, bolster the capacity or the workforce system to provide quality employment and training services and programs. Freely Associated States migrants can potentially benefit from access and participation in these programs to improve their employment outcomes.

Since 2003, the Marshall Islands and Micronesia no longer receive WIA title I funding for employment and training services provided through the WIA Adult, Dislocated Worker and Youth programs, but have been receiving funds from the Department of Education's appropriation (see Compact of Free Association Amend-

ments of 2003, Public Law 108–188 (December 17, 2003)), codified at 48 U.S.C. 1921d(f)(1)(B)(iii) (the “Compact”).

ALIGNING HAWAII’S PREPAID HEALTH CARE ACT AND THE AFFORDABLE CARE ACT

Question. Hawaii has traditionally experienced a much lower rate of uninsured individuals due to the landmark State law, the Prepaid Health Care Act (PHCA), which requires employers to provide healthcare coverage to full-time employees. As the State works to implement elements of the Affordable Care Act (ACA), questions have arisen regarding the ability for Hawaii’s law to interact with the ACA in a manner that would allow Hawaii residents maximum benefits. Will there be further guidance from the Department of Labor (DOL), specific to Hawaii’s healthcare environment, on how the PHCA can work in conjunction with the requirements of the ACA? Is it DOL’s desire for Hawaii to maintain the requirements of the PHCA?

Answer. DOL is committed to working with the State of Hawaii regarding the coordination of the PHCA and the ACA. DOL also works with our Federal partners in ACA implementation, such as the Department of the Treasury and the Department of Health and Human Services, on these issues, as necessary. Conversations about specific interactions have already begun and will continue to ensure the best result for Hawaii residents and their health coverage.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

GOVERNMENT ACCOUNTABILITY OFFICE PRINCIPLES FOR SUCCESSFUL COLLABORATION BETWEEN EMPLOYERS AND EMPLOYEES

Question. In the January 2012 Government Accountability Office (GAO) report, “Innovative Collaborations between Workforce Boards and Employers Helped Meet Urgent Local Workforce Needs”, GAO identified six principles for successful collaboration, including leadership, leveraging resources, and providing business responsive services by examining 14 examples of collaborations between local workforce board, employers, community colleges, Manufacturing Extension Partnerships (MEPs), economic development and others. How is the Department of Labor (DOL) using its resources to ensure that all boards and the entire system are putting these principles in place?

Answer. GAO’s report findings validate the Department’s longstanding position that stronger partnerships between employers and the public workforce system improve employment and retention outcomes for our Nation’s workers. The report also echoes the Department’s strategic thinking on the importance of linking workforce services to meet the needs of regional and local economies, and the need for public workforce system reform through the reauthorization of the Workforce Investment Act of 1998 (WIA).

A key area of exploration for the Department is enhancing our dual-customer approach to effectively serve both workers and employers. We continue to provide technical assistance on business engagement to workforce system practitioners. For example, in May 2011, we provided in-person and virtual training for business liaisons in local workforce areas, and established a set of online resources available for business liaisons across the country. In 2012, we are planning to offer a series of activities and learning opportunities to promote and enhance services to business customers, beginning with a National Job Fair Month, scheduled for June 2012. In addition, we want to emphasize that while the Department provides policy leadership and guidance to the One-Stop delivery system, States have a critical role in making business engagement a priority, including tracking data on services to employers. The Department’s on-line technical assistance platform for workforce practitioners contains numerous examples of promising State and local practices in business engagement.

The Department is also working across Federal agencies to streamline administrative processes and better align resources and programs to ensure effective service delivery. The Departments of Labor, Health and Human Services, and Education continue to seek opportunities to develop joint guidance to State and local grantees, and to implement cross-cutting demonstration projects that encourage partnerships and improve models for delivering quality services across programs at lower costs.

WORKFORCE INVESTMENT ACT PROGRAM PERFORMANCE

Question. The annual performance results for WIA programs this past year noted that nearly 8.7 million workers received assistance and more than one-half of the people who got help through WIA gained employment, despite the fact that there are nationally more than four jobseekers for every available job. On top of that, 4

out of 5 job seekers who gained employment through WIA were retained in their employment according to the Department's data. Additionally, 8 out of 10 employers who utilized the workforce system were satisfied by the assistance they received from the workforce system. What does this data reveal about WIA programs ability to effectively respond during periods of high unemployment, such as the country has experienced for the last several years?

Answer. These data illustrate in a statistical manner the value of the services provided by WIA programs. The workforce system experienced a tremendous increase in demand for its services during recent economic downturn. In response, the Department has implemented various strategies including:

- on-the-job training;
- setting new goals for the increased attainment of industry-recognized credentials, including degrees and certificates by workforce system participants;
- issuing guidance on entrepreneurship and self-employment activities;
- emphasizing the importance of longer-term training; and
- encouraging the development of career pathways, especially for low-skilled youth and adults.

The benefits of these strategies are evidenced by the higher-employment outcomes of WIA program completers.

It is worth noting that according to the latest Job Openings and Labor Turnover Survey data provided by the Bureau of Labor Statistics (BLS), there are roughly 12.8 million unemployed Americans looking for work and 3.5 million job openings. This ratio shows that the average job seeker only has a 27-percent chance of obtaining the job they want and need due to the high level of competition. However, WIA program completers are finding employment at more than twice that rate, further showing the value of WIA program services in helping job seekers gain skills that employers demand.

Although the Department is proud of the accomplishments of the workforce system, we recognize more must be done to create an economy that is built to last. The President's blueprint for growth includes new proposals that would allow the Department to pursue additional strategies intended to strengthen manufacturing, energy, education, and skills training. Additionally, the reauthorization of WIA remains a unique opportunity to modernize and position the workforce system to help even more workers and employers.

JOB CORPS CENTER CLOSURES

Question. Please provide a detailed plan regarding the Department's plan to identify and close "low-performing" Job Corp centers. Please include a time line, a description of the selection factors, the Department's definition of "low-performing" and which centers the Department would currently label as "chronically low-performing." Please also include a description of the cost-effective strategies identified in rigorous evaluations that the Department plans to move toward as well as the changes in performance measurement and reporting. Finally, please describe how the Department will work with the Department of Agriculture regarding the evaluation of Civilian Conservation Centers.

Answer. Chronically low-performing centers are those that have consistently failed to meet performance goals over the past several program years. The Department is using its existing performance measures as the key component for developing its methodology for identifying centers for closure that will be published in the Federal Register for the public and stakeholders to provide feedback, prior to its use in selecting centers for closure. A timeline has not yet been developed for the closure process.

The Department will ensure that it follows the legislatively mandated process for closing a Job Corps center, per section 159 of the WIA, which includes the following:

- Advance announcement to the general public of the proposed decision to close the center, through publication in the Federal Register or other appropriate means;
- Establishment of a reasonable comment period, not to exceed 30 days, for interested individuals to submit written comments to the Secretary; and
- Notification of the Member of Congress who represents the district in which such center is located within a reasonable period of time in advance of any final decision to close the center.

As you may know, the U.S. Department of Agriculture Forest Service operates 28 Job Corps centers under an Interagency Agreement with the DOL. The performance of these centers is evaluated in the same manner as those centers operated by private entities under contract with the Department. DOL's Federal staff perform the same on-site and electronic monitoring of the operated centers, including the devel-

opment and implementation of performance improvement plans, when necessary. All Job Corps centers will be evaluated for closure using the same methodology.

The Department is currently conducting a study to review the program's operations and performance management practices. The final results of this study will be available in summer 2013 and will be used to implement reforms and efficiencies system-wide.

Regarding changes to performance metrics and reporting, beginning in Program Year 2010, the Department began tracking Job Corps student attainment of industry-recognized credentials. These credentials, which include industry certifications, state licensures, and pre-apprenticeship credentials, provide students with geographic and economic mobility. They demonstrate to employers that Job Corps graduates have attained the skills and knowledge necessary to compete in today's workforce.

The Department is also taking steps to make Job Corps' performance measures more transparent and accessible to the public and the program's stakeholders. The Office of Job Corps has launched on its Web site an interactive map (at http://www.jobcorps.gov/AboutJobCorps/performance_planning/omsdata.aspx) that provides information on each Job Corps centers' performance. Job Corps will also offer an online guide explaining the program's performance management system in layperson terms. Later this year, the Department will submit a report to the Congress detailing the results of each of the metrics outlined in the WIA.

JOB CORPS CENTER CONTRACTS

Question. Please provide a description of the process the Department uses to award contracts for Job Corp centers. Also please describe any planned changes to this process, the rationale for any changes, and the anticipated impacts of such changes.

Answer. DOL uses competitive procedures prescribed by the Federal Acquisition Regulations (FAR) 6.1 and FAR 6.2. In accordance with FAR Part 10 and FAR 19.502-2, DOL reviews the market research conducted by the Contracting Officers to determine if a requirement shall be set-aside for small business concerns, HUBZone small business concerns, 8(a) firms, or Service Disabled Veteran Owned Small Business concerns. On rare occasions, and only as permitted by the exceptions provided in FAR 6.3, DOL uses this authority to award contracts without competitive procedures.

DOL utilizes "contracting by negotiation" techniques defined under FAR Part 15 and, when doing so, conducts a trade-off analysis among evaluation factors to determine which contractor offers the best value to the Government. When the Department conducts such a trade-off analysis, technical approach (e.g., quality of services provided to the students) is the most important evaluation factor.

Due to pending litigation, the Department cannot comment on any planned changes to this process.

REGIONAL OFFICE CONSOLIDATION

Question. Please provide a detailed description of the Department's regional office closure plan including specific offices and locations. In addition, please describe how the services provided by such center will be provided under the consolidation plan.

Answer. The budget proposes adopting a leaner, more efficient approach for five offices within the DOL:

- the Occupational Safety and Health Administration (OSHA);
- the Office of the Solicitor (SOL);
- the Office of Public Affairs (OPA);
- the Women's Bureau (WB); and
- the Employee Benefits Security Administration (EBSA).

In fiscal year 2013, each of these Bureaus will consolidate their regional offices to ensure that they are strategically placed to perform DOL's key functions across the country while eliminating unnecessary administrative costs.

In an effort to streamline agency operations, the OSHA proposes to reorganize its regional structure and jurisdictional authority from its current operation of 10 Regional Offices (ROs) to 7. The reorganization will involve the consolidation of OSHA's Regions 1 (Boston) and 2 (New York); Regions 7 (Kansas City) and 8 (Denver); and Regions 9 (San Francisco) and 10 (Seattle). The estimated savings would come largely from the saved compensation from three Regional Administrator positions and related benefits. Additional savings would be achieved through reduced rent needs and travel expenditures.

The Solicitors' Office (SOL) is working on regional office consolidation to better align legal offices with the Department's component agency structures, with even-

tual reduction from eight to six SOL regions. As an initial step, SOL is planning to reduce one region (Kansas City) in fiscal year 2012.

OPA consolidation of regional offices includes the closure of offices in Denver, Colorado and Seattle, Washington. These offices have been essentially closed since fiscal year 2011 due to attrition of Federal staff. OPA will continue to meet agency goals and objectives continuing to have the workload of the Denver and Seattle locations processed and managed by the remaining regional offices in Chicago, Dallas, and San Francisco.

For the WB, the consolidation of regional offices will refocus the agency to its policy responsibilities as it works through other DOL agencies for its outreach functions. The Department strongly supports the work of the WB and believes that increased collaboration with other regional DOL agencies will allow the Bureau to more effectively and efficiently carry out its mission.

The WB is developing objective criteria to guide the process for consolidation of its regional offices. The goal is to continue to serve the highest number of women possible in the most coordinated and economically efficient manner. We anticipate that we will be able to achieve this goal by maintaining those WB regional offices in geographical locations where other DOL regional offices exist and opportunities for sister agency collaboration will be maximized.

The Department remains committed to the advancement and rights of working women, particularly those who are the most vulnerable. Consolidating the Bureau's regional offices will result in savings that the budget would reinvest, dollar-for-dollar, in the enforcement of the Family and Medical Leave Act and Fair Standards Labor Standards Act—two laws that have a direct and tangible benefit for women in the workforce.

As with the WB, the EBSA is still developing the details of its effort to consolidate regional offices. The objective of EBSA's consolidation is to increase the efficiency and effectiveness of the enforcement and worker assistance operations. Similar to OSHA's approach, a primary guiding principle in the EBSA effort is to not allow a reduction in front-line enforcement or other services for the public because of consolidation. Some of the specific factors that EBSA is considering in identifying the regions proposed for consolidation options include the closer alignment of regional offices with financial centers, number of plans, participants and beneficiaries, and total plan assets; a better alignment of regional workload; the elimination of some split State responsibility in regional jurisdictions; and taking advantage of the regional locations of other DOL offices such as SOL and the Office of Assistant Secretary for Administration and Management.

CONSOLIDATION OF WORKFORCE INVESTMENT ACT PROGRAM EVALUATIONS

Question. Please describe how the Department will sufficiently evaluate programs under title I of the WIA should program evaluation and research responsibilities be consolidated under the Departmental Program Evaluation office as proposed under the budget. What impact, if any, would such consolidation have on the gold standard evaluation?

Answer. The fiscal year 2013 budget proposes the use of a set-aside to finance evaluations for DOL's WIA programs, as well as pilots, demonstrations, and research considered applied research for employment and training programs, building on language that was included in the 2012 enacted appropriations bill. The 0.5 percent evaluation set-aside, which currently applies to the rest of the Department's funding, is intended to ensure that sufficient funding is available to carry out comprehensive, rigorous, and robust research and evaluations and to promote greater stability of funding for these efforts across the Department as a whole. Specifically, the Department is requesting that up to 0.5 percent of the amounts appropriated for training and employment services also be made available to support evaluations under the oversight of the Department's Chief Evaluation Officer. The projects on Employment and Training Administration (ETA) programs will continue to be guided by the current Five-Year Research and Evaluation Strategic Plan, which is specified under WIA section 171, and ETA's Five Year Learning Agenda developed jointly with the Chief Evaluation Office. This set-aside proposal for evaluations is an addition to a provision included in the Consolidated Appropriations Act of 2012 that authorized the Secretary to "reserve not more than 0.5 percent from each appropriation made available in this Act identified in subsection (b) in order to carry out evaluations of any of the programs or activities that are funded under such accounts."

There will be no effect on the Workforce Investment Act Adult and Dislocated Worker Programs Gold Standard Evaluation (WGSE); that evaluation is included in the ETA Strategic Plan and in the ETA Learning Agenda. Initiated in fiscal year 2010, the WGSE is a random assignment evaluation of two major programs under

title I of WIA. The evaluation measures the postprogram impacts on employment and earnings of receiving intensive services and training funded through WIA, as compared to receiving core services only and/or services funded through other sources. The complete evaluation is being conducted over the course of 7 years and represents a major improvement in the specificity and quality of previous WIA evaluations. We anticipate the final report being available in late 2017.

WORKFORCE INVESTMENT ACT RESEARCH PROGRAMS

Question. How does the Department plan to conduct pilot, demonstration, and research projects under WIA should funding for such projects be eliminated as proposed under the budget?

Answer. In fiscal year 2013, the Department requests the use of a set-aside funding mechanism to finance evaluations, as well as pilots, demonstrations, and research for employment and training programs. The new set-aside approach is intended to ensure that sufficient funding is available to carry out comprehensive, rigorous, and robust research and evaluations and to promote greater stability of funding for these efforts across all DOL programs, including the WIA, Job Corps, Unemployment Insurance, and the Employment Service. The projects that the Department undertakes will continue to be guided by the current Five-Year Research and Evaluation Strategic Plan, which is specified under WIA section 171, and ETA's Five Year Learning Agenda developed jointly with the Chief Evaluation Office. Specifically, the Department is requesting that up to 0.5 percent of the amounts appropriated for these programs be made available to support this effort. Evaluations (which may include demonstration components) and applied research projects using these funds will be conducted by DOL's ETA under the oversight of the Department's Chief Evaluation Officer. This set-aside proposal builds on the provision included in the Consolidated Appropriations Act of 2012 that authorized the Secretary to "reserve not more than 0.5 percent from each appropriation made available in this Act identified in subsection (b) in order to carry out evaluations of any of the programs or activities that are funded under such accounts." The Department considers pilots and demonstrations previously funded under WIA section 171 to be components of evaluations designed to test program interventions, services, and models.

In addition, WIF will support pilot and demonstration activities to test innovative approaches to the delivery of employment and training services.

WORKFORCE INVESTMENT ACT "PAY FOR SUCCESS" PROJECTS

Question. Please provide a detailed description of how "Pay for Success" projects will be identified for award and implemented under the Workforce Investment Fund (WIF).

Answer. ETA plans to make available approximately \$20 million for Pay for Success pilot grants, funded out of the fiscal year 2012 Workforce Innovation Fund (WIF). In piloting the Pay for Success model, which is currently being piloted in the United Kingdom, the Department will provide funding for projects that will demonstrate the feasibility and viability of this innovative financing model. Under the Pay for Success grants, third-party investors pay the operating costs of an intervention, with the goal of achieving pre-negotiated outcomes. The Government repays the principal investment made for funding the intervention and a return on investment only if results are achieved. In this way, the model is different from how Government agencies typically fund services; Government funding is shifted from paying for specific processes and services to paying for specific outcomes.

The Department plans to announce the competition for Pay for Success pilot project grants in a Solicitation for Grant Applications to be published in spring 2012. Eligible applicants will be State, local, or tribal government entities in partnership with a managing intermediary organization. This partnership must agree to a common goal of achieving specific workforce development-related outcomes. On the basis of this partnership, the intermediary will raise operating capital from philanthropic, private sector, and/or other social investors, manage the delivery of services, and be responsible for achieving outcomes and overall cost savings to the public sector as negotiated with the Government. The independent investors take on the risk of funding the project based on an expectation of an additional return on their investment if project outcomes are met. An independent entity, procured by the applicant, will verify if outcomes have been met for the purposes of repayment. The Department will pay the administrative costs of the grantee and the costs of the independent validator as they occur. Upon verification of the achievement of negotiated outcomes by the independent validator, the Department will confirm that the validation methodology was followed and make the appropriate payments to the

State/local/tribal government grantee, which then flows through the intermediary to the investor(s). If the outcomes are not achieved, the Department will not release the funds. To support grantees' success and workforce system knowledge about Pay for Success, the Department will provide technical assistance and evaluation of the Pay for Success financing strategy.

Grants under the Pay for Success financing model will be awarded competitively to those highly qualified applicants who best address the following key elements in their proposals:

- a well-defined problem and associated target population;
- a flexible and adaptive preventative service delivery strategy;
- a commitment of funds from independent investors to cover all operating costs of the intervention;
- one or more well-defined, achievable target outcomes;
- a well-defined outcome measurement and verification methodology;
- a project timeline that clearly indicates the date by which the outcome will be achieved and validated;
- a financial model that shows public sector cost savings or efficiency gains; and
- a payment arrangement between the applicant and the intermediary, to be triggered by the verified achievement of the proposed outcome(s) within the grant period.

To the extent funds are not used for PFS grants, they will be allocated to fund non-PFS projects under the WIF.

TARGETING TEEN UNEMPLOYMENT UNDER THE WORKFORCE INNOVATION FUND

Question. Please provide a justification for the Department's request to target youth younger than the age of 20 within the WIF.

Answer. The teen unemployment rate continues to be at or near historic highs. In March 2012, the seasonally adjusted unemployment rate for individuals age 16–19 was 25 percent, nearly three times the overall unemployment rate of 8.2 percent. In addition, the Nation's high school dropout rate remains too high. It is critical for the Department to invest in innovative projects focused on improving services for disconnected youth so that they acquire the skills and tools necessary to build successful careers. In addition, the goal is to focus specifically on younger youth because less is known about what interventions are effective for them. However, while the \$10 million innovation fund set aside is focused on youth ages 16 through 19, the Department anticipates other innovation projects may serve the broader pool of disconnected youth.

WORKFORCE INNOVATION FUND FUNDING AWARDS

Question. Please explain how the Department plans to target and award WIF funding should funding not be contributed by programs under the Department of Education.

Answer. The Department will coordinate with the Departments of Education and Health and Human Services in the administration of the WIF to encourage collaboration across program "silos". In fiscal year 2011, the Department consulted with its partner agencies in the development of the WIF grant competition and invited partner agency staff to help panel applications. We anticipate working with our colleagues at the Departments of Education and Health and Human Services to provide technical assistance to grantees on cross-program alignment as needed.

REBRANDING AND STRENGTHENING ONE-STOP CAREER CENTERS

Question. Please describe how the Department's plans to distribute and administer the additional \$50 million in funds requested under the Workforce Information-Electronic Tools-System Building line for rebranding and strengthening the one-stop career centers, including how such funds will be distributed to the States. Please provide a description of the activities planned with this funding and the timeline for implementation.

Answer. Under the President's fiscal year 2013 budget proposal, the Department will:

- Use a significant portion of the funds (approximately 70 percent) to support collocation among partner programs, increase the number of American Job Centers and service points, and increase public awareness and accessibility of workforce services through nationwide outreach and education using the American Job Center brand. These funds would be distributed to states and locals, with a small national reserve for administration and technical assistance.
- To increase the number of service points, funds can be used to establish new service points for workforce services in local communities, such as computers

at a library or community-based organization to access online services, or expanding access to workforce services within community colleges and schools, or even creating kiosks in major commercial chains.

- The recipients may also use these funds to expand workforce services during hours convenient for working adults and businesses, particularly small businesses. In addition, States will use the funds to fully implement the American Job Center brand, and funds could support Web site adjustments and outreach through multiple media. The Department will also seek to create a national outreach and education plan to increase awareness and usage of the public workforce investment system.
- The Department would begin this initiative within 45 days of enactment of an appropriations act, and complete it within a year.
- The Department will use the remaining funds to expand current national electronic tools to provide more interactivity between the online customer and the virtual services currently available through www.CareerOneStop.org. The new electronic tools would include a jobseeker portfolio, an interactive resume analysis tool, an interactive knowledge and diagnostic database providing automated responses to common questions, and virtual chats with career counselors. For jobseekers who lack computer skills or Internet access, the Department will also expand its telephone contact centers to provide on the phone some of the personal interaction offered through staff-assisted services at brick and mortar One-Stop Career Centers. Within 120 days of enactment of an appropriations act, the Department would begin to offer expanded services through its telephone contact centers. Requirements definition and development of the new on-line electronic tools features would begin within 90 days of enactment of an appropriations act, and phase one of the new Web site features would launch within a year of enactment of an appropriations act.

CONTINUING WOMEN IN APPRENTICESHIP AND NONTRADITIONAL OCCUPATIONS ACT
MISSION

Question. Please describe how the Department will serve the mission and intent of the Women in Apprenticeship and Nontraditional Occupations (WANTO) program through other activities.

Answer. The Department remains firmly committed to the goals of the WANTO program and will continue to work tirelessly to promote opportunities for women to enter Registered Apprenticeship and to access to non-traditional occupations.

The Department will continue to address the goals and objectives of WANTO through revisions to the Equal Employment Opportunity regulations governing Registered Apprenticeship as well as through technical assistance efforts and guidance from ETA, in conjunction with the WB. We also believe that the broader workforce investment system can help women access the supports and services needed to enter and stay in nontraditional jobs. The number of female participants receiving services through the various workforce programs has increased in the last few years by more than 40 percent, to more than 15.7 million. In some American Recovery Act and Reinvestment grants, particularly the Pathways Out of Poverty grants, we were encouraged by solid outcomes for those projects that trained women in clean energy jobs. The Department will utilize these findings to inform new technical assistance to the broader workforce system.

Last, pre-apprenticeship has shown promise in creating a more diverse, next generation of apprentices. ETA is developing a national framework to establish consistency and quality across pre-apprenticeship programs that can help women and other under-represented populations gain greater access to apprenticeship and non-traditional employment opportunities.

COMMUNITY COLLEGE CAREER FUND

Question. When does the administration plan to provide legislative recommendations for the new community college to career fund?

Answer. On March 20, 2012, H.R. 4227, Workforce Investment Act of 2012 was introduced, including provisions that would establish a Community College to Career Fund. These provisions reflect extensive technical assistance that the Departments of Labor and Education provided and thus, align with the priorities and activities envisioned in the administration's Community College to Career Fund proposal.

GUIDANCE FOR H-2A PROGRAM USERS

Question. Secretary Solis, as you know, ensuring a stable workforce for our Nation's agriculture producers is critical to keeping food on our plates and not rotting

in fields. The H-2A program, which is the pathway to bringing farmworkers in to meet these needs legally, has been the subject of regulatory tweaking during both this administration and the prior administration. My farmers are looking for consistency across the Department—for all of your employees to be saying the same thing, at any given time. I've been working with both the agriculture and labor constituencies for many years now trying to find a path forward in the form of AgJOBS. Given that legislation is not likely to move, it's incumbent on all of us—the Congress, and the agencies charged to implement H-2A program—to provide farmers and farmworkers with consistent guidelines and recommendations.

Secretary Solis, my farmers are telling me that the Department lacks clear and consistent instruction for H-2A program users. For example, one grower is currently awaiting results from a DOL audit while simultaneously preparing contracts for the upcoming harvest season. However, since the grower has not seen the results of the audit, it is unclear how he can properly and accurately write his new contracts to avoid another audit. My staff have also intervened in several cases when Department requirements and State requirements were directly in conflict. Our farmers, your staff and congressional staff should not have to spend countless hours ironing out inconsistencies within the H-2A program, but should instead spend that time making the program work and ensuring the health and safety of our farmworkers.

Madam Secretary, how will you lead your staff from the top-down to ensure that the Department provides consistent guidelines for users of the H-2A program?

Answer. The Department understands the important role that agriculture, especially apple and cherry production, plays in the State of Washington's economy. The issuance of the 2010 H-2A Final Rule was a top management priority for the Department, making it possible for all those who are working hard on American soil to receive fair pay while at the same time expanding opportunities for U.S. workers. We share your concerns about this workforce issue and view the H-2A program as a legal means by which growers may obtain foreign labor, but only when they have first recruited U.S. workers and given them a fair opportunity to secure these jobs.

We know employers with legitimate needs are successfully using the H-2A Program, and I assure you that we are continuing to take steps to assist H-2A employers in complying with the program's requirements by providing consistent and clear guidance and continuing to process applications efficiently. For example, we implemented a number of actions designed to clarify program requirements for participating employers and improve program performance. Over the past year, the Department engaged in extensive outreach and education efforts to familiarize program users with regulatory changes implemented through the 2010 H-2A Final Rule, including hosting three national stakeholder briefings in December 2011. Each of these briefings was designed to assist H-2A employers in preparing their agricultural job offers and applications for the 2012 planting season.

The Department continues to meet with employers, including those representing Washington State, and other stakeholders to provide additional assistance and explanation of the H-2A program's requirements. The Department is continuing its efforts to make the program more effective and efficient for employers. The following are a few examples of resources for the Department has produced and posted on its Web site to make the H-2A program most user-friendly for employers:

- a new employer Handbook;
- “Filing Tips” to avoid common mistakes;
- four rounds of frequently asked questions to provide clear and useful guidance to growers; and
- other technical assistance materials all aimed at providing consistent guidelines to farmers participating in the H-2A program. All of these resources are available on the H-2A page of the Department's foreign labor certification Web site at <http://www.foreignlaborcert.doleta.gov/h-2a.cfm#>.

We are pleased with these efforts and our actual program performance under the new regulations has improved significantly over prior years. For fiscal year 2011, the Department certified 93 percent of all H-2A applications filed covering more than 74,000 farm worker positions with approximately 85 percent of our final decisions issued timely. In the first 6 months of fiscal year 2012, the Department received more than 3,700 H-2A applications requesting more than 46,000 farm workers—a 3-percent increase more than the same period a year ago. Employers received certifications for approximately 95 percent of H-2A applications filed with more than 82 percent of our final decisions issued timely. We believe these performance data indicate the H-2A Program is being widely used, and we expect that our performance will continue to improve.

The Department will continue to work directly with employers participating in the H-2A Program who encounter issues or problems with their application. The H-2A Final Rule includes a process for employers to correct application or job order defi-

iciencies, rather than having the application denied. However, I feel obligated to note that some of these required modifications are not the result of changes in the H-2A Final Rule, but rather the employer's (or their representative's) failure to comply with long-standing program requirements such as offering to pay the most current reimbursement to workers for meals when traveling or paying the current hourly Adverse Effect Wage Rate (AEWR). Requiring that an employer offer and pay the appropriate subsistence level and wage rate is essential to meeting our statutory mandate to ensure that the employment of H-2A workers will not have an adverse effect on the wages and working conditions of similarly employed U.S. workers.

In other instances, the requested modifications are necessary to ensure the employer meets the eligibility criteria for participating in the H-2A Program only where there is a legitimate temporary need. Based on our program experience, we know that a large number of issues or deficiencies which affect our timely processing of applications pertain to applicant error or oversight and not from policy or regulatory disagreements.

Question. Will you direct your staff to work in partnership with H-2A users on issues that arise that are problematic for the Department and/or H-2A users?

Answer. The Department has been and continues to be willing to work with H-2A users on issues that arise that are problematic for the Department and/or H-2A users. For instance, in an effort to improve customer service and provide greater assistance to the employer community in complying with program requirements, we recently expanded the use of email to quickly communicate and resolve minor deficiencies with employer-filed H-2A applications. Once an employer corrects these minor deficiencies, the application and job order are accepted for processing, and the employer is provided with instructions through email for completing the application process. This E-Mail Pilot Notification Program has been well received by the grower community and, as a result, our deficiency rate has significantly decreased. For the first 6 months of fiscal year 2012, the percent of employer-filed applications requiring a formal notice of deficiency was 38 percent; compared to approximately 66 percent in fiscal year 2011.

Finally, in an effort to continue the progress in improving communications and work in a closer partnership with growers, the Office of Foreign Labor Certification recently established an H-2A Ombudsman Program whose primary purpose is to facilitate the fair and equitable resolution of concerns that arise within the H-2A Program community by conducting independent and impartial inquiries into issues related to the administration of the program and proposing internal recommendations designed to continuously improve the quality of services provided to H-2A Program users. A number of growers and worker advocacy organizations are already taking advantage of the new Ombudsman Program in order to resolve their issues. To get more information on the H-2A Ombudsman Program and how your constituents can get connected, please visit our Web site at: http://www.foreignlaborcert.doleta.gov/h-2a_ombudsman_program.cfm.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

H-2B RULE 2

Question. American consumers are searching for more ways to "Buy American" and support their local food producers. According to some estimates, the United States already has a severe seafood trade deficit with imports accounting for 86 percent of all seafood consumed. Did Department of Labor (DOL) review any specific studies on the economic impact of the H-2B regulations announced last month (the "H-2B Rule 2 Regulations") on the U.S. seafood industry? Did DOL solicit input from the Department of Commerce on the impact of the H-2B Rule 2 Regulations on the seafood industry?

Answer. Although the Department did not specifically solicit input from the Department of Commerce, it did provide opportunity for all interested parties to provide their views on, and analysis of, the proposed rule leading to the Temporary Non-agricultural Employment of H-2B Aliens in the United States Final Rule published February 21, 2012. See 76 FR 15130 for the notice of proposed rulemaking and 77 FR 10038 for the final rule. Comments in response to the proposed rule provided only anecdotal information on the impacts of the proposed rule on the seafood processing industry. We reviewed the comments received, and based on our review of existing data and the information received from the public, there was no indication that the Department overlooked or failed to consider economic studies or analysis specific to the seafood industry.

Question. Would the DOL be willing to delay implementation of H-2B Rule 2 Regulations (set to go into effect on April 23d) until the Small Business Administration (SBA) is able to complete an economic impact study of the impact of the final rules on small businesses that participate in the H-2B program?

Answer. The Department has provided ample time and opportunity for stakeholders, including the SBA, to provide their views on, and analysis of, the Temporary Non-agricultural Employment of H-2B Aliens in the United States Final Rule published February 21, 2012 (77 FR 10038). The Department met with a wide variety of stakeholders, including small and seasonal business representatives, during the development of the proposed rule published March 18, 2011 (76 FR 15130), upon which this Final Rule is based. The SBA's Office of Advocacy reviewed the proposed rule prior to its publication, during clearance required by Executive Order 12866. In addition, the Department provided the public 60 days in which to provide comment on the rule and during that 60-day public comment period, the Department met with stakeholders during a Small Business Roundtable, convened by the Office of Advocacy. The Chief Counsel for Advocacy submitted a comment on the proposed rule, which the Department addressed in the Final Rule, including by identifying a number of changes (e.g., such as extending the length of the three-fourths guarantee calculation period from 4 weeks to 12 weeks for job orders lasting 120 days or more and 6 weeks for job orders lasting less than 120 days, adding catastrophic man-made events such as oil spills or controlled flooding to the list of triggers that employers could use to request cancellation of the job orders, send workers home, and relief from the three-fourths guarantee, and reducing the period during which employers are required to accept State Workforce Agency referrals of U.S. applicants from the later of 3 days before the date of need or the date of the last H-2B worker's departure to 21 days before the date of need) intended to alleviate the concerns Advocacy expressed. Finally, the Office of Advocacy also reviewed the Final Rule prior to publication under Executive Order 12866. SBA has had more than a year to complete and provide to the Department their analysis of the economic impact of the Temporary Non-agricultural Employment of H-2B Aliens in the United States Final Rule published February 21, 2012 (77 FR 10038) and has not yet elected to do so.

On April 26, 2012, the court in the U.S. District Court for the Northern District of Florida, Pensacola Division, granted a nationwide preliminary injunction enjoining the Department of Labor from enforcing the Temporary Non-agricultural Employment of H-2B Aliens in the United States Final Rule published February 21, 2012 (77 FR 10038).

Question. The H-2B Rule 2 Regulations require employers guarantee both H-2B and "corresponding" American workers a total number of work hours equal to at least 75 percent of the workdays in every 12-week period—regardless of whether unforeseen factors like hurricanes or oil spills mean that production may be shut down. Although employers may seek relief from the three-quarters guarantee following a serious disaster, what guarantee can you provide that DOL will respond in a timely manner to these requests so that small businesses participating in the program are not penalized by an unforeseen disaster? Given the gulf coast's track record with disasters and its dependence on workers in the H-2B program, this is a key issue for many seafood businesses along our coastline.

Answer. In the H-2B Notice of Proposed Rulemaking, the Department proposed to allow employers to terminate a job order in the event of an unforeseeable, catastrophic event (such as a hurricane) in order to address circumstances beyond the control of the employer or the worker. In response to employer comments on the proposed rule, the Department modified the provision in the Final Rule to include acts of man (such as an oil spill or controlled flooding) as well as acts of God. Termination of the job order under this provision allows employers to end a worker's employment and fulfill the three-fourths guarantee through the job order termination date, as opposed to fulfilling the three-fourths guarantee through the entire period of the job order.

The Department recognizes that a timely response to an employer's request to seek relief under this provision is a key issue for businesses, including coastal seafood firms, and is confident in our process for responding to employers. The Department's Employment and Training Administration (ETA) has established a process for employers to electronically submit requests to terminate the job order and ETA commits to responding to terminations requests within 2 working days of receipt of such requests.

Please note that on April 26, 2012, the court in the U.S. District Court for the Northern District of Florida, Pensacola Division, granted a nation-wide preliminary injunction enjoining the DOL from enforcing the H-2B Final Rule.

OPERATING THE VOLUNTARY PROTECTION PROGRAM WITH REDUCED RESOURCES

Question. In the President's fiscal year 2013 budget, DOL has proposed reducing Voluntary Protection Program (VPP) budget by more than \$3 million and reducing the number of full-time equivalents (FTEs) by 31. This drop is problematic because Occupational Safety and Health Administration's (OSHA) proposed workload for fiscal year 2013 includes only 60 approvals for new VPP sites. Currently, there are more than 100 sites in the VPP in and actively pursuing VPP status in the State of Louisiana. Collectively, these sites employ approximately more than 20,000 workers. How will the proposed shift in the DOL's OSHA resources from compliance assistance to enforcement impact these VPP sites in terms of their ability to either obtain or retain VPP their ability to participate in the VPP in 2012 and 2013?

Answer. The reduction of \$3 million and 31 FTE is proposed for OSHA's entire Federal Compliance Assistance budget activity, not solely VPP. This reduction would be achieved through the consolidation of compliance assistance personnel in geographically dense regions and the completion of outreach and training materials development in fiscal year 2012, which will not be needed in fiscal year 2013, and will help offset the very urgent need for increased resources for OSHA's whistleblower protection responsibilities. In addition to taking steps to enhance the efficiency of compliance assistance, OSHA will no longer offer the Corporate and Merit VPP programs. The agency plans to focus on maintaining the number of current VPP sites by recertifying 280 current sites.

It is important to note that none of the steps we are taking will eliminate the access of small businesses to the VPP program. In addition, we are maintaining the increase for our State Consultation program, which is the largest source of OSHA assistance to small businesses.

Question. According to Government Accountability Office (GAO) report on the VPP published in May 2009, approximately 80 percent of VPP worksites have fewer than 500 employees. Has OSHA studied and concluded separately on the impact on small businesses of the fiscal year 2013 DOL budget proposal to shift OSHA resources from compliance assistance to enforcement?

Answer. In its report, GAO was looking at the size of the worksite and not the size of the company owning the worksite. Only 6 percent of the total number of VPP sites meet the small business definition (250 or fewer employees and are not part of a corporation/organization with 500 or more employees).

OSHA's Safety and Health Achievement Recognition Program (SHARP) is a recognition program similar to VPP that is focused exclusively on small businesses. Employers that have a full On-site Consultation visit and meet other requirements may be recognized under SHARP for their exemplary safety and health management systems. As of February 29, 2012, there were 1,568 SHARP sites, of which 154 are new SHARP site that were initially recognized in fiscal year 2011.

In fiscal year 2012, the On-site Consultation Program budget was increased, which enabled OSHA to increase its commitment to assisting small businesses with identifying workplace hazards, providing advice on compliance with OSHA standards and assisting in the establishment of safety and health management systems. This increased commitment to assisting small businesses will continue in fiscal year 2013.

Question. What are OSHA's plans to review the impact on small businesses that participate in the VPP of implementing a user fee system to fund VPP?

Answer. OSHA has no plans to implement a user fee system to fund VPP.

MEASURING VOLUNTARY PROTECTION PROGRAM PERFORMANCE

Question. The May 2009 GAO report found merit in the VPP programs overall, but that OSHA had not developed goals or measures to assess the performance of the VPP, and the agency's efforts to evaluate the program's effectiveness had not been adequate. OSHA generally agreed with the GAO Report's recommendations to develop procedures and measures to assess the performance of the VPP. What is the current status of implementing the recommendations from the GAO report for assessing the performance of the VPP?

Answer. OSHA has implemented a number of new policies to improve the performance of VPP participants is continuing to evaluate and develop ways to improve internal controls and measurement of program performance and effectiveness as part of the ongoing VPP continuous improvement process. The Assistant Secretary's series of VPP policy memoranda (five to date, the earliest signed August 3, 2009, and the most recent, June 29, 2011) include instructions to strengthen nationwide consistency in OSHA's administration of VPP; improve the quality and documentation of OSHA actions following a fatality at a VPP site; strengthen internal controls, audit procedures, tracking, and proper documentation of OSHA actions; and improve

annual data submissions required of all VPP participants and OSHA's review of the submissions and follow-up actions. OSHA continues to provide GAO with annual updates on its recommendations to improve administration and oversight of VPP.

OSHA formed a VPP Review Workgroup in 2011 made up of representatives from OSHA's National and Regional Offices. The group was responsible for conducting a comprehensive review of the VPP and submitting recommendations to the Assistant Secretary for improving the program and developing goals and measures. The Workgroup reviewed extensive documentation and also interviewed Regional and National Office managers and staff, VPP participants, and other external stakeholders to solicit their views and recommendations for improving VPP. OSHA has begun working on suggested recommendations for changes that are determined to be key and that will strengthen the program's effectiveness and integrity.

QUESTIONS SUBMITTED BY SENATOR JACK REED

WORK SHARING

Question. My work-sharing legislation was recently signed into law. Many States are now awaiting guidance from the Department in order to implement work sharing or strengthen their existing program.

When will the Department issue guidance, specifically with respect to Federal financing and grants? What are the Department's plans for formulating model work-sharing legislation? What are the Department's plans for fulfilling the intent and purpose of the legislation—to encourage more States to adopt work-sharing, strengthen existing programs, and prevent layoffs—and maximize outreach to State work force agencies and businesses?

Answer. The Department has been working as quickly as feasible to implement the many reforms to the Unemployment Insurance program contained in the Middle Class Tax Relief and Job Creation Act of 2012, including the Short Time Compensation (STC) or work-sharing provisions. Early priorities were implementation of the complex changes to the Emergency Unemployment Compensation program and the requirement that states provide re-employment services and re-employment and eligibility assessments for Emergency Unemployment Compensation (EUC) claimants, since these provisions had to be implemented by States immediately.

With regard to the STC provisions, to inform our guidance and to meet the statutory requirement to consult with stakeholders and program experts, the Department held "listening sessions" via two Webinars on March 19 and 20, 2012. The Department envisions there will be several pieces of program guidance. The first guidance will address the new program definition, the transition provisions for States currently operating STC programs, new program reporting requirements, and the process for 100-percent reimbursement of STC benefits for States currently operating STC programs. The first guidance will provide preliminary information on the new 2-year Federal STC program and the grants. Our current target for issuing this guidance is the first week of May 2012. Model legislative language is in development and should be ready to release by the end of May 2012. As soon thereafter as feasible, the Department will issue more comprehensive guidance on the new 2 year Federal STC program and the grants, which is already in development. Subsequent to each piece of guidance, the Department will host Webinars with States to review the guidance and offer technical assistance.

The Department is excited to be implementing the STC provisions in the act as a critical lay-off aversion tool for States. We currently are developing a robust outreach and technical assistance plan to support State take-up and employer engagement, including collection and dissemination of best practices. We will be happy to share that plan upon completion.

LIBRARIES AND THE WORKFORCE INVESTMENT SYSTEM

Question. Public libraries are a key access point to our workforce investment system. However, they are often connected to the one-stop system on an ad hoc basis. What role will public libraries play in the American Job Center Network (AJCN) proposal that the administration rolled out on March 12, 2012?

Answer. Libraries will play a key role in the AJCN. The Employment and Training Administration (ETA) has met with representatives from the Institute of Museum and Library Services (IMLS) and the American Library Association (ALA) to brief them on the AJCN proposal. All three organizations have agreed to work together to meet the goals of the AJCN proposal. ETA representatives have participated at Library events sponsored by IMLS and ALA to discuss the administration

proposal and will provide training to library staff on the Department of Labor (DOL) electronic tools designed to assist job seekers.

Question. Please provide an update on the activities and outcomes as a result of the Department's Memorandum of Understanding with IMLS.

Answer. DOL and the Institute of Museum and Library Services (IMLS) entered into a partnership in October 2009 in recognition of the important roles that both the public workforce system and libraries have in addressing the varied employment-related needs of American workers, job seekers, unemployed workers, and employers. IMLS and the Department continue to involve their respective strategic partners in the workforce and library systems to raise awareness and share examples of partnerships at the local level. In June 2010, the Department published a Training and Employment Notice announcing the ETA-IMLS partnership to the workforce system and highlighting examples of partnerships between the workforce system and public libraries at the State and local levels.

Additionally, the Department has:

- provided information on where to find libraries on the Department's CareerOneStop Web site—America's Service Locator;
- provided electronic training materials on various electronic tools (e.g., mySkills myFuture, ReEmployment portal, Workforce3One, CareerOneStop electronic tools) for distribution at national meetings of the Public Library Association (PLA) and ALA;
- delivered Webinars to the public workforce system and library staff nationwide to promote and identify effective partnerships between the public workforce system and libraries, and provided training to library staff on ETA electronic tools; and
- continued to interact with leaders at IMLS and the ALA.

Most recently, the Department has met with representatives from the IMLS and the ALA to brief them on AJCN proposal and has invited their input and participation in this initiative.

Question. How many of the first round applicants for the Workforce Innovation Fund (WIF) have included working with public libraries as part of their proposal? In the next round of applications, will the Department emphasize public libraries as key partners in an innovative workforce investment strategy?

Answer. The WIF grant solicitation closed on March 22, 2012, and applications are being paneled. The Department will continue to emphasize the importance of a wide range of partners, including libraries, as appropriate, in future rounds.

JOB CORPS

Question. The Department has rightly been focused on working with Job Corps Centers to strengthen accountability and improve outcomes for students. However, the Department's interpretation of the small business set-aside requirements may mean that performance is not one of the key criteria for awarding or renewing Job Corps contracts.

What criteria are used in the Department's determination to set aside a Job Corps contract? Are factors such as center performance, operator past performance, and student outcomes the primary factors in set aside determinations?

Answer. Employment and Training Administration (ETA) supports the use of small businesses as part of the economic engine for the economy. ETA's determination to set aside Job Corps procurements arises under the express terms of Federal Acquisition Regulations (FAR) section 19.502-2(b), which requires the Contracting Officer to set aside a procurement more than \$150,000 for small businesses, "when there is a reasonable expectation that: (1) Offers will be obtained from at least two responsible small business concerns offering the products of different small business concerns; and (2) Award will be made at fair market prices."

In determining if there is a reasonable expectation that offers will be obtained from at least two responsible small business concerns, the Contracting Officer performs market research. This market research may include an analysis of prior procurement history and recent performance of contractors similar in size, scope, and complexity to the pending requirement. Thus, contractor quality and performance are primary factors in the small business set-aside determinations.

The Contracting Officers in the ETA use market research, most often via a sources sought notice, to arrive at the most suitable approach for acquiring services, as discussed in FAR 10.000. ETA uses the resulting market research to determine if there is a reasonable expectation that offers will be obtained from at least two responsible (i.e., capable) small businesses and that the award will be made at fair market prices. ETA's market research allows DOL to identify companies that have experience performing services of a similar size and scope to that of the contract

in question. For example, if a contractor has operated one or more Job Corps centers within the recent past that were similar in size and scope to the requirement, DOL will consider that information in assessing the available sources to compete for a potential contract award.

In addition, the procurement process includes an analysis of several evaluation factors in which technical approach (i.e., quality of services provided to the students) is the most important. Also, companies' past performance is evaluated during the procurement process and is considered in this analysis. Past performance is not the most important factor, but it is an important factor that is considered in the evaluation. Also, the past performance evaluation includes a consideration of the student outcomes achieved if the contractor has past performance that includes operating a Job Corps center.

Question. Are there Job Corps centers that have chronically underperformed under several different operators? What performance criteria has the Department considered in making its estimates of the number of centers that could potentially be closed for chronic low performance?

Answer. Yes, there are Job Corps centers that have had more than one operator and have continued to underperform. The Department is using its existing performance measures as the key component for developing its methodology for identifying centers for closure that will be published in the Federal Register for the public and stakeholders to provide feedback, prior to its use in selecting centers for closure. A timeline has not yet been developed for the closure process.

QUESTIONS FROM SENATOR BARBARA A. MIKULSKI

H-2B PROGRAM RULES

Question. It is my understanding that the Department of Labor (DOL) currently requires that all workers requested on an application be brought over on that application's singular date of need. This policy has been raised as a concern in the context of the upcoming comprehensive rule, which among many provisions, will require that employers pay each H-2B employee three-quarters of the hours guaranteed in the contract, over a 12-week period.

Does the Department believe that practical interaction of these two policies—that all workers must come over at once, and then be paid three-quarters of the hours in the contract—is a realistic expectation of employers in the H-2B program?

Answer. The Immigration and Nationality Act provides for the importation of foreign workers in nonagricultural employment through the H-2B program. The Department's Employment and Training Administration (ETA) approves applications for foreign workers under the H-2B program only if no U.S. workers are available for the job. To determine the availability of U.S. workers for the job, ETA requires employers to test the labor market—that is, to see whether U.S. workers are available for the job under the conditions specified in the job order and for the period of need specified in the job order. To allow employers to recruit for U.S. workers based on an application representing a singular date of need when, in fact, the employer has multiple dates of need, unfairly discriminates against U.S. workers who may be available for some of the later period, but not the entire period, indicated on a singular job order. The Department takes very seriously its responsibility to ensure that employers are not authorized to bring in foreign workers when U.S. workers are available for the jobs. In addition, both the 2008 DOL regulations and those from the Department of Homeland Security prohibit the practice known as "staggered entry dates" on a single labor certification. In other words, if an employer needs workers at different times (staggered) in their DOL-approved period of temporary need, they are required to submit separate applications for those "staggered" dates of need in order to timely test the labor market for domestic workers.

The three-fourths guarantee is a necessary protection that ensures that workers—both United States and H-2B workers—are given a chance to evaluate the desirability of the offered job and that their commitment to a particular employer results in a real job that meets reasonable expectations for the full-time work that is required for an employer to participate in the H-2B program during the period requested by the employer. The three-fourths guarantee also ensures that employers do not overstate their need for workers, thereby using visas that could have gone to other employers with legitimate needs.

Question. If so, does that assessment hold true for small, coastal businesses that are dependent on nature, such as the seafood industry?

Answer. The Department recognizes the impact weather can have on seasonal businesses and therefore, included a provision whereby employers can seek to have

their job orders terminated in the event of fire, weather, or other act of God that makes fulfillment of the job order impossible. The Department also included catastrophic or man-made events, such as controlled flooding or oil spills as reasons for termination of the job order. An employer whose contract is terminated under this provision would be required to comply with the three-fourths guarantee provision through the cancellation of the contract rather than through the entire period of the job order.

Question. Has the Department taken a thorough review to make sure that its existing regulations work in harmony with its revised regulations in order to make sure that they are imposing requirements on small businesses which are readily achievable?

Answer. The Department carefully reviewed the proposed requirements, comments received on the proposed rule, and current program operations and sought to achieve a final rule that balances important protections for U.S. workers, H-2B workers, and employers who seek to play by the rules with the needs of employers using the H-2B program.

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

WORKFORCE INNOVATION FUND

Question. Madam Secretary, I remain concerned that as more workforce training programs become competitively awarded they will not reach those for whom training programs are intended. I also have reservations about appropriating a third year of funding for the Workforce Innovation Fund (WIF), a competitive program whose first year of funding has not been awarded yet. Why is \$100 million from the Department of Labor (DOL) in fiscal year 2013 necessary for an unproven, untested program that already has \$175 million in the bank?

Answer. The purpose of WIF is to support innovative approaches to the design and delivery of employment and training services that generate long-term improvements in the performance of the workforce system, both in terms of employment and training outcomes and cost-effectiveness. Each grant awarded under WIF must include an independent third-party evaluation; thus, we anticipate that the benefit of WIF investments will extend not only to those individuals who receive services under the grant, but also to the broader workforce system, which will be able to learn about and adopt those practices shown to be promising. We believe having this source of funding is critical to drive continuous innovation and evolution in the largely formula-funded WIA system.

Fiscal year 2011 WIF resources must be obligated by September 30, 2012. This extended period of obligation was intentional to provide the Department with sufficient time to create a well-designed program in consultation with workforce system stakeholders and Federal agency partners, including the Departments of Justice and Education. We intend to award approximately \$118 million of fiscal year 2011 funds and approximately \$30 million of the fiscal year 2012 funds by September 30, 2012 under SGA-DFA-PY11-05. The remaining \$20 million of fiscal year 2012 funds will be used to fund Pay for Success grants under the solicitation we anticipate releasing this spring. By the time fiscal year 2013 funds become available, the first round of WIF grantees will have been operational for at least a year, giving us valuable information about the program and which innovations warrant further support in the form of additional grants.

GOVERNOR'S SET ASIDE

Question. The Governor's Workforce Investment Act (WIA) set-aside allows 15 percent of WIA funding to be used by the Governor, at the State level, to pursue creative workforce development initiatives. In both fiscal years 2011 and 2012 and proposed for 2013, the set-aside is reduced to 5 percent.

The fiscal year 2013 budget proposal states that the funding for the WIF will offset the loss of such funds for statewide initiatives by providing targeted demonstration projects across the country. However, the loss of funds from the reduction in the set-aside is significantly more than the WIF request in 2013.

Are you concerned that the WIF grants will not be awarded to every State and that Governors no longer have the flexibility to implement innovative statewide projects?

Answer. WIF will test the most compelling and innovative models across the country and build knowledge that can be applied to future programming. While there will be an effort to fund high-quality applications across the country, we do not expect that will be awarded to every State. By the time fiscal year 2013 funds become

available, approximately \$154 million in WIF grants (fiscal year 2011 funds and part of fiscal year 2012 funds) will have been operational for at least a year. Funding for the fiscal year 2013 WIF will provide States with another opportunity to participate in the initiative.

VETERANS—TRANSITION ASSISTANCE PROGRAM

Question. In the past several years, the unemployment rate for veterans has been significantly higher than the national average. It is critical that veterans can transition effectively out of military service into civilian life.

The budget request assumes that 160,000 transitioning servicemembers are expected to use the Transition Assistance Program (TAP) in fiscal year 2013. However, it is my understanding that with the new requirement that all separating servicemembers participate in the TAP, combined with the high number of veterans separating from service this year, the amount of veterans using the TAP could be as high as 290,000. It is critical that adequate funding be provided for TAP to ensure our servicemembers receive proper services during their transition period.

Madam Secretary, are you concerned the budget request cannot support increased TAP utilization?

Answer. We are looking at the issue you have highlighted to ensure that we have the ability to meet needs of separating servicemembers. In fiscal year 2011, Veterans' Employment and Training Service (VETS) conducted 4,200 TAP Employment Workshops to more than 144,000 servicemembers and their spouses at military installations worldwide using a combination of State Workforce Agency employees and contract facilitators. With the passage of the VOW Act, and based on separation projections from Department of Defense (DOD), we anticipate that participation in the DOL Employment Workshop will increase by nearly 40 percent to approximately 201,000 in fiscal year 2013. We are continuing to work with DOD to refine those separation estimates and to better understand the plans of our DOD and VA partners for delivering their components of the TAP workshops.

MANDATORY PROPOSALS

Question. Madam Secretary, I believe it is important to review the entire budgetary picture when appropriating funding. Although the Senate Appropriations Committee only has jurisdiction over the discretionary side of the ledger, it is still critical that we understand how much funding programs receive in mandatory dollars so we are able to make responsible choices.

The President has recently announced several large, mandatory programs that affect the DOL. In particular, he has announced an \$8 billion Community College Initiative which will be funded by \$4 billion from the DOL and \$4 billion from the Department of Education; \$4 billion for the "Reemployment Now" Initiative; and \$12.5 billion for a "Pathways Back to Work" fund.

Madam Secretary, how will these programs supplement current worker training programs?

Answer. The administration's proposals that you mention will help community colleges and businesses train Americans to acquire the critical skills that employers need to succeed and help businesses succeed and grow. While the DOL has worked closely with local businesses and community colleges through various workforce system programs, the Community College to Career Fund provides the resources and support necessary to enhance the development and improvement of educational and career training programs for workers. These investments will give more community colleges the resources they need to become community career centers where people learn crucial skills that local or regional businesses are looking for right now. Through increased employer partnerships, this investment will also ensure that employers have the skilled workforce they need and that workers are gaining industry-recognized credentials and receiving training relevant to the local or regional needs of employers to build strong careers.

This administration is committed to protecting the financial integrity of the Unemployment Insurance (UI) system and helping unemployed workers return to work as swiftly as possible, and the Reemployment NOW Initiative supports that effort. The proposed Reemployment NOW program would provide funds for programs that allow the flexible use of unemployment benefits for short-term on-the-job training or for claimants to start their own businesses. The bipartisan Middle Class Tax Relief and Job Creation Act of 2012 adopted a number of the reforms the President proposed in the American Jobs Act, including some of the initiatives that would be eligible for funding under the Reemployment NOW Initiative. This new law, enacted in February 2012 extends UI to prevent 6 million long-term unemployed Americans looking for work from losing their benefits, while at the same time reforming the

system to help them build real skills and connect to real jobs. For example, as the President proposed last year, Reemployment and Eligibility Assessments (REAs) and Reemployment Services (RES) are now required for claimants entering the Emergency Unemployment Compensation (EUC) program. That initiative is already being implemented by the States. REAs and RES have been found to be highly effective at helping UI claimants find higher-paying jobs sooner, while at the same time saving money for the UI system. The Middle Class Tax Relief and Job Creation Act also included the President's proposal for making EUC recipients eligible for State Self-Employment Assistance programs, which provide support to claimants who start their own businesses. Finally, the new law allows for 10 States to conduct demonstration programs similar to the proposed Bridge to Work program that would help speed claimants' return to work. These demonstrations would allow States to use funds from the unemployment trust fund, but the programs must be cost neutral.

Building on successful American Recovery and Reinvestment Act programs that provided employment opportunities for low-income adults and youths, the Pathways Back to Work Fund makes it easier for the long-term unemployed and low-income workers to remain connected to the workforce and gain new skills for long-term employment, through subsidized employment and other innovative work-based strategies. Pathways Back to Work offer a win-win strategy for job seekers and employers. It gives job-seekers an opportunity to gain and demonstrate in-demand skills for an extended period of time, while earning much needed income to support themselves and their families and stimulate their local economies. At the same time, it provides employers with a low-risk approach to staffing their businesses and building their talent pipeline to remain competitive. The "earn and learn" approaches to be supported by Pathways Back to Work are an important complement to more traditional, classroom-based occupational training currently supported by DOL and enhance the ability of program participants, particularly those lacking work experience, to benefit from occupational training.

Question. How can you ensure that such an influx of funding, twice the size of the DOL's current discretionary budget, will be efficiently and effectively spent?

Answer. DOL will work to ensure that these requested mandatory grant dollars are efficiently and effectively spent through the same strong management and oversight processes it uses now for its grants. DOL already utilizes comprehensive processes to regularly review and monitor all of its grantees, including an electronic grants management system, required quarterly reporting from all grantees on their financial and technical performance, and on-site grantee monitoring visits. DOL reviews grantees' progress against the program performance metrics of entered employment, employment retention and average earnings, and plans to use this set of common measures as the basis for future programs in addition to any program-specific measures. DOL also provides technical assistance to help grantees meet the outcomes to which they commit in their grant statements of work.

DOL is also working to leverage its investments to increase their impact across the country by coordinating with other Federal agencies on a number of initiatives. Examples of inter-agency coordination activities include joint guidance on programs serving similar populations, jointly funded discretionary grant programs, and efforts to identify opportunities for promoting joint strategic planning across programs.

DUPLICATION AND OVERLAP

Question. The Government Accountability Office (GAO) released a report in February that stated, "HHS is collaborating with Labor to conduct an evaluation to better understand policies, practices, and service delivery strategies that lead to better alignment of the Workforce Investment Act and Temporary Assistance for Needy Families."

Can you provide further information on this collaboration, including examples of State and local practices that may be models for other areas to follow and how the Workforce Investment Act (WIA)/Temporary Assistance for Needy Families (TANF) duplication can be reduced?

Answer. The Department of Health and Human Services (HHS) is working in close collaboration with the DOL to conduct an evaluation to better understand policies, practices, and service delivery strategies that lead to better alignment of WIA and TANF, including identifying promising State and local practices for successful coordination between these programs. The Work Participation and TANF/WIA Coordination Study will identify strategies to improve the employment outcomes of current and former TANF recipients, reduce administrative inefficiencies, and remove the structural and policy barriers that inhibit coordination between WIA and TANF. Researchers also will document the reasons for collaboration and the process

for creating and sustaining partnerships. A technical workgroup of subject-matter experts is currently working on selecting States and local areas for approximately nine site visits, to be conducted during summer 2012, to examine governance structures, policy coordination, service delivery pathways, shared data systems, and funding. We anticipate that the final report will be available for dissemination in spring 2013. The Departments will share the results of the evaluation with the public workforce system and other stakeholders.

As another example of DOL–HHS collaboration, a report entitled “Using TANF Funds to Support Subsidized Youth Employment: The 2010 Summer Youth Employment Initiative” was published and posted recently on both Departments’ Web sites. This work is the culmination of the Departments’ continued collaboration throughout a study to evaluate WIA and TANF coordination and the potential benefits and challenges of the TANF-funded summer youth employment initiative. Funded through an Interagency Agreement between the Departments, this study followed up on the 2010 joint DOL–HHS letter that encouraged States to use TANF funds for subsidized youth employment and for workforce and human service agencies to co-enroll youth in WIA and TANF programs.

Question. GAO report also noted that the DOL will award competitive grants to encourage States to reduce program overlap. Can you describe the program overlap that could be eliminated through these grants?

Answer. By September 30, 2012, DOL intends to award approximately \$118 million of fiscal year 2011 funds and approximately \$30 million of the fiscal year 2012 funds provided for competitive grants under WIF. The WIF provides States and local areas with an opportunity to pursue a variety of innovation strategies, including those that foster stronger cooperation across programs and funding streams—such as integrated data management information systems, “braided” funding, or changes that create a more seamless service delivery experience for participants who need help from multiple programs.

DOL also anticipates awarding up to \$20 million through a separate grant competition for Pay for Success pilot projects to support an innovative approach to funding public social service programs, for example through leveraged capital from private or philanthropic investors. Under the Pay for Success model, the government pays for services only after clearly defined outcomes are achieved. This allows effective and evidence-based solutions to be identified and implemented while maximizing taxpayer dollars by paying only for demonstrated results.

It is our goal that grants awarded under WIF will achieve greater efficiency in the delivery of quality services, such as achieving positive outcomes for a lower cost or reducing program overlap and administrative costs. We expect that successful strategies will be sustained beyond the grant period through other funding streams currently available to grantees.

Question. At last year’s hearing, we discussed GAO’s 2011 report on duplication across job training programs. In particular, the report stated that 44 of the 47 Federal employment and training programs identified overlap with at least one other program. What steps has the DOL taken to reduce duplication within job training programs over the past year?

Answer. DOL recognizes that there are opportunities for the further alignment and streamlining of employment and training programs, and our fiscal year 2013 budget reflects this reality by including several proposals. These proposals include expansion of the WIF which will support innovative ways of delivering services working across program silos; the transfer of the Senior Community Service Employment Programs to the HHS, where the program can work more closely with other senior-serving programs; developing single access points for job seekers to access all available services through a rebranded and improved network of American Job Centers; the elimination of the Women in Apprenticeship and Nontraditional Occupations and Veterans Workforce Investment grant programs, whose missions can be met through other programs and activities; and the merging of the Trade Adjustment Assistance and WIA Dislocated Worker program into a single program providing a uniform and comprehensive suite of services to all displaced workers in fiscal year 2014.

UPPER BIG BRANCH

Question. The recent internal review by the Mine Safety and Health Administration (MSHA) regarding the tragic accident at Upper Big Branch claimed that much of the managerial and personnel issues in district 4 stemmed from budget cuts prior to 2006. However, MSHA’s budget increased from \$246.3 million in fiscal year 2001 to \$277.7 million in fiscal year 2006. Blame can be placed on many factors for the Upper Big Branch tragedy, but Secretary Solis, why did DOL choose to place culpa-

bility mainly on funding levels, especially given that MSHA's budget increased \$129 million from fiscal year 2000–2010?

Answer. The internal review is about more than funding levels. The internal review team was comprised of career MSHA employees with various specialties and expertise who did not have current enforcement responsibility in Coal Mine Safety and Health District 4. Their report attributes the shortcomings identified to a number of underlying causes in addition to resources, including inspector inexperience, management turnover, supervisory and managerial oversight, internal communication of policies, and training. We are looking at all of these issues to ensure they are addressed.

As Assistant Secretary Main recently noted during testimony before the House Education and Workforce Committee:

“The internal review team found the number of coal enforcement personnel had eroded to 584 by the end of fiscal year 2005, a result of attrition and budget constraints. By comparison, there were 653 such personnel in fiscal year 2001. Following the 2006 Sago, Darby and Aracoma disasters, MSHA received additional funds to hire more inspectors. However, despite efforts to re-establish staffing levels, by the time of the UBB explosion, the inspection and supervisory staff was significantly composed of new inspectors, replacing a number of experienced inspectors who retired. For example, from fiscal year 2005 to fiscal year 2008, MSHA lost 252 coal enforcement personnel from its ranks. Some inspectors retired, were recruited by industry, moved to new positions within the agency, or left MSHA for other reasons . . . The budget constraints and constant loss of experienced personnel due to attrition adversely affected the entire agency.”

I appreciate all of the support that the subcommittee has provided to ensure that MSHA obtains the funding needed not only to meet these critical inspection activities, but in related activities such as the work that MSHA and the Office of the Solicitor are doing to address the backlog of cases before the Federal Mine Safety and Health Review Commission.

PENSION BENEFIT GUARANTEE CORPORATION

Question. Secretary Solis, as Chair of Pension Benefit Guaranty Corporation (PBGC), how are you addressing the systemic problems uncovered in the Inspector General reports on the National Steel and United Airlines (UAL) pension plans? What timelines have been set up to address the serious issues raised in the report, to include the possible reorganization of the Benefits Administration and Payment Department office?

Answer. The PBGC Office of Inspector General (OIG) found long-standing systemic failures at the PBGC that resulted in errors in the valuations of assets of the terminated UAL and National Steel pension plans, as well as other plans trustee by the PBGC. The OIG uncovered serious flaws in the work of the original contractor and the re-valuation work prepared by a second contractor. The PBGC board is working with the OIG and the PBGC leadership to ensure that appropriate steps are taken to remedy deficient asset valuations for terminated plans, erroneous benefit determinations for affected participants, and any systemic failures.

PBGC is redoing the asset valuations for the pension plans of UAL and National Steel and taking other actions to make corrections where necessary. The board and PBGC are committed to finalizing the asset re-valuations for UAL and National Steel as quickly as possible without sacrificing accuracy or quality. Participants in UAL or National Steel plans whose benefits change as a result of the asset re-valuation will be notified this summer.

For other asset valuations, PBGC is using the experience gained from the UAL and National Steel reviews to develop a risk-based approach to screen the other plans on which the original contractor worked, and to identify plans where contractor errors may have affected beneficiaries. The PBGC continues to review its actions with the OIG and the board.

By law, the PBGC's Director is responsible for administering the PBGC's operations, and the board is responsible for setting policy and providing oversight. The Board is committed to holding the PBGC management accountable for effectively selecting and monitoring outside auditors. This is a core management function of being a good steward for the plans the PBGC trustees and for making sure these mistakes do not happen again. Over a year ago, PBGC began a strategic review to make improvements to the Benefits Administration and Payment Department's (BAPD) organizational structure and operations. Based on that review, PBGC identified a wide range of actions to address long-term systemic failures within BAPD and to ensure that BAPD has sufficient expertise to effectively select and monitor

outside auditors. The agency has already begun to make changes in its organization, personnel and processes, including the qualifications and training of BAPD staff, improved contractor management, and improved quality control overall.

WYOMING JOB CORPS CENTER

Question. Secretary Solis, can you provide an update on the progress of the Wyoming Job Corps Center, including when you anticipate publishing a construction bid in the Federal Register and your timeline for opening the Center?

Answer. A new center in Wyoming is planned to open after program year 2013.

VOLUNTARY PROTECTION PROGRAM

Question. Assistant Secretary Michaels recently stated the Voluntary Protection Program (VPP) would be expanded. However, the budget request for the Occupational Health and Safety Administration (OSHA) decreases compliance assistance in fiscal year 2013. Further, OSHA is projected to conduct far fewer VPP site evaluations (down 40 percent from fiscal year 2011) and will completely halt the corporate and merit VPP program at new sites. Can you explain why the Department is announcing VPP is expanding, when no budget documents support this claim?

Answer. Assistant Secretary Michaels supports the expansion of VPP to additional worksites that meet the criteria for VPP participation. To that end, OSHA plans to approve 60 new VPP sites and to recertify 280 during fiscal year 2013. The VPP program is not being cut. In order to achieve efficiencies, OSHA will no longer offer its Corporate and Merit VPP programs. It is also important to note that none of the steps we are taking will eliminate the access of small businesses to the VPP program.

In May 2004, OSHA created the VPP Corporate Pilot to significantly expand participation in VPP by allowing corporations committed to VPP and interested in achieving VPP recognition at multiple facilities a more efficient means of accomplishing this. Over the years, several of the corporate participants have failed to meet their commitments to bring in 10 participants within 5 years and others have chosen to drop out of the program. In addition, it became clear that the Pilot did not produce the expected application and onsite evaluation efficiencies. Eliminating VPP Corporate will not adversely affect a company's ability to achieve VPP status.

After evaluating participation in the Merit program, OSHA has concluded that its resources could be more effectively used for site visits to bring qualified companies directly into VPP rather than putting resources into developing new VPP candidates, many of whom never qualify for VPP, spend little time in the program after qualifying, or would qualify without the Merit program. Resources OSHA previously used for site visits and reevaluations for Merit participants will be directed towards new VPP sites and recertifications of existing sites.

FARM LABOR

Question. Secretary Solis, the DOL announced it would re-propose a regulation on the existing agriculture "parental exemption" after the original, highly controversial proposed rule was withdrawn. The original proposal significantly narrowed the application of the parental exemption by limiting it to parents that wholly owned the family farm. This change ignored the structure of modern agriculture. While I appreciate the rule being withdrawn, I question whether a re-proposal is even necessary.

Why is DOL moving forward with another rule? Will DOL rewrite the new rule based on the numerous public comments that were made? Is DOL conducting outreach with the agriculture industry to ensure that the new rules take into account the current structure of the modern farm?

Answer. As you may know, DOL announced on April 26, 2012, the withdrawal of the proposed rule addressing hired farm workers under the age of 16. In the same announcement, DOL committed to working with the U.S. Department of Agriculture and with rural stakeholders, such as the American Farm Bureau Federation, the National Farmers Union, the Future Farmers of America, and 4-H, to develop an educational program to reduce accidents to young workers and promote safer agricultural work practices.

QUESTION SUBMITTED BY SENATOR THAD COCHRAN

GULFPORT JOB CORPS CENTER

Question. The Gulfport Job Corps Center was destroyed by Hurricane Katrina in 2005. Since that time, I worked to appropriate both dedicated funding of \$14 million, as well as other annual construction funds for use towards the rebuilding efforts for that facility. The bulk of the dedicated \$14 million in funding was used for a temporary facility and to construct a dorm, but I understand that \$4.5 million in dedicated funds remain. I continue to work on behalf of the community to ensure that the new facility balances their priorities with the best interest of the Job Corps training activities. It is my understanding that the Department of Labor (DOL) is continuing to consult with the Gulfport community, as well as the State of Mississippi, to resolve outstanding issues relating to specific design details. Please discuss the path forward for this project as well as your plan to protect the money that has been reserved for the Gulfport Job Corps facility's new construction. Will the construction phase cost more than the remaining dedicated funds? If so, how will you approach securing the balance?

Answer. I recognize that you have been a tireless champion for the Job Corps program and have been very eager to see us move from a temporary facility to a permanent one in Gulfport—one that we both hoped would serve double the amount of students of the temporary center, while creating employment opportunities for the community both in the construction and operations phases.

Several months ago, the redevelopment of the Gulfport Job Corps Center was placed on hold as the project proposed the demolition of the former 33rd Avenue High School, which was eligible for inclusion in the National Registry of Historic Places. Since that time, DOL has been engaged in the section 106 process, as outlined in the National Historic Preservation Act, to gather feedback and input from interested parties before making a determination to move forward with the proposed project. In addition to the DOL and the Advisory Council on Historic Preservation, this process has included consultation with the Mississippi Department of Archives and History (MDAH), the city of Gulfport, and Gulfport community members.

Because a mutually agreeable resolution to move forward with the proposed project was not reached, on Friday, March 16, 2012, DOL terminated the construction contract to redevelop the Gulfport Job Corps Center. This will allow the portion of the project's funding that expires on June 30, 2012, to be reallocated prior to its expiration. The remaining \$4.5 million of funding dedicated to the project does not expire and will remain available for future redevelopment efforts.

DOL is committed to serving the youth of the Gulfport community, having operated a center in this gulf coast region for more than 30 years. The DOL will work with the MDAH, the city of Gulfport, and all identified consulting parties to begin a new section 106 process for the redevelopment of the Gulfport Job Corps Center, which will inform future decisions about the establishment of a permanent center in Gulfport, Mississippi.

As you point out, the cost of a new construction project will exceed the remaining amount of dedicated funds. By redistributing the funding from the cancelled contract to other shovel-ready projects, our intent was to free up future years' construction funding for Gulfport, rather than allowing those funds to expire. As you know, the Job Corps program receives an annual Construction, Rehabilitation, and Acquisition (CRA) appropriation each year, and develops a funding plan with priority given to the most critical deficiencies. As with each new funding cycle, DOL will review the redesign for a Gulfport Center redevelopment project alongside the program's other construction and rehabilitation needs before making a final funding determination. We will continue to work with the Appropriations Committee and your office on this matter and appreciate your support for the Job Corps program.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

PROPOSED COMPANIONSHIP EXEMPTION RULE

Question. At a January 25, 2012 briefing, representatives of the Department of Labor's (DOL) Wage and Hour Division and the Centers for Medicare & Medicaid Services (CMS) told my staff that they did not meet with a single State's Medicaid Director.

Did DOL directly consult or meet with any State Medicaid Directors when promulgating the proposed rules? If yes, please provide details regarding which State Medicaid Directors DOL met or consulted with, the substance of their recommendations, and how their recommendations were incorporated into the proposed rule and

accompanying economic impact analysis. If no, will DOL be willing to withdraw the rule to meet with State Medicaid Directors and conduct a more comprehensive analysis of the impact of the rule on State Medicaid programs and budgets that incorporates their recommendations before moving forward?

Answer. In development of the proposed rule, Application of the Fair Labor Standards Act to Domestic Service (76 FR 81190, December 27, 2011), DOL reviewed publicly available data to estimate the impact of the proposed revisions, and consulted with the Department of Health and Human Services' CMS. A significant number of comments were received on the Department's proposed rule, including a few from State Departments of Human Services, as well as from the National Association of Medicaid Directors representing the Nation's 56 State and territorial Medicaid agencies. DOL is currently reviewing the comments received on the proposed rule and will continue to consult with the Centers for Medicare and Medicaid Services on this important matter. Any final rule resulting from this Notice of Proposed Rulemaking will address comments received on the proposal, including those expressing concerns about the potential impact of the proposal on State Medicaid budgets.

Question. On March 12, 2012, the Office of Advocacy at the Small Business Administration sent a letter to you stating that DOL's economic analysis does not fully reflect the information provided by small businesses in the companion care industry and recommending that DOL consider the impact and regulatory alternatives, as required under the Regulatory Flexibility Act, before moving forward. Will the DOL withdraw the proposed rule to conduct a more thorough economic impact analysis that accurately reflects the nature of the private market for companion services, economic impact of the rule on small businesses, and alternatives proposed by industry?

Answer. On December 27, 2011, DOL published a proposed rule: Application of the Fair Labor Standards Act to Domestic Service. After two extensions of public comment period, the comment period closed on March 21, 2012. The preliminary regulatory impact analysis contained in the proposed rule is based on the best available data. DOL relied on data from: the Bureau of Labor Statistics (BLS) 2009 Occupational Employment Survey employment and wages by State for the standard occupational codes covering Personal Care Aides and Home Health Aides, the workers most likely to be impacted by the proposed rule; BLS National Employment Matrix, 2008; BLS Quarterly Census of Employment and Wages, 2009, the 2007 Statistics of U.S. Businesses, and the 2007 Economic Census by State for industries most likely to be impacted by the proposed rule, Home Health Care Services, and Services for Elderly and Persons with Disabilities. In estimating the number of employees potentially impacted, and the average hours worked by home health aides, DOL also considered research from Paraprofessional Healthcare Institute (PHI) which was based, in part, on the Centers for Disease Control and Prevention's (CDC) National Home Health Aide Survey.

The letter from the Office of Advocacy at the Small Business Administration was received during the comment period for the proposed rule and is a part of the rulemaking record. See Office of Advocacy, Winslow Sargeant, comment id: WHD-2011-0003-7756 available at: <http://www.regulations.gov/#!documentDetail;D=WHD-2011-0003-7756>. In its comment letter, the Office of Advocacy referenced the Small Business Roundtable it had convened; a summary of the Small Business Roundtable meeting as well as materials provided to the Department during that meeting are part of the rulemaking record (document id: WHD-2011-0003-3235, available at: <http://www.regulations.gov/#!documentDetail;D=WHD-2011-0003-3235>). In addition, the Office of Advocacy's letter mentioned comments submitted as part of the rulemaking record, including those from the International Franchise Association which submitted, as part of its comment, a study it commissioned by IHS Global Insight, and the California Association of Health Services at Home. These comments are included in the rulemaking record (<http://www.regulations.gov/#!documentDetail;D=WHD-2011-0003-9590> and <http://www.regulations.gov/#!documentDetail;D=WHD-2011-0003-0134>, respectively).

DOL is continuing to review the comments received on the proposed rule, including the letter from the Office of Advocacy and the comments referenced in that letter; however, we note that very little economic data was provided by the more than 26,000 individuals who commented on the proposal. The comments and other materials are part of the rulemaking record, available at: <http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=WHD-2011-0003>.

PROPOSED CHILD AGRICULTURAL SAFETY RULE

Question. Based on the major effects this rule would have on the agriculture community do you plan to delay implementation of the rule and hold more listening ses-

sions with stakeholder groups to gain a better understanding of the complexities in a farming operation?

Answer. As you may know, the Department announced on April 26, 2012, the withdrawal of the proposed rule addressing hired farm workers under the age of 16. In the same announcement, the Department committed to working with the U.S. Department of Agriculture (USDA) and with rural stakeholders, such as the American Farm Bureau Federation, the National Farmers Union, the Future Farmers of America, and 4-H, to develop an educational program to reduce accidents to young workers and promote safer agricultural work practices.

Question. If you cannot commit to delaying the implementations, what assurances can you give farmers that this will not limit the ability for their children to help out on the family farm?

Answer. As you may know, the Department announced on April 26, 2012, the withdrawal of the proposed rule addressing hired farm workers under the age of 16. In the same announcement, the Department committed to working with USDA and with rural stakeholders, such as the American Farm Bureau Federation, the National Farmers Union, the Future Farmers of America, and 4-H, to develop an educational program to reduce accidents to young workers and promote safer agricultural work practices.

PROPOSED COMMUNITY COLLEGE CAREER FUND

Question. The President's fiscal year 2013 budget includes \$8 billion in new spending, over 3 years, to support a new community college career fund for the Departments of Labor and Education to jointly support new partnerships between States, community colleges and businesses that will train 2 million workers for good-paying jobs in high-growth and high-demand industries.

While I appreciate the goals of this proposal, we are continually facing significant near and long-term funding gaps in the Pell grant program. Based on the March 2012 Congressional Budget Office baseline estimates, it is projected that Pell grant funding requirements will balloon to \$30.7 billion in fiscal year 2014, resulting in a funding gap of between \$6 billion and \$9.7 billion. At the same time, the maximum Pell grant award in 2012–2013 is \$5,550, while the average tuition rate at community colleges in the United States is under \$3,000 per year. Therefore, rather than creating another duplicative program, wouldn't the requested \$8 billion be better spent in support of Pell grants, which would then enable more low-income students to attend the university or community college of their choice?

Answer. The Pell grant program and the Community College to Career Fund serve two different purposes and are complementary rather than duplicative. DOL supports the Pell grant program's goal of expanding low-income students' access to postsecondary education and believes this program is a key component for meeting the President's goal of every American completing at least 1 year of postsecondary education or training. Unlike Pell grants, which are awarded to individual students, the Community College to Career Fund will support competitive grants to community colleges that have partnered with employers to provide individuals with the training and industry-recognized credentials that are needed by employers. In addition to providing training to individuals, the Community College to Career Fund primarily will be used to address the serious capacity shortages of many community college training programs in high-growth occupations. In combination, the Pell grant program and Community College to Career Fund will provide individuals with access to a greater range of education and training opportunities.

QUESTIONS SUBMITTED BY SENATOR MARK KIRK

VETERANS' JOBS PROGRAMS

Question. I am the co-chair of the Veterans Jobs Caucus in the Senate, which is working to ensure that our veterans have access to and information about available jobs especially as they return from overseas. I was a co-sponsor of the first "Hiring Our Heroes" fair held in Chicago last spring, sponsored by the U.S. Chamber of Commerce. The U.S. Chamber has held numerous similar fairs across the country over the last year, with the 100th being in Chicago at the end of this month.

A number of programs and initiatives exist across different agencies that are designed to help our veterans enter the civilian workforce. While agencies like the Departments of Labor (DOL) and the Veterans Affairs and the Office of Personnel Management all have something to add to these programs, I am concerned that a lack of coordination and duplicative efforts are actually hindering the end goal: to get veterans jobs. Especially as the Veterans Opportunity to Work (VOW) to Hire

Heroes Act, passed last fall by the Congress, comes online, I have the following questions: Which is the lead agency responsible for coordinating veterans' jobs programs? And who within DOL is the point person on interagency coordination?

Answer. DOL's Veterans' Employment and Training Service (VETS) is the lead agency for employment and training programs for veterans. Deputy Assistant Secretary Junior Ortiz is the point person, and ensures coordinated efforts amongst other Federal agencies in issues and initiatives related to veteran employment.

Question. How is DOL ensuring that you handle initiatives that fall within your jurisdiction and expertise, such workforce training?

Answer. DOL has developed an internal workgroup that leads and oversees all efforts related to employment and training for veterans. This workgroup is co-chaired by the VETS Deputy Assistant Secretary, John Moran, and Employment and Training Administration (ETA) Deputy Assistant Secretary, Gerri Fiala. The mission of the workgroup is specifically to monitor all initiatives, legislative requirements, and ongoing programs that directly benefit our transitioning servicemembers and veterans.

Question. What is DOL doing to ensure that veterans know where to go to find jobs that match up the skills they have developed in the military with the needs in the civilian workforce?

Answer. VETS has recently redesigned our Transition Assistance Program (TAP) Employment Workshop, which includes a module specifically on transferrable skills. During the Employment Workshop, participants are educated on the services available through the nearly 3,000 American Jobs Centers funded through DOL. With the recent passage of the VOW to Hire Heroes Act, attendance at our TAP Employment Workshop is now mandatory for all separating military personnel with only limited exceptions.

DOL funds several employment programs for job seekers, which are operated out of the American Jobs Centers. These centers serve as the cornerstone for the Nation's workforce investment system. By law, veterans receive priority of service in all DOL-funded programs administered through the American Jobs Centers. DOL and the State workforce agencies actively outreach to both job seekers and employers to raise awareness of the services available at these centers. Outreach to job seeking veterans occurs prior to separation for both active duty military and members of the Guard and reserves. American Jobs Centers staff are often present at the Transition Assistance Program Employment Workshop and at demobilization events.

During job fairs, American Jobs Center staff will make contact with participants and ensure they are aware of the services available.

Disabled Veterans Outreach Program (DVOP) specialists conduct targeted outreach to located those veterans that face barriers to employment. Typical outreach will include visits to Homeless Veteran Reintegration Program grantees, homeless shelters, Vet Centers, and VA Medical Centers.

Further, VETS provides grants to each State to fund two staff positions DVOP specialists and Local Veterans' Employment Representative staff to provide specialized services to veterans.

In addition, DOL launched a new suite of on-line tools, My Next Move for Veterans (www.MyNextMove.org/vets). On My Next Move for Veterans, transitioning servicemembers and veterans can access a simple and quick search engine where they enter their military experience (branch of service and military occupation code or title) and link to the resources they need to explore information on civilian careers and related training, including information they can use to write résumés that highlight related civilian skills.

QUESTION SUBMITTED BY SENATOR JERRY MORAN

ADDRESSING THE SHORTAGE OF MEDICAL LABORATORY TECHNICIANS

Question. One of the many challenges facing our Nation involves a shortage of well-trained allied health professionals to meet the increasing medical needs of the aging workforce. Hospitals, laboratories, and other employers in my home State of Kansas and across the country are having difficulty finding medical laboratory technicians (lab techs) who can fill current job openings. As a lab tech, an individual with a 2-year degree in laboratory science can earn an annual salary of around \$35,000–\$50,000, but employers are struggling to find qualified individuals with the appropriate education and training to fill these science and healthcare jobs.

Does the Department of Labor (DOL) currently direct any Federal funding it receives to initiatives that support laboratory education programs in community col-

leges and other educational institutions to address this healthcare workforce shortage?

Answer. Yes, through the American Recovery and Reinvestment Act of 2009 (ARRA), DOL awarded more than \$150 million to projects focused on healthcare under the Healthcare and Other High-Growth and Emerging Industries grant program. The grants allow community colleges, community-based organizations, State workforce agencies, and other public entities to deliver training that leads to employment in a range of healthcare fields, including laboratory technicians. In addition, DOL recently awarded more than \$130 million to healthcare-focused projects under the H-1B Technical Skills Training grants. This grant program is designed to provide education, training, and job placement assistance in the occupations and industries for which employers are using H-1B visas to hire foreign workers, and the related activities necessary to support such training. DOL also funded 18 projects that include healthcare as a focus area under the first year of the Trade Adjustment Assistance Community College and Career Training (TAACCCT) program. The TAACCCT program provides \$2 billion over 4 fiscal years to institutions of higher education to expand and improve their ability to deliver education and career training programs that can be completed in 2 years or less; result in skills, degrees, and credentials that prepare program participants for employment in high-wage, high-skill occupations; and are suited for workers who are eligible for training under the TAA for Workers program. DOL intends to widely disseminate the results, including curricula, of successful grantees from these initiatives to the public workforce system and stakeholders.

Question. The Bureau of Labor Statistics estimates that there will be almost 11,000 laboratory professional job openings each year annually through 2018. However, our Nation is currently only graduating around 5,000 students each year that are capable of filling these job openings. What actions is DOL taking to address this workforce shortage?

Answer. DOL will continue to address the education and training needs of the healthcare sector through workforce development programs that are designed to be responsive to the demands of the labor market, especially at the regional level. These programs will continue to support training programs for industries and occupations that are high-growth, including laboratory professionals. These activities will occur through both the formula-funded public workforce investment system, as well as discretionary grant programs, such as future years of the TAACCCT program previously discussed.

JOB CORPS

Question. As a supporter of Job Corps, it is essential that students enrolled in this education and job training program receive the best instruction and support. What is the DOL doing to ensure that student outcomes and performance remain the foundation of Job Corps' procurement policies and practices?

Answer. As you know, Job Corps provides high-quality services to help students acquire the skills and tools they need to be successful in good jobs or further education. Thus, all contract statements of work, which describe the contractor's expected outcomes, required deliverables, and levels of performance, are crafted with the intent of ensuring that students receive quality education, training, and support services. The program's policies and requirements are either directly stated, or incorporated by reference, in Job Corps' Outreach and Admissions, Center Operations, and Career Transition Services contracts. Contracts are performance-based, providing financial incentives and penalties directly tied to student outcomes.

Question. What is DOL's justification for its current use of the "Rule of Two" in Job Corps operations contracting?

Answer. Job Corps procurements are governed by Federal Acquisition Regulation (FAR) section 19.502-2(b), which requires the Contracting Officer to set aside a procurement more than \$150,000 for small businesses,

"when there is a reasonable expectation that: (1) Offers will be obtained from at least two responsible small business concerns offering the products of different small business concerns; and (2) Award will be made at fair market prices."

Due to pending litigation, DOL cannot comment further on its use of the "Rule of Two" in Job Corps operations contracting.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you very much, Madam Secretary.
Secretary SOLIS. Thank you very much.

[Whereupon, at 11:45 a.m., Wednesday, March 14, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2013**

WEDNESDAY, MARCH 28, 2012

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD-124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Pryor, Mikulski, Brown, Shelby, Cochran, and Moran.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF FRANCIS S. COLLINS, M.D., Ph.D., DIRECTOR

ACCOMPANIED BY:

ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

GRIFFIN P. RODGERS, M.D., M.A.C.P., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

HAROLD VARMUS, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE

RICHARD J. HODES, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING

THOMAS R. INSEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH, ACTING DIRECTOR, NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come to order.

Dr. Collins, welcome back to the subcommittee. Welcome also, Dr. Harold Varmus, Director of the National Cancer Institute (NCI); Dr. Tony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Griffin Rodgers, Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); Dr. Richard Hodes—again, good to see you again—Director of the National Institute on Aging (NIA); and Dr. Thomas Insel, both the Director of the National Institute of Mental Health and the Acting Director now of the new National Center for Advancing Translational Sciences (NCATS).

Again, my personal and professional thanks to all of you and the hundreds of thousands of people who are supported by National Institutes of Health (NIH) funding. Because of all of you, America is the world leader in biomedical research.

But how long America can maintain that status is a matter of growing concern. The threat of sequestration looms large. The Congressional Budget Office (CBO) has estimated that most non-defense discretionary programs, such as NIH, will be cut by about 7.8 percent next January if the Congress does not enact a plan before that time.

The budget plan proposed by the House Budget Committee chairman, which the House will vote on this week, is even more worrisome. In fiscal year 2013, the Ryan plan would cut nondefense spending by 5 percent. The following year, the plan will cut non-defense spending by 19 percent.

If that cut were applied equally across the Government, the number of new NIH grants for promising research projects would shrink by more than 1,600 in 2014 and by more than 16,000 during the next decade. That means 16,000 fewer opportunities to gain insights and possibly find cures for cancer and Alzheimer's and diabetes, and any number of other diseases.

Such a cut would be devastating not only for medical research but also for our economy. A study released last week by United for Medical Research concluded that, in 2011, NIH funding supported more than 430,000 jobs across the country. The link for this report follows: <http://www.unitedformedicalresearch.com/wp-content/uploads/2012/07/NIHs-Role-in-Sustaining-the-US-Economy-2011.pdf>.

Again, it always amazes me how most people think that all of that money goes to Bethesda, Maryland, and that is not so. Most is awarded to researchers at academic institutions all across the United States.

This same research also found that NIH research generated \$62 billion in new economic activity last year. So now imagine cutting NIH funding by 19 percent in 2014.

Again, a classic case of pennywise and pound-foolish thinking, especially when China, India, and Europe are spending more, not less, on medical research.

But even under the best-case scenario, the budget for NIH is likely to remain tight for the immediate future, so we must do everything we can to ensure that NIH makes the most effective use of the money that is available.

That was part of the thinking behind the new NCATS, which this subcommittee created in last year's appropriations bill.

NCATS brings together, under one roof, translational activities that were already being funded but scattered throughout the NIH. For virtually no additional money, NIH now has an opportunity to address translational sciences in ways that we've never done before.

So, I look forward to hearing more about NCATS and other topics from our witnesses. And again, I just thank all of you for your great leadership of one of the great institutions of this country, the NIH.

And with that, I will yield to Senator Shelby for his opening statement.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman.

I want to thank, at this time, Dr. Collins and the Center Directors who've joined us today to discuss the important role the NIH plays in every American's life.

For the millions of Americans suffering from a serious illness, biomedical research is the beginning of hope. NIH-funded research investigates ways to prevent disease, understand its causes, and develop more effective treatments.

A continued commitment to NIH is essential to addressing our Nation's growing health concerns and to spur medical innovation for the next generation of treatment and cures.

Unfortunately, the NIH budget request for the year 2013 abandons that commitment. The proposed budget for NIH is \$30.86 billion, which is claimed to be level funding from fiscal year 2012. However, this amount does not take into account the additional funding the Department of Health and Human Services (HHS) requested for Departmentwide evaluation activities.

If this so-called evaluation tap is agreed to, it will reduce the NIH budget by \$215 million, bringing the budget request below the 2012 level.

Further, the administration's request does not keep pace with biomedical research inflation, and as a result, in inflationary adjusted dollars, the NIH is 17 percent—that's right, 17 percent—below where they were 10 years ago.

Without sustained support for the NIH, the translation of discoveries from bench to bedside will be dramatically slowed, and the United States will surrender its role as a world leader in scientific research.

I do not agree with the funding level proposed by the administration for the NIH. I believe that the NIH funding should be a priority and that its benefits extend well beyond its research discoveries.

In 2011, NIH research funding supported 432,000 jobs nationwide. The research carried out by the NIH in this network of 325,000 researchers at 3,000 institutions across the country serves this Nation with the goal of improving human health.

However, Dr. Collins, I understand that your request attempts to live within the confines of a difficult budget environment. That said, I'm concerned about several of the proposed changes to awarding grant funding.

For example, you proposed capping the grant amount that a principle investigator can receive at \$1.5 million. This proposal discourages success by limiting awards to some of the most successful scientists who accordingly receive the most grant funding.

NIH awards grants through a highly competitive, two-tiered, independent, peer-review process that ensures support of the most promising science and the most productive scientists. By limiting grant award amounts, you're changing the system from one that grants awards based on science, merit, and good ideas, to one based on whether an investigator has previously received a grant.

I'm also troubled with the proposals to cap inflationary cost and reduce the average award of competing research project grants below the fiscal year 2012 level. While I recognize that you're trying to keep your success rate high and fund as many grants as possible, I question whether this is the right approach. We do not want the only results of this change to be scientists spending more time chasing grants than making discoveries, and I don't believe you do either.

I understand that constrained budgets lead to tough decisions. However, it is critical that the NIH not lose sight of its goal to fund the best science in the hope of reducing the burden of illness.

A fundamental part of the NIH success over the years has been that scientific need and opportunity have always dictated NIH funding priorities.

Dr. Collins, I would caution you on opening the door to targeting particular diseases for funding as proposed in the fiscal year 2013 budget. The last thing I imagine you want is the President deciding what specific diseases deserve NIH research.

Finally, as we continue to operate in a tough budget environment, I think we need more out-of-the-box thinking to stimulate the research community in imaginative ways. In particular, I want to highlight such an approach at the NCI.

Dr. Varmus has started a new program to answer the provocative questions in cancer research. This project focuses scientists on 24 unanswered, perhaps nonobvious, questions as defined by the research community.

With more than 750 research teams submitting proposals, this project shows there are innovative ways to energize the research community, even when budgets are constrained.

And as the Congress faces unprecedented challenges to reduce Government spending, we must all face the consequences of tough choices. Certainly, these are difficult times, but I believe biomedical research is a necessary and worthy investment in the health of our people and the vitality of our communities.

PREPARED STATEMENTS

Funding for the NIH lays the foundation for drug and device discoveries over the next 10 years. Biomedical research is an answer to lowering, I believe, our Nation's healthcare costs. This is not the time to abandon our commitment to the health of all Americans and to the NIH.

PREPARED STATEMENT OF SENATOR RICHARD C. SHELBY

Thank you, Mr. Chairman. I want to thank Dr. Collins and the Center Directors who joined us today to discuss the important role the National Institutes of Health (NIH) plays in every American's life.

For the millions of Americans suffering from a serious illness, biomedical research is the beginning of hope. NIH-funded research investigates ways to prevent disease, understand its causes, and develop more effective treatments.

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If this so-called “evaluation tap” is agreed to, it will reduce the NIH budget by \$215 million, bringing the budget request below the fiscal year 2012 level.

Further, the administration’s request does not keep pace with biomedical research inflation. As a result, in inflationary adjusted dollars, the NIH is 17 percent less than where they were 10 years ago. Without sustained support for the NIH, the translation of discoveries from “bench to bedside” will be dramatically slowed and the United States will surrender its role as the world leader in scientific research.

I do not agree with the funding level proposed by the administration for the NIH. I believe that NIH funding should be a priority and that its benefits extend well beyond its research discoveries.

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However, Dr. Collins, I understand that your request attempts to live within the confines of the difficult budget environment.

That said, I am concerned about several of the proposed changes to awarding grant funding.

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I understand that constrained budgets lead to tough decisions. However, it is critical that the NIH not lose sight of its goal to fund the best science in the hope of reducing the burden of illness.

A fundamental part of the NIH’s success over the years has been that scientific need and opportunity have always dictated NIH funding priorities. Dr. Collins, I caution you on opening the door to targeting particular diseases for funding as proposed in the fiscal year 2013 budget. The last thing I imagine you want is the President deciding what specific diseases deserve NIH research dollars.

Finally, as we continue to operate in a tough budget environment, I think we need more out-of-the-box thinking to stimulate the research community in imaginative ways. In particular, I want to highlight such an approach at the National Cancer Institute.

Dr. Varmus has started a new program to answer the “provocative questions” in cancer research. This project focuses scientists on 24 unanswered, perhaps non-obvious, questions as defined by the research community. With more than 750 research teams submitting proposals, this project shows that there are innovative ways to energize the research community, even when budgets are constrained.

As the Congress faces unprecedented challenges to reduce government spending, we must all face the consequences of tough choices.

Certainly these are difficult times, but I believe biomedical research is a necessary and worthy investment in the health of our people and the vitality of our communities.

Funding for the NIH lays the foundation for drug and device discoveries over the next decade. Biomedical research is the answer to lowering our Nation’s healthcare costs. This is not the time to abandon our commitment to the health of all Americans and the NIH.

Senator SHELBY. Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Shelby.

Senator Inouye regrets that he could not be present but has a statement to be included in the record.

[The statement follows:]

PREPARED STATEMENT OF SENATOR DANIEL K. INOUE

Mr. Chairman, thank you for chairing this hearing to review the President's fiscal year 2013 budget for the National Institutes of Health.

Mahalo (thank you), Dr. Collins, for joining us today. In this challenging fiscal environment, I will do my best to support the continued progress of science and U.S. competitiveness.

Senator HARKIN. Now we'll turn to Dr. Francis Collins, the 16th Director of the National Institutes of Health, a physician-geneticist noted for discoveries of disease genes and, of course, his leadership of the Human Genome Project.

Prior to becoming Director, he served as a Director of the National Human Genome Research Institute (NHGRI) at NIH.

Dr. Collins received his B.S. from the University of Virginia; M.D. from University of North Carolina at Chapel Hill; and Ph.D. from Yale University.

Dr. Collins, you're no stranger to this subcommittee. We welcome all of you here. Your statement of course, as usual, will be made part of the record in its entirety.

And I ask you to please proceed as you so desire. I won't put any clock time on it, so take whatever time you desire. If it starts going more than 10 minutes, however, we will get a little nervous, okay?

Welcome back. Please proceed.

SUMMARY STATEMENT OF DR. FRANCIS S. COLLINS

Dr. COLLINS. Thank you and good morning, Mr. Chairman and members of the subcommittee. I'm pleased to be here with my colleagues to present the President's budget request for the NIH for fiscal year 2013.

And I must begin by thanking you, Mr. Chairman, and the subcommittee members, for the ultimate fiscal year 2012 appropriation, which maintained NIH's budget at the fiscal year 2011 level. And we're also very grateful for your leadership in creating the new National Center for Advancing Translational Sciences (NCATS).

I do want to express my concern, since we're here in front of the subcommittee, about the health of Senator Kirk, and convey best wishes for a speedy recovery from all of us in the NIH community.

In the next few minutes, I want to offer some details associated with our budget request, to discuss the health and economic benefits of biomedical research, as you have done in your opening statements, and talk about the promise that lies at the intersection of the life sciences and technology.

As you can see here, and I'm going to show you some visuals, the President's fiscal year 2013 budget request for NIH is \$30.86 billion, the same overall program level as in fiscal year 2012. This proposed appropriation will enable us to invest in areas with extraordinary promise for medical science.

We will also use these resources wisely to encourage a vigorous workforce prepared to tackle major scientific and health challenges.

As in the past, we will continue to support a wide array of research mechanisms, from investigator-initiated research to larger and more complex team and center efforts.

In fiscal year 2013, NIH expects to support an estimated 9,415 new and competing Research Project Grants (RPGs). That's an in-

crease of 672 more than the estimate for fiscal year 2012, with an average cost of about \$431,000. For fiscal year 2013, total RPGs are expected to number around 35,888.

And also, to nurture early career scientists, we will continue our efforts to ensure that the success rates for investigators submitting new applications are the same, whether the applicant is first-time or more experienced.

To maximize funding for investigator-initiated grants and to continue our support of first-time researchers, we've had to make some tough choices.

For example, we propose to reduce budgets for noncompeting RPGs by 1 percent from the fiscal year 2012 level and to restrain growth in the average size of new awards. In addition, we will no longer assume out-year inflationary increases for new and continuing grants.

Other highlights of the fiscal year 2013 request include a \$40 million ramp up of the Cures Acceleration Network (CAN) and additional support for Alzheimer's disease research, \$80 million coming as part of an HHS-wide initiative.

NIH-funded research has prevented untold human suffering by enabling Americans to live longer, healthier, and more productive lives, and let me mention a few examples.

Life expectancy: A child born today can look forward to an average lifespan of almost 79 years. That's nearly three decades longer than one born in 1900.

Cardiovascular disease: During the last half-century, our Nation's death rates for heart disease and stroke have fallen by 70 percent.

Infant mortality: We've achieved an impressive 40-percent reduction in this vital area over the last two decades.

In cancer, the just released 2012 annual report to the Nation on the status of cancer shows a continuing decline in death rates for most cancers, along with a drop in the overall rate of new cancer diagnoses.

And today's biomedical research holds much, much more promise. For example, I want to show you this picture of a recent publication of research on Alzheimer's disease, and this represents a new opportunity in translational research through what we would call drug repurposing.

Recently, a team of researchers, some supported by NIH, found that a drug called bexarotene, a drug originally developed for treating a type of skin cancer, can clear beta-amyloid, as you see in the before and after picture, in mouse models of Alzheimer's disease in just 72 hours.

In people with Alzheimer's, beta-amyloid accumulates in the brain like this, eventually leading to the death of neurons. Hope for bexarotene has gone particularly high because it has already been studied in humans, providing a wealth of information about dose and toxicity, and providing the opportunity to initiate clinical trials.

And that's not all. Here's a list, Senator and members of the subcommittee, of just a few of the many recent examples of progress in biomedical research, scrolling by here. I wish I could tell you the

details of each one, but this opening statement would then go on for most of the day.

I would like, however, to talk something about the U.S. economy, as you have touched on, both of you, in your opening statements.

As our Nation struggles to recover from a difficult period, it's worth pointing out that Government investments in biomedical research are a terrific way to spur economic growth. A recent analysis estimated that every \$1 of NIH support returns \$2.21 in goods and services to the local economy in just 1 year. And on average, every NIH grant creates seven high-quality jobs.

Furthermore, NIH serves as the foundation for the entire U.S. medical innovation sector, a sector that employs 1.42 million directly and supports an additional 6.6 million jobs in the United States, resulting in a total employment impact of more than 8 million jobs, generating \$84 billion in wages and salaries, and exporting \$90 billion in goods and services.

Already referred to, the latest figures from the United for Medical Research report paint a similar picture. According to their update, NIH recently, directly and indirectly, supported more than 432,000 American jobs, spurring more than \$62 billion in economic activity.

And here's another thing to consider: NIH funding is the foundation for long-term U.S. global competitiveness in industries such as biotech, drug development, and medical devices. Around the world, many nations are following America's success story and ramping up their investments in the life sciences.

Global research and development (R&D) spending across the world is expected to grow by about 5.2 percent to more than \$1.4 trillion in 2012. India has posted double-digit percentage increases in R&D for several years. Europe plans to increase research spending by 40 percent over the next 7 years. China has just announced that it will increase its investment in basic research by 26 percent in 2012. And Vladimir Putin has voiced his intention to increase support for research in Russia by 65 percent during the next 5 years.

Let me now turn to a few areas that are driving medical research. No less a futurist than Steve Jobs once predicted, "I think the biggest innovations of the 21st century will be the intersection of biology and technology." And he was spot on.

One striking example is the cost of sequencing a human genome. Eleven years ago, it cost \$100 million. Five years ago, \$10 million. Today, less than \$8,000 and heading down.

Within the next year or two, in fact, a couple of U.S. companies plan to sell machines that can sequence a genome in a single day for \$1,000 or less, using devices like the one I'm holding up here, the size of a postage stamp. That's a sequencing machine. It used to be as big as a phone booth or bigger. This is a new model.

This will revolutionize how doctors diagnose and treat diseases and will allow researchers to pursue previously unimaginable scientific questions.

So this kind of advance in technology empowers both basic and applied research, and NIH is a leading supporter of basic biomedical research in the world.

Slightly more than one-half of NIH's budget is being invested to support this kind of fundamental research. In our view, there is no competition between basic and applied research. They're synergistic. And our support of basic research makes possible a wide range of new biological discoveries.

Take the example of induced pluripotent stem cells, stem cells derived from patients' own skin cells. This technology is now being used to develop exciting new models of disease, so-called "diseases in a dish," that are expanding our understanding of human biology, as well as opening the door to new treatment possibilities.

But let's be honest. There's much work yet to be done. Despite phenomenal progress in basic science, we still lack effective treatments for far too many diseases.

And the translational pipeline is long; 14 years on the average. And it's terribly leaky.

A recent article in the *Journal Nature Reviews Drug Discovery* found that despite huge R&D investments, the number of new drugs approved per \$1 billion, as you see here, has fallen steadily since 1950. Bottlenecks continue to vex this process, resulting in long development times, high failure rates, and steep costs.

We need to re-engineer this pipeline, and that's why our new center, NCATS, is already working with industry to develop innovative ways to speed the flow of new therapies to patients.

Mr. Chairman, I've described the administration's fiscal year 2013 request for NIH, the health and economic benefits of biomedical research, and the synergy between basic and translational research at NIH that's made possible by today's technological advances. But I'd like to close with a story that ties these points together.

As toddlers, the twins Alexis and Noah Beery were diagnosed with a rare and devastating movement disorder called dystonia. Although they initially responded to standard treatment, their symptoms reappeared and worsened.

Noah developed severe tremors in his hands. And Alexis encountered even greater difficulties. As you can see in this heartbreaking video clip, she began falling frequently and had frightening episodes where she could not breathe.

Desperate for answers, doctors at Baylor College of Medicine sequenced the twins' genomes. The result was the discovery of a never-before described genetic mutation affecting neurotransmitters in the brain. After being put on a new treatment regimen tailored to their unique genetic profile, the twins' symptoms began to improve within just 2 weeks.

In fact, Alexis' breathing is so much better today that she has joined the school's track team.

Tonight in a NOVA special on advances in genetic medicine, PBS viewers will be able to witness the twins' progress. And here's a sneak peak. That's Noah and Alexis, healthy, happy, and enjoying themselves on a trampoline.

PREPARED STATEMENTS

While this study centers on teens with a rare disease, the outcome carries a message of hope for all of us. It points directly to

the promise that NIH research offers the patients of today and tomorrow.

So thank you for this opportunity, Mr. Chairman and members of the subcommittee. And my colleagues and I will be glad to answer your questions.

[The statements follow:]

PREPARED STATEMENT OF FRANCIS S. COLLINS, M.D., PH.D.

NATIONAL INSTITUTES OF HEALTH'S MISSION

Good morning, Mr. Chairman and distinguished members of the subcommittee. I am Francis S. Collins, M.D., Ph.D., and I am the Director of the National Institutes of Health (NIH). I have with me Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Disease (NIAID); Richard J. Hodes, M.D., Director of the National Institute on Aging (NIA); Thomas R. Insel, M.D., Director of the National Institute of Mental Health (NIMH), and the Acting Director of the new National Center for Advancing Translational Sciences (NCATS); Griffin P. Rodgers, M.D., Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK); and Harold E. Varmus, M.D., Director of the National Cancer Institute (NCI).

It is a great honor to appear before you today to present the administration's fiscal year 2013 budget request for the NIH.

First, I would like to thank each of you for your continued support of NIH's mission to seek fundamental knowledge about the nature of living systems and to apply it in ways that enhance human health, lengthen life, and reduce suffering from illness and disability. In particular, I want to thank the subcommittee for your support during the fiscal year 2012 appropriations process, for the ultimate appropriation of \$30.62 billion for NIH, and for the provisions that established NCATS.

As the largest supporter of biomedical research in the world, NIH has been a driving force behind decades of advances that have improved the health of people across the United States and around the world.

NIH basic research and translational advances have prompted a revolution in the diagnosis, treatment, and prevention of disease. Biomedical research funded by NIH has prevented immeasurable human suffering and has yielded economic benefits as well, thanks to U.S. citizens living longer, healthier, and more productive lives. These benefits include:

- nearly 70-percent reduction in the death rate for coronary disease and stroke in the last half century;
- effective interventions for HIV/AIDS prevention and treatment, such that an AIDS-free generation may be within our grasp;
- nearly 30-percent decline during the last three decades in the age-standardized prevalence of chronic disability among American seniors;
- 40-percent decline in infant mortality during 20 years and better treatments for premature and low-weight births that result in increased infant survival, the prevention of cerebral palsy, and better developmental outcomes; and
- more than 150 U.S. Food and Drug Administration (FDA)-approved drugs and vaccines, or new uses of existing drugs.¹

The administration's fiscal year 2013 budget request for NIH is \$30.86 billion, which is the same overall program level as fiscal year 2012. This proposed appropriation will enable us to spark innovation and invest in areas of extraordinary promise for medical science. We will also invest these resources wisely to encourage a vigorous workforce that is prepared to tackle major scientific and health challenges.

Within the administration's fiscal year 2013 budget, we will continue to protect and increase Research Project Grants (RPGs), NIH's fundamental funding mechanism for investigator-initiated research. NIH expects to support an estimated 9,415 new and competing RPGs in fiscal year 2013, an increase of 672 more than the estimate for fiscal year 2012, with an average cost of about \$431,000. For fiscal year 2013, total RPGs are expected to number around 35,888.

To maximize funding for investigator-initiated grants, and to continue our support of first-time researchers, we propose to reduce budgets for noncompeting RPGs by 1 percent from the fiscal year 2012 level and to restrain growth in the average size of new awards. We will also no longer assume out-year inflationary increases for

¹ Stevens, A.J., et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*. N. Engl. J. Med., 364: 535–41, 2011.

new and continuing grants. To nurture early career scientists, we will continue our efforts to ensure that the success rates for investigators submitting new R01 applications are the same whether the applicant is first-time or more experienced.

In fiscal year 2013, we will also conduct an additional review of proposed awards to any principal investigator (PI) who already has NIH funding of \$1.5 million or more in total annual costs, approximately 6 percent of PIs. This review will be conducted by each institute's advisory council. This is similar to a policy the National Institute of General Medical Sciences (NIGMS) has had since 1998, which will serve as a model for NIH. We recognize that some types of research, notably large complex clinical trials, routinely will trigger this review. We also know that some of our most productive investigators are leading significant research teams that require more than \$1.5 million to be sustained. This extra level of review will not be viewed as a cut-off point but as an opportunity to apply additional scrutiny to be sure any added resources are justified by exceptional scientific promise.

Another significant change in the fiscal year 2013 request is an 11-percent increase in the NCATS budget. The proposed budget includes an increase of \$39.6 million for the Cures Acceleration Network (CAN), which received \$10 million for start-up funding in fiscal year 2012. As you know, Mr. Chairman, CAN will fund initiatives to address scientific and technical challenges that impede translational research, and to advance the development of "high-need cures" by accelerating the pace and reducing the time between research discovery and therapeutic treatment. In total, nearly one-half of the increase requested for NCATS will be used to transition programs from the Common Fund, allowing the Common Fund to support additional cross-cutting, trans-NIH programs.

I would also note that the fiscal year 2013 NIGMS budget would decrease by \$48.3 million (after comparability adjustments), primarily due to not continuing the 21 percent increase that the Congress provided in fiscal year 2012 for the Institutional Development Awards (IDeA) program. The budget of the Office of the Director is also cut by 1.9 percent from fiscal year 2012 enacted level, reflecting a reduced request for the National Children's Study (NCS); we will implement alternative sampling approaches that will reduce costs and still achieve the ambitious objectives of the study.

In fiscal year 2013, the President is also proposing to spend \$80 million from the Prevention and Public Health Fund to provide additional support for Alzheimer's research as part of the national plan to address Alzheimer's disease. As many as 5.1 million Americans currently suffer from Alzheimer's disease, more than 280,000 more Americans will be diagnosed with the disease this year, and nearly 800 of our fellow citizens are diagnosed every day. By the year 2030, the last baby boomer will turn 65 and 7.7 million Americans older than the age of 65 will have Alzheimer's disease.² Today, Alzheimer's and other dementias cost the United States economy more than \$180 billion a year and if no cures and therapies are found, will cost the United States \$1.1 trillion annually by 2050. The \$80 million of new funding will support research with a strong focus on the prevention of Alzheimer's disease, including research to identify genes that cause this disease, to develop tests for high-risk individuals, and to identify possible targets for therapeutic development.

INVESTING IN BASIC SCIENCE, APPLYING KNOWLEDGE TO THERAPIES

NIH's commitment to basic research provides the foundation for understanding the underlying causes of diseases which is essential to the development of promising treatments and cures for some of our Nation's most debilitating diseases and conditions. Apple Computer founder, Steve Jobs, has been quoted as saying: "I think the biggest innovations of the 21st century will be the intersection of biology and technology."³ Jobs was absolutely right: today technological advances are driving science. We need look no further than the cost of DNA sequencing to see this dynamic at work. The cost curve for sequencing is dropping at a breathtaking rate; sequencing speed has increased even faster than computer processing speed. What's more, the average cost of sequencing an entire genome has fallen from about \$3 billion 12 years ago, to \$10 million 5 years ago, to about \$7,700 today. Two U.S. companies have recently announced that they are manufacturing machines that will sequence an individual's genome in 1 day for approximately \$1,000, and that the first such instruments will go on sale before year's end. Lower sequencing costs will likely revolutionize how clinicians diagnose and treat diseases and enable the research community to pursue previously unimaginable scientific questions.

² Alzheimer's Association, 2011 Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia, Volume 7, Issue 2.

³ Isaakson, Walter, *Steve Jobs* (New York: Simon & Schuster, 2011) 539.

NIH is the leading supporter of basic biomedical research in the world. Put plainly, if we don't fund basic research, most of this work would not get done, and it would be only a matter of time before this wellspring of new understanding and new therapies would dry up. NIH's funding for basic research is slightly more than one-half (54 percent) of research funding, and this balance between basic and applied research has remained fairly constant over the past decade.

I also would like to address what may be a misconception about a competitive tension between basic and applied research at NIH. As our support of basic research has enabled new discoveries, NIH-funded scientists have always worked to turn the most compelling of them into medical advances. Basic discovery and the development of therapies go hand-in-hand at NIH. The two types of research have—and always will—exist together in a continuum. Today, I would like to highlight just a few areas in which basic research advances are opening up new translational opportunities.

Human Microbiome Project.—One fascinating area of basic research is the Human Microbiome Project, an initiative supported through the NIH common fund. This project is giving us wonderful insights into the sweeping range of bacteria that live on and in each of us, and is expanding our knowledge about the role of these microbial communities in health and disease. Recent scientific evidence suggests that changes in the composition and activity of the human microbiome may contribute to obesity, which may provide us with new ways of addressing this serious threat to our Nation's health.

Undiagnosed Diseases Program.—Another recent example emphasizes the “virtuous cycle” between basic and clinical research. The NIH clinical center has recently established a groundbreaking program that seeks to identify the cause of illnesses that have remained unsolved by other medical practitioners. Since the program started in 2008 some 1,700 people with undiagnosed conditions have been referred to Dr. William Gahl, and more than 300 have been accepted for an initial week of consultations and testing. In the 15 to 20 percent of cases that we have successfully diagnosed, it has taken from a week to as long as 2 years to resolve. For example, a pair of sisters from Kentucky suffered from joint pain and mysterious calcification of the arteries in their extremities. Full evaluation and DNA sequencing led to the discovery of an entirely new genetic condition, where a previously unknown enzyme pathway in their arteries was blocked. This has led to a dramatic new understanding of how the large arteries in all of us maintain their normal health, with immediate research spinoffs in the basic and clinical arenas.

Alzheimer's Disease.—NIH-supported investigators are expanding our understanding of Alzheimer's disease in ways that may open doors to new therapies. Using mice genetically engineered to make the abnormal human tau protein—a protein already identified in the brains of Alzheimer's patients—scientists found that Alzheimer's disease appears to spread through the brain in much the same way that an infection or cancer moves through the body. The abnormal tau protein started in one area of the brain in the mice and, over time, spread from cell to cell to other areas of the brain in a pattern very similar to the earliest stages of human Alzheimer's disease. The discovery of the tau pathway could influence the direction of future research and give investigators a target for drug development that might arrest Alzheimer's disease progression at very early stages when the disease is most amenable to treatment.⁴

Alzheimer's disease also stands to benefit from translational research by way of drug rescuing and repurposing. Recently, a team that included NIH-supported investigators reported that bexarotene, a drug compound originally developed for treating T-cell lymphoma (a type of skin cancer), was capable of clearing the protein beta-amyloid quickly and efficiently after only a short exposure to the compound in Alzheimer's disease mouse models. Beta-amyloid accumulates in the brain of Alzheimer's patients due to an impaired ability to clear the protein, leading to a build-up of beta-amyloid plaques and ultimately neuronal death. These findings are exciting because, in time, they could benefit patients with Alzheimer's disease. Hopes are particularly high because the drug used in the study has already been studied in humans, providing a wealth of information about dosage and toxicity.⁵

Cystic Fibrosis.—In a step towards personal medicine, the FDA in January approved Kalydeco, the first drug to treat an underlying cause of cystic fibrosis (CF). Twenty-three years ago, I co-lead the team that discovered the gene responsible for

⁴Liu L, Drouet V, Wu JW, Witter MP, Small SA, et al. (2012) Trans-Synaptic Spread of Tau Pathology In Vivo. PLoS ONE 7(2): e31302. doi:10.1371/journal.pone.0031302.

⁵Cramer PE, Cirrito JR, Wesson DW, Lee CYD, Karlo JC, et al. (2012) ApoE-Directed Therapeutics Rapidly Clear β -Amyloid and Reverse Deficits in AD Mouse Models. <http://www.sciencemag.org/content/early/2012/02/08/science.1217697.full.pdf>.

CF. Mutations in this gene cause a protein to malfunction, resulting in a sticky buildup of mucus in the lungs and digestive tract that eventually causes fatal health problems. Kalydeco, which was developed by Vertex Pharmaceuticals, counters one of these mutations, which affects about 4 percent of people with CF. Vertex is now testing the drug in combination with another new compound to target a more common mutation found in 90 percent of CF patients.

CLINICAL RESEARCH: NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

The translation of basic biological discoveries into clinical applications is a complex process that involves a series of intricate steps. These steps range from the discovery of basic information about the causes of disease, an assessment of whether that information has the potential to lead to a clinical advance, the development and optimization of therapeutics to test in human trials, and ultimately, the application of the approved therapy, device, or diagnostic in the real world. Drugs exist for only about 250 of the more than 4,400 conditions with defined molecular causes.⁶ And it takes far too long and far too much money to get a new drug into our medicine cabinets. This is an old problem that cries out for new and creative solutions.

In the past, drug development was based on a short list of a few hundred targets, but with advances in technology, we are now able to identify thousands of new potential drug targets.⁷ We can also study whole pathways, organ systems, or even entire organisms rather than limiting the research to a single aspect of cell biology or physiology. Technologies such as large-scale sequencing, robotic high-throughput screening, and real-time imaging modalities uncover massive amounts of data that may one day lead to new therapies to prevent, treat, and possibly cure diseases. Many of the NIH institutes are deeply engaged in these efforts. But we face serious engineering challenges. To put it simply, the current translational science framework pursued in both the public and private sectors, largely focused on individual projects on specific diseases, has not been fully able to utilize recent scientific advances to address the bottlenecks that lead to long development times, high failure rates, and high costs. This month's issue of *Nature Reviews Drug Discovery* includes a review that demonstrates that, despite huge investments in biomedical science and technology, the number of new drugs approved per billion R&D dollars spent has been cut in one-half every 9 years since 1950.⁸ NCATS is the catalyst we need to reengineer the discovery and development process.

To tackle this problem in a science-driven way, NIH proposed the creation of NCATS with the goal to develop and test innovative tools, technologies, and approaches that will enhance the development of drugs and diagnostics for application in all human diseases. NIH has the expertise and enthusiasm to tackle this as a scientific problem. By focusing on the development of innovative new methods for conducting translational science, as opposed to developing therapeutics themselves, NCATS can enable others to bring new medical products to patients in a highly efficient, cost-effective manner. In the 4 months since it was established, NCATS has already developed three new initiatives in partnership with industry, academia, and other government agencies.

In the first initiative, NIH is working closely with several pharmaceutical companies to develop model agreements for a new pilot program to rescue failed drugs. Pharmaceutical companies have access to promising compounds that have been shown to be safe in humans, but that did not prove effective in treating the condition for which they were intended. Researchers are now learning that a compound that is a failure for one condition may help to treat another. To capitalize on this, NCATS is developing a pilot program in partnership with industry that will seek to crowd source some of the most promising of these compounds to the brightest minds in science, an unprecedented opportunity for NIH-funded researchers, and a new way to bridge academic science with industrial expertise.

Second, NCATS is partnering with the Defense Advanced Research Projects Agency (DARPA) to develop a chip that will mimic how humans respond to a drug. Scientists funded by NIH and DARPA will spend 5 years working closely with each other to place 10 diverse human tissues on a chip so that they will interact with drugs the same way that they do in living patients. By providing a better model

⁶Braun, et al., "Emergence of orphan drugs in the United States: a quantitative assessment of the first 25 years." *Nature Rev. Drug Discov.* 9(521), 2010; Online Mendelian Inheritance in Man, <http://www.ncbi.nlm.nih.gov/omim/>.

⁷Collins, F.S., "Reengineering Translational Science: The Time is Right." *Sci. Transl. Med.*, 3(90):90cm17, 2011.

⁸Scannell JW, Blanckley A, Boldon H, & Warrington B. (2012). Diagnosing the decline in pharmaceutical R&D efficiency. *Nature Reviews Drug Discovery* 11, 191-200. doi:10.1038/nrd3681.

to predict drug safety and efficacy, the most promising drug candidates can be identified more quickly and moved forward into development. FDA will be heavily involved in an advisory capacity to ensure this research aligns with regulatory requirements.

In the third initiative, NCATS is working closely with industry to develop systematic ways to identify the most promising drug targets from the troves of data pouring out of basic research labs. To turn these discoveries into therapies, scientists in academia and industry need to be able to sift quickly and accurately through these data to identify the best targets. NCATS, along with industry partners, is taking the lead on developing a consortium that will strive to come up with the most streamlined ways to conduct target validation.

I want to emphasize that these and other initiatives within NCATS will provide resources and expertise to assist the basic research community in moving their discoveries to the next phase, as well as stimulate the basic research enterprise. For example, the Molecular Libraries and Imaging Program, originally implemented through the NIH Common Fund, has been successful in the development of chemical probes for basic and translational research. Many of these new probes have been, or are being, modified for use in the clinic, resulting in patent applications, licenses to pharmaceutical companies, and new therapeutic strategies.

In the months before NCATS was created by this subcommittee, NIH engaged in an unprecedented outreach campaign to make sure that all stakeholders—including industry—had an opportunity to comment on the proposed Center. In addition to NIH's scientific management review board and advisory council to the Director, NIH consulted with the boards of the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Association, the R&D heads of pharmaceutical and biotechnology companies, and the investment banking and venture capital communities. In addition, NIH held a series of workshops with pharmaceutical and biotech firms to discuss drug rescue and repurposing and target validation.

It is important to note that NCATS' work will assist all of NIH's Institutes and Centers in their translational and drug development efforts. NCATS will provide NIH Institutes and Centers the tools, methodology, and infrastructure necessary to speed new approaches to therapeutic treatments. The new Center also will work with other NIH Institutes and Centers to convene workshops with industry, non-profits, and other government agencies to explore critical translational areas and innovative public-private sector partnerships.

With the fiscal year 2013 budget, NIH will pursue efforts to streamline and shorten the pathway from discovery to health through several new and ongoing initiatives and programs.

ECONOMIC RETURNS AND GLOBAL COMPETITIVENESS

In our knowledge-based world economy, innovation in medical research has been able to generate growth, high-quality jobs, better health, and better quality of life for all Americans. Investment in NIH continues to bring new ways to cure disease, alleviate suffering, and prevent illness. Furthermore, it generates new economic activity and employment in the communities that receive its funds. One study estimates that every \$1 of NIH support returns \$2.21 in goods and services in just 1 year, and that on average, every NIH grant creates seven high-quality jobs.

Investments in the biomedical infrastructure, in scientists' ideas, and in workforce training are essential to drive the innovation that will spur America's economic recovery and future growth. NIH serves as the foundation for the entire U.S. medical innovation sector that employs 1 million United States citizens, generates \$84 billion in wages and salaries, and exports \$90 billion in goods and services.⁹ United for Medical Research has just released an updated version of their report "An Economic Engine: NIH Research, Employment, and the Future of the Medical Innovation Sector." According to UMR data, the \$23.7 billion NIH spent extramurally in the U.S. in 2011 directly and indirectly supported 432,092 jobs, enabling 16 States to experience job growth of 10,000 jobs or more, and propelling \$62.135 billion in new economic activity.

Thanks in large part to NIH-funded medical research, Americans are living longer, healthier, more rewarding lives. A child born today can look forward to an average life span of almost 79 years, an increase of nearly three decades over life expectancy in 1900. The economic value of these gains in average life expectancy

⁹Ehrlich, Dr. Everett, *An Economic Engine: NIH Research, Employment and the Future of the Medical Innovation Sector*, 8, United for Medical Research (May 2011).

in the United States has been estimated at \$95 trillion for the period from 1970–2000.¹⁰

NIH funding is the foundation for long-term U.S. global competitiveness in industries such as biotechnology, medical devices, and pharmaceutical development. Around the world, many nations are following suit and beginning to ramp up their own investment in the life sciences. Global R&D spending is expected to grow by about 5.2 percent to more than \$1.4 trillion in 2012.¹¹ India has posted double-digit increases for several years, and Europe plans to increase research spending by 40 percent over the next 7 years. Even Vladimir Putin has announced the intention to increase support for research in Russia by 65 percent over the next 5 years. China has just announced that it will increase its investment in basic research by 26 percent in 2012.¹² To be sure, the scale of China's effort does not match ours. However, Chinese scientists are second only to the United States in the number of scientific manuscripts published annually, and China's intention to compete with us is obvious.

The United States must compete in training America's next generation to make tomorrow's health discoveries and ensure continued scientific leadership.

A PATIENT STORY

Mr. Chairman, this morning I've described the promise that inexpensive whole-genome sequencing holds for future medical practice, the synergy between basic and translational research at NIH, and the need for NCATS. I'd like to close my testimony by telling you a story—a story about real patients—that ties my three points together.

As toddlers, twins Alexis and Noah Beery were diagnosed with a rare and devastating movement disorder, called dystonia. Although they initially responded to empirical treatment, their symptoms reappeared and worsened as they entered their teenage years. Noah developed severe tremors in his hands. Even worse, his sister Alexis began falling frequently and had frightening episodes where she couldn't breathe.

Desperate for answers, doctors at Baylor College of Medicine sequenced the twins' genomes. The result? Discovery of a never-before described genetic mutation affecting neurotransmitters in the brain. After being put on a new treatment regimen tailored to their unique genetic profile, the twins' symptoms began to improve within just 2 weeks. I recently saw a video of the two of them doing tricks on a trampoline. In fact, Alexis' breathing is so much better today that she's joined her school's track team. While this story centers on two teens with a rare disease, the outcome carries a message of hope for all of us. It points directly to the promise that NIH research offers the patients of today and tomorrow.¹³

In conclusion, we have never witnessed a time of greater promise for advances in medicine than right now. NIH is prepared to continue our long tradition of leading the world in the public support of biomedical research. Successful development of prevention strategies, diagnostics, and therapeutics will require bold investments in research across the spectrum from basic science to clinical trials, as well as new partnerships between the public and private sectors. With your support, we can promise continuing advances in medicine, creation of new economic opportunities, and stimulation of American global competitiveness in science, technology, and innovation.

PREPARED STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Mr. Chairman and members of the subcommittee: I am pleased to present the President's fiscal year 2013 budget request for the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The fiscal year 2013 NIAID budget of \$4,495,307,000 includes an increase of \$10,210,000 more than the comparable fiscal year 2012 level of \$4,485,097,000.

¹⁰ Murphy, K.M., & Topel, R.H. (2006). "The value of health and longevity". *Journal of Political Economy*, 114(5), 871-904.

¹¹ Grueber, Martin, 2012 Global R&D Funding Forecast, 3, *Batelle and R&D Magazine* (December 2011).

¹² Hvistendahl M. (2012). "A Bumper Year for Chinese Science." *Science* Vol. 335, No. 6073 p.1156. doi: 10.1126/science.335.6073.1156.

¹³ Bainbridge MN, et al. (2011). Whole-Genome Sequencing for Optimized Patient Management. *Science Translational Medicine* 3, 87re3. doi: 10.1126/scitranslmed.3002243.

NIAID conducts and supports biomedical research to understand, treat, and prevent infectious and immune-mediated diseases, including HIV/AIDS, tuberculosis, malaria, influenza, emerging and re-emerging infectious diseases, asthma and allergic diseases, autoimmune diseases, and the rejection of transplanted organs. I appreciate the opportunity to highlight our recent scientific advances and to describe some of our most promising research aimed at improving public health and quality of life.

INFECTIOUS DISEASES RESEARCH

HIV/AIDS.—In the 30 years since AIDS was first recognized in the United States, the substantial NIAID investment in basic, translational, and clinical HIV/AIDS research supported consistently by this subcommittee has resulted in many groundbreaking discoveries. With this commitment, we have made significant progress, including strengthening HIV prevention efforts and developing nearly 30 antiretroviral drugs to suppress HIV. Thirty years ago, HIV/AIDS was for the most part a death sentence. Today, if a young person enters the clinic with early HIV disease and begins appropriate therapy, he or she can expect to live a near-normal lifespan, a milestone unimaginable at the start of the HIV/AIDS pandemic.

I am pleased to report landmark advances and opportunities in HIV/AIDS research this year. In December 2011, the journal *Science* named an NIAID-funded international HIV prevention study its breakthrough of the year, reinforcing that the investment in NIH research continues to pay extraordinary dividends for public health. This study, known as HPTN 052, demonstrated that HIV-infected heterosexual individuals who began taking antiretroviral medicines when their immune systems were still relatively healthy, rather than later, were 96 percent less likely to transmit the virus to their uninfected sexual partners. This study convincingly demonstrates that antiretrovirals not only can be life-saving to people infected with HIV but also can prevent transmission of the virus to their uninfected sexual partners. Other studies have shown that medically supervised adult male circumcision has proven to be highly effective and durable in preventing the acquisition of HIV infection. In addition, pre-exposure prophylaxis of at-risk uninfected individuals may be an important means of preventing HIV infection.

HIV vaccines still represent the best long-term hope for ending the HIV pandemic. Building on the promising results of the United States Army-NIAID RV144 HIV vaccine clinical trial, which found a “prime-boost” vaccine candidate to be safe and modestly effective at preventing acquisition of HIV, NIAID is working to understand the immune mechanisms that explain these results, to optimize the protective immune responses elicited by the vaccine candidate, and to develop and evaluate new vaccine candidates. We also are encouraged by the discovery by NIAID-supported scientists of human antibodies that can block a wide range of HIV strains. We are expanding clinical testing in this area, and insights gained from these studies will guide future HIV vaccine research.

These research advances taken together with the implementation of other evidence-based HIV prevention and treatment strategies make the possibility of an “AIDS-free generation” in the foreseeable future eminently feasible. This July, we will consider strategies to implement these important findings during the International AIDS Society Conference in Washington, DC.

Tuberculosis and Malaria.—NIAID continues to invest in basic and clinical research and collaborate with global partners, including the World Health Organization’s Stop Tuberculosis (TB) Partnership, to combat the co-infections that often accompany HIV infection, including TB and malaria. Building on these efforts, we now have a substantial development pipeline of TB treatments and vaccines. NIAID has developed a Strategic Blueprint for TB Vaccines that proposes new research pathways for achieving a licensed TB vaccine. For malaria, NIAID supported early-stage basic research that ultimately led to the development by others of the first moderately successful malaria vaccine candidate aimed particularly for children, RTS,S/AS01, a science runner-up breakthrough of the year in 2011. In addition, the NIAID Vaccine Research Center is partnering with a biotechnology firm to undertake clinical studies of a novel malaria vaccine candidate, PfSPZ. NIAID also plays a leading role in the international Malaria Eradication Research Agenda initiative.

Other Infectious Diseases of Domestic and Global Health Importance.—NIAID’s longstanding investments in basic and clinical research have led to many successes in vaccine development for diseases of worldwide public health concern, including gastroenteritis caused by rotavirus, pneumonia, hepatitis A, and deadly meningitis caused by *Haemophilus influenzae* type b. These are among the vaccines now being delivered to countries around the world; where they have been deployed, substantial reductions in morbidity and mortality have been observed. NIAID has assumed a

major leadership role in the “Decade of Vaccines” initiative, a 10-year collaborative effort coordinated by the Bill & Melinda Gates Foundation, to develop and deliver vaccines to the world’s poorest countries. NIAID will continue research on other urgently needed vaccines, including vaccines for Group B streptococci, Epstein-Barr virus, and hepatitis C virus.

Seasonal and pandemic influenzas remain critical global health and economic threats. NIAID has made significant progress in the development and testing of vaccines to protect people from influenza, including the elderly, young children, and those with asthma. Recently, NIAID researchers demonstrated that a “prime-boost” gene-based vaccination strategy could activate the immune system and lead to broadly neutralizing antibody responses against influenza viruses. This finding and those from other researchers signal that we are closer to developing a “universal” vaccine that could protect against multiple strains of seasonal and pandemic influenza viruses.

This year, in response to the growing public health issue of antimicrobial resistance, NIAID will expand our clinical trials networks developed originally for HIV/AIDS to investigate this important concern. In addition, NIAID will support research to determine how to preserve the effectiveness of current antibiotics.

NIAID’s biodefense research has yielded numerous scientific advances as we have moved from a “one bug-one drug” approach to a more flexible, broad-based product development strategy that utilizes sophisticated genomic and proteomic platforms to address infectious disease outbreaks, whether they are deliberately introduced or naturally occurring. As part of this effort, NIAID has awarded contracts for the development of broad-spectrum therapeutics against emerging infectious disease and biodefense agents.

RESEARCH ON IMMUNOLOGY AND IMMUNE-MEDIATED DISORDERS

NIAID was highly gratified that the 2011 Nobel Prize in Physiology or Medicine was awarded to three NIAID grantees:

- Bruce A. Beutler;
- Jules A. Hoffmann; and
- the late Ralph M. Steinman.

Their research has been pivotal in understanding the human immune response, and it is helping to inform the development of new vaccines and vaccine adjuvants that may provide better protection against infectious diseases.

NIAID’s commitment to basic immunology research has led to advances in the treatment of immunological conditions such as the rejection of transplanted organs. In 2011, the *Journal of the American Medical Association* published an NIAID Immune Tolerance Network study demonstrating that children who receive liver transplants may not need lifelong anti-rejection therapy to maintain the transplanted organ. Other NIAID-supported investigators demonstrated that some kidney transplant recipients who also received bone marrow from the kidney donor can maintain their kidney grafts without immunosuppressive drugs.

CONCLUSION

NIAID basic and clinical research on infectious and immune-mediated diseases will continue to promote the development of vaccines, therapeutics, and diagnostics to improve health and save millions of lives worldwide. NIAID remains committed to supporting highly meritorious research with the goal of translating fundamental scientific findings into public health advances.

PREPARED STATEMENT OF GRIFFIN P. RODGERS, M.D., M.A.C.P., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Mr. Chairman and members of the subcommittee: I am pleased to present the President’s fiscal year 2013 budget request for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH). The fiscal year 2013 budget includes \$1,792,107,000, which is \$2,798,000 less than the comparable fiscal year 2012 appropriation of \$1,794,905,000. Complementing these funds is an additional \$150 million also available in fiscal year 2013 from the special statutory funding program for type 1 diabetes research. The NIDDK supports research on a wide range of common, chronic, costly, and consequential diseases and health problems that affect millions of Americans. These include diabetes and other endocrine and metabolic diseases; digestive and liver diseases; kidney and urologic diseases; blood diseases; obesity; and nutrition disorders.

BUILDING NEW OPPORTUNITIES: BASIC RESEARCH DISCOVERIES

From in-depth exploration of fundamental biologic processes, NIDDK-supported scientists are achieving remarkable advances and building the foundation for previously unimaginable strategies to improve health and quality of life. Among these advances, recent NIDDK-supported research into genetic risk factors for diabetes, inflammatory bowel disease, obesity, liver disease, and the kidney disease focal segmental glomerular sclerosis, along with other studies are providing insights into disease development and whether an individual is likely to respond to a given therapy. Investigating the different types of bacteria that reside in the intestines, researchers have discovered surprising links to obesity, inflammatory bowel disease, fatty liver disease, and other health conditions. Scientists supported by our institute are also designing novel intervention strategies and testing these in pre-clinical, laboratory models. For example, pursuing a treatment for fecal incontinence, researchers used tissue engineering to build muscle implants in mice with promising initial results, providing hope for future therapeutic use in people. Other scientists examined a potential drug for the rare disease Neimann-Pick type C in experiments with isolated human cells, and found encouraging results.

We will continue support for basic research across the Institute's mission, to gain further insights into health and disease and propel new ideas for interventions. Examples include research to identify type 2 diabetes risk genes in minority populations disproportionately affected by this disease; to discover environmental factors that trigger type 1 diabetes in genetically susceptible individuals; to elucidate the causes and consequences of a form of diabetes that can strike people with cystic fibrosis; to increase understanding of intestinal stem cells, which could benefit a variety of digestive diseases; and to augment knowledge of blood cells and hematologic diseases.

PREVENTING AND TREATING DISEASE—IN CLINICS AND COMMUNITIES

Through innovative design and rigorous testing of interventions—whether in the operating room, doctor's office, or home or community settings—NIDDK-supported researchers are improving lives with new approaches to prevent, treat, and reverse diseases and disorders. For example, investigators previously showed that intensive blood glucose control, beginning soon after diagnosis of type 1 diabetes, reduced early signs of complications; now, after an average 22-year follow-up, the researchers demonstrated that controlling blood glucose reduced the risk of developing kidney disease by 50 percent, preserving kidney function for decades. The first cystic fibrosis therapy targeting a specific molecular defect gained U.S. Food and Drug Administration (FDA) approval. This important advance was a culmination of research supported in part by NIDDK, from the historic gene discovery (by the NIH Director) to clinical trials of the drug. With cutting-edge tissue engineering, researchers have successfully generated urethras to replace defective tissue and ameliorate urination difficulties in boys. A network of investigators found that vitamin E helps reduce fatty liver disease in children. In studies that may alert clinicians to patients with heightened need for intervention, scientists found that elevated levels of the hormone FGF-23 mark increased risk for heart disease and death in people with chronic kidney disease, while high levels of certain amino acids in the blood signify increased risk for type 2 diabetes.

Looking forward, NIDDK is committed to continuing funding for clinical research. Because many diseases within our mission disproportionately affect certain populations, we will also continue to seek insights and answers to health disparities. As just a few examples of our many clinical studies, Institute-supported scientists will conduct trials of approaches to prevent or slow the onset of type 1 diabetes, and they will press forward in developing technology to create an artificial pancreas for people with diabetes. In a new effort, the Institute is planning a comparative effectiveness study of commonly used drugs for type 2 diabetes. We will also continue a promising, long-term clinical trial of a lifestyle intervention designed to promote weight loss and improve health in obese people with type 2 diabetes. Among multifaceted efforts to meet the challenge of obesity will be a consortium studying lifestyle interventions for overweight and obese pregnant women, to improve the health of both mother and child. The Institute will continue to support clinical studies for a range of liver diseases; for example, a multicenter research network is planning trials of different treatment strategies for hepatitis B, including comparative effectiveness research. Multiple efforts will pursue approaches to combat chronic kidney disease, polycystic kidney disease, primary glomerular disease, and other forms of kidney disease and injury. We have also spearheaded an initiative encouraging studies to prevent and treat obesity, diabetes, and kidney disease in military populations. NIDDK continues to support a multi-disciplinary study in chronic urologic

pelvic pain, and will support a new research network to improve measurement of the complex symptoms of lower urinary tract dysfunction in men and women and to advance clinical studies. To maximize the reach and benefits of interventions proven successful in clinical trials, we will sustain support for translational research, to implement these in real-world medical practice and community settings, cost effectively, for diverse populations. For example, an NIDDK-funded research project provided the first demonstration that YMCAs, now officially called Ys, can deliver a group-based version of the lifestyle intervention shown to reduce type 2 diabetes in the Diabetes Prevention Program clinical trial.

SUPPORTING AN INNOVATIVE, MULTIDISCIPLINARY WORKFORCE

Research breakthroughs happen only through the efforts of a creative, well-trained workforce. Thus, NIDDK will continue programs to train and support researchers at all stages of their careers, and to ensure that we benefit from the best scientific minds. NIDDK supports summer research opportunities for underrepresented high school and college students, workshops for minority investigators and new investigators, a new initiative for professional societies to promote diversity in the research workforce, and other efforts. We will continue to support investigator-initiated projects, along with solicited research that is guided by input from expert researchers and the public.

INTEGRATING SCIENCE-BASED INFORMATION INTO PRACTICE

We will also continue to support education, outreach, and awareness programs. These efforts include materials tailored for diverse audiences and span the range of diseases within our mission, to bring vital, science-based knowledge to healthcare providers, patients and their families, and the general public.

In closing, NIDDK's future research investments will build upon findings from past and ongoing studies, pursue promising new opportunities, and tackle critical challenges toward innovative and more effective prevention and treatment strategies. Our research will be guided by five principles:

- maintain a vigorous investigator-initiated research portfolio;
- support pivotal clinical studies and trials;
- preserve a stable pool of new investigators;
- foster research training and mentoring; and
- disseminate science-based knowledge through education and outreach programs.

PREPARED STATEMENT OF HAROLD VARMUS, M.D., DIRECTOR, NATIONAL CANCER INSTITUTE

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Cancer Institute (NCI) of the National Institutes of Health (NIH). The fiscal year 2013 NCI budget of \$5,068,864,000 includes an increase of \$2,717,000 more than the comparable fiscal year 2012 level of \$5,066,147,000.

As many of you will read upon its release later today, the 2012 annual report to the Nation on the status of cancer offers a generally encouraging view of cancer trends. The report documents that death rates from all cancers combined for men, women, and children in the United States continued to decline between 2004 and 2008, the latest year for which we have complete analysis. Age-adjusted mortality rates for 11 of the 18 most common cancers among men and for 14 of the 16 most common cancers in women have declined. The overall rate of new cancer diagnoses, also known as incidence, among both men and women also declined over similar periods, although for women the decline leveled off from 2006–2008.

These continued declines in death rates for most cancers, as well as the overall drop in incidence, are powerful evidence that our Nation's investment in many fields of cancer research produces life-saving approaches to cancer control. The breadth of the Nation's cancer portfolio and our ability to pursue many different approaches to cancer research must match the heterogeneity of cancer itself, which we now understand to be literally hundreds of genetically distinct diseases with many avenues to prevention, screening, diagnosis, and treatment.

BASIC AND SCIENCE

A large part of the NCI basic research portfolio uses molecular biology and genetics to deepen our knowledge about the origins and behavior of cancers and to develop drugs and understand drug resistance. For example, decades of basic research culminated in development of the molecularly targeted drug Gleevec (imatinib).

Since the U.S. Food and Drug Administration (FDA) approved the drug in 2001, it has been the treatment of choice—and a very effective one—for chronic myelogenous leukemia (CML) as well as a few other cancers. Targeted drugs usually inhibit enzymes—in this case, kinases—that are essential to the survival of cancer cells, rather than broadly killing all rapidly dividing cells in the body. In CML, the target is the abnormal protein made by fused genes, BCR-ABL, in cancerous blood cells, where in its activated or “on” state the mutant enzyme pushes white blood cells into overdrive, causing disease. Gleevec blocks the mutant enzyme, kills cancer cells, and returns the blood system and the patient to a normal state.

But despite Gleevec’s generally powerful effects, some CML patients relapse when new mutations make the BCR-ABL protein resistant to Gleevec, allowing the abnormal enzyme to drive white blood cell growth again despite treatment. This phenomenon, drug resistance, is now being encountered with the several other targeted therapies more recently introduced for lung cancer, melanoma, and other cancers. So it is encouraging to report that NCI-supported research has identified a number of drugs targeting BCR-ABL proteins even after they acquire mutations that confer resistance to Gleevec. Two of these, approved a few years ago, did not overcome relatively common resistance mutation. But a third generation of drugs is able to do that, in an interesting new way, by freezing the target protein in an inactive conformation, so that its enzyme cannot work. This example illustrates another important point. Many different research streams—from genetics to structural biology to pharmacology—were required for these advances in treatment. The need to bring together multidisciplinary teams to focus on key questions like drug resistance in cancers increasingly defines modern biomedical research.

To strengthen NCI’s ability to drive similar discoveries, NCI this year consolidated a number of its genomics initiatives—including the flagship program The Cancer Genome Atlas (TCGA)—into a single Center for Cancer Genomics. TCGA’s aim is to characterize comprehensively the genomic alterations in hundreds of samples of about 20 known tumor types. With the project nearing completion on schedule, the vast influx of data promises to dramatically alter our knowledge of the genetic changes that drive cancer development. The new center will work with other components of NCI to ensure that the findings are applied to developing new diagnostics and therapeutics and are integrated swiftly into medical practice.

SCREENING AND PREVENTION

Early detection of cancer can enhance therapy. Last year I briefed this subcommittee on the recently concluded National Lung screening trial, which had demonstrated that current and former smokers who were screened with low-dose helical computed tomography were 20 percent less likely to die of lung cancer compared to others who received standard chest xrays.

Recent findings from another long-term study also point to screening as an effective way to cut deaths from another common cancer—colorectal adenocarcinoma, which kills about 49,000 Americans every year. Clinical studies, several funded by NCI, have consistently demonstrated that tests for fecal blood and direct observation of the colon with endoscopy can effectively reduce the mortality rates associated with colorectal cancer—by up to 50 percent, according to one recent estimate. NCI also is investing in studies to understand behavioral and economic barriers to screening to increase screening rates, especially among minority populations.

DIAGNOSIS AND TREATMENT

One of the most critical aspects of cancer is its remarkable heterogeneity—cancer is actually a collection of hundreds of genetically distinct diseases, each with its unique vulnerabilities. Lung adenocarcinomas, for instance, develop through a variety of genetic changes, and each pattern of changes requires a different therapeutic approach. Just a few years ago, it was recognized that up to 7 percent of lung adenocarcinomas contain a fused chromosome that activates the protein made by a gene called ALK to cause cancerous growth. FDA last fall approved crizotinib to treat patients with the abnormal ALK gene. Crizotinib blocks the activity of the enzyme, again a kinase, produced by the fused ALK gene, similar to the action of Gleevec in CML. This oral drug has been approved by the FDA and must be used with a companion molecular test to make sure it is used to treat only tumors with the abnormal ALK gene.

Another potential treatment recently emerged from academic research laboratories, this one for metastatic prostate cancer. MDV-3100 is a so-called anti-androgen therapy that prevents male hormones from stimulating the growth of prostate cancer cells through androgen receptors—preventing testosterone from binding to androgen receptors and preventing the androgen receptor from initiating

the production of proteins that induce tumor growth. Current anti-androgen drugs suppress the growth of prostate cancer cells temporarily, but in most patients, the cancer ultimately develops resistance to these drugs by increasing the amount of receptors. MDV-3100, by contrast, binds so tightly to the androgen receptors that it prevents them from functioning even when the receptor numbers are very high. The new drug performed so well that the clinical trials were halted early, and the drug now awaits approval at FDA.

PROVOCATIVE QUESTIONS

During the past 14 months, NCI has brought together researchers to propose, craft, and debate what they consider to be the critical questions in cancer research that may fall outside our current sphere of focus, but that could lead to important discoveries about the causes and behaviors of cancers. NCI convened 17 workshops across the country that identified some 24 provocative questions, and NCI has set aside an initial \$15 million from its fiscal year 2012 budget to fund some of the more than 750 applications received under this program. While this initiative does not replace NCI's longtime and essential emphasis on funding investigator-initiated research, it represents a useful new approach to making the greatest impact with our research dollars.

The Congress's past investments in cancer research are the reason we are able to report promising scientific findings each year, and why the report to the Nation continues to show steady progress against a wide range of cancers. We are now able to define genetic changes that cause cancer, use them to control cancer with more precise tools, and thereby reduce the Nation's cancer burden. The President's budget for 2013 for the NCI will provide the support for discoveries in basic science, cancer control and prevention, for early detection and diagnosis, and for methods to prevent, treat, and in some instances, cure cancers.

PREPARED STATEMENT OF RICHARD J. HODES, M.D., DIRECTOR, NATIONAL INSTITUTE ON AGING

Mr. Chairman and members of the subcommittee: I am pleased to present the President's fiscal year 2013 budget request for the National Institute on Aging (NIA) of the National Institutes of Health (NIH). The fiscal year 2013 budget includes \$1,102,650,000, which is \$522,000 more than the comparable fiscal year 2012 level of \$1,102,128,000.

More than 40 million people age 65 and older live in the United States, and data from the Federal Interagency Forum on Aging-Related Statistics indicate that their numbers will double by 2040. In less than 50 years, the number of "oldest old"—people ages 85 and older—may quadruple. As record numbers of Americans reach retirement age and beyond, profound changes will occur in our economic, healthcare, and social systems.

NIA leads the national effort to understand aging and to identify and develop interventions that will help older adults enjoy robust health and independence, remain physically active, and continue to make positive contributions to their families and communities. We support genetic, biological, clinical, behavioral, and social research related to the aging process, healthy aging, and diseases and conditions that often increase with age. We also carry out the crucial task of training the next generation of researchers who specialize in understanding and addressing the issues of aging and old age.

BUILDING MOMENTUM IN THE FIGHT AGAINST ALZHEIMER'S DISEASE

Estimates of how many people in the United States currently have Alzheimer's disease (AD) range from 2.7 to 5.1 million, depending on how AD dementia is defined and measured. However, scientists agree that unless the disease can be effectively treated or prevented, the numbers will increase significantly if current population trends continue.

At the same time, there has never been greater cause for optimism. In recent years, we have expanded our understanding of how the disease takes hold and progresses, identified promising targets for intervention, and developed new models to speed discovery. For example, researchers have developed a mouse model that expresses human tau, one of AD's pathological hallmarks, and discovered that tau pathology is transmitted from cell to cell, beginning in the brain's entorhinal cortex and spreading from one brain region to the next. This discovery provides insight into AD's earliest development and offers a model for testing mechanisms and functional outcomes associated with disease progression. In another study, investigators

“reprogrammed” human skin cells into induced pluripotent stem cells, which then differentiated into working neurons; this breakthrough will facilitate the study of AD in human neurons and provide important insight into the etiology of the disease.

Advances in imaging technology, most notably through the NIH-supported Alzheimer’s Disease Neuroimaging Initiative (ADNI), have expanded our ability to understand the underlying pathology of AD, diagnose the disease, track the progress of interventions, and even identify individuals at risk. ADNI data were also used last year to develop new, more comprehensive diagnostic guidelines at both the clinical and pathological levels.

NIH currently supports more than 35 clinical trials, including both pilot and large-scale trials, of a wide range of interventions to prevent, slow, or treat AD and/or cognitive decline; more than 40 compounds are in preclinical development through the AD Translational Initiative. NIA also participates in the NIH Neuroscience Blueprint under which investigators developing new compounds will have access to drug development services not typically available to the academic research community.

Investigators are also “re-purposing” treatments for other diseases as treatments for AD, with encouraging results. For example, a pilot clinical trial recently demonstrated that a nasal-spray form of insulin was able to delay memory loss and preserve cognition in people with cognitive deficits ranging from mild cognitive impairment (often a precursor condition to AD) to moderate AD. In a separate study, the skin cancer drug bexarotene promoted clearance of amyloid-beta and reversed cognitive deficits in mice. These preliminary findings offer new and exciting possibilities for the effective prevention and treatment of AD.

NIA has been an active participant in the implementation of the National Alzheimer’s Project Act, including the development of a national plan to address AD. A new Presidential initiative to boost support for AD research, which will provide an additional \$50 million in fiscal year 2012 and \$80 million in fiscal year 2013 for the disease, will stimulate and support important groundbreaking work in a number of areas, including AD-extensive whole genome sequencing to identify genetic risk and protective factors for AD. Our activities will be informed by input from expert advisors participating in the May 2012 Alzheimer’s Disease Research Summit.

UNDERSTANDING AGING AT THE MOST BASIC LEVEL

NIA initiatives on the molecular mechanisms of aging, from in-depth study of single cells to the broad study of organisms at the systems level, continue to advance our understanding of the basic underpinnings of the aging process. For example, investigators recently found that it was possible to delay onset of age-related changes in the skeletal muscle, fat, and eye tissues in mice by removing senescent cells—i.e., cells that are alive but no longer functional. The study also found a slowing of progression of age-related disorders in the mice. These results suggest that cell senescence may be a fundamental mechanism that drives aging.

IMPROVING THE HEALTH AND WELL-BEING OF OLDER AMERICANS

As the American population continues to age, it is imperative that we identify the optimal means to address the unique health needs of older individuals. For example, the Centers for Disease Control and Prevention reports that fully one-half of older Americans have at least two chronic health conditions that compromise quality of life. NIA is participating in a trans-NIH initiative to develop interventions to modify behavior and improve health outcomes among individuals with or more chronic conditions.

Increased adherence to recommended medication regimens promises substantial improvements in public health as well as savings in healthcare costs. NIA-supported investigators found that simply encouraging people to write down the time and date when they plan to receive a flu vaccination can significantly increase vaccination rates. NIA also participates in an NIH-wide initiative to identify practical interventions to improve medication adherence in the primary care setting.

Studies have shown that regular physical activity can improve physical performance in older people, but definitive evidence that physical activity can prevent mobility disability is lacking. NIA supports the Lifestyle Interventions and Independence for Elders Study to assess the effects of a structured physical activity program in 1,600 sedentary older individuals. With the U.S. Surgeon General, NIA has also launched its nationwide Go4Life campaign to motivate older Americans to engage in physical activity and exercise.

In the past year, preliminary results were released from the “Oregon Lottery” study, in which randomly selected low-income Oregon residents were able to enroll in the State’s Medicaid program. Compared to a control group, the new Medicaid

enrollees reported improved health and well-being, as well as reduced financial strain. Use of important types of healthcare services such as preventive care also increased.

EMPOWERING THE NEXT GENERATION OF AGING RESEARCHERS

The need for healthcare professionals who specialize in the unique needs of older individuals is becoming ever more urgent. We must not only increase the number of practicing physicians trained in geriatrics and in subspecialty fields related to the health problems of elders but also foster the development of the next generation of physician-scientists whose clinical research will lead to improved care and more effective treatment options for older patients with complex medical conditions. Recently, NIA established the Grants for Early Medical/Surgical Subspecialists' Transition to Aging Research (GEMSSTAR) program to promote future leaders in clinical aging research through support of physicians who seek to become clinician-scientists in geriatric aspects of their subspecialty. NIA has also established a program targeting undergraduate students from diverse backgrounds in order to advance their interest in and knowledge of aging issues.

PREPARED STATEMENT OF THOMAS R. INSEL, M.D., ACTING DIRECTOR, NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

Mr. Chairman and members of the subcommittee: It is a privilege to present to you the President's budget request for the newly established National Center for Advancing Translational Sciences (NCATS) for fiscal year 2013. The fiscal year 2013 budget of \$639,033,000 includes \$64,320,000 more than the comparable fiscal year 2012 level of \$574,713,000. We are thankful for your support for this new Center and look forward to sharing progress with you as the Center evolves.

Our mission is to catalyze the generation of innovative methods and technologies that enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. As such, NCATS will focus on addressing scientific and technical challenges in order to reduce, remove, or bypass significant hurdles across the continuum of translational research. These advances will enable others in both the public and private sectors to develop drugs and diagnostics more efficiently for any number of human diseases—ultimately accelerating the pace in which new therapeutics are delivered to the patients who need them.

FULFILLING OUR MISSION

In achieving its aims, NCATS activities will be guided by three important principles:

- facilitate—not duplicate—other translational research activities supported by NIH;
- complement—not compete with—efforts already underway in the private sector; and
- reinforce—not reduce—NIH's commitment to basic research.

These guiding principles underscore the role of NCATS as a catalytic hub for evidence-based research on the process of translating scientific discoveries into new diagnostics and therapeutics.

Key to the success of the NCATS mission is identifying, studying, and reducing significant bottlenecks in the process of translation, which will require extensive consultation with experts across disciplines and sectors. NIH held numerous workshops for stakeholders to solicit ideas for the NCATS research agenda. A working group of several NIH Institute and Center Directors, including those most involved in translational research, clarified the need for a new effort focused on the discipline of translation, providing tools and resources that could facilitate research across NIH. A working group of the NIH advisory committee to the Director, comprised of experts from industry, private equity firms, nonprofits, and academia identified the need for NCATS to catalyze, invigorate and streamline translational sciences nationally and globally. Many areas of priority were identified, including research on biomarkers, predictive toxicity, target validation, regulatory science and de-risking the pipeline. The perspectives of both of these working groups are reflected in several of the NCATS initiatives being pursued, ensuring that NCATS is not duplicating other efforts at NIH or competing with efforts in industry.

NCATS is currently assembling an advisory structure comprising both the NCATS advisory council and the Cures Acceleration Network (CAN) review board. These individuals will span many sectors, from patient advocacy organizations to pharma-

ceutical industry and private equity firms, along with renowned experts in translational science and regulatory review.

CATALYZING INNOVATION IN CLINICAL RESEARCH

Re-engineering and accelerating the clinical research enterprise is a major priority for NCATS. The Clinical and Translational Science Awards (CTSAs), which represent nearly three quarters of the proposed NCATS budget, will lead our efforts to re-engineer and accelerate clinical research. Across the Nation, CTSA institutions have been supporting first-in human trials for rare and common diseases; developing and testing innovative trial designs; and developing postmarketing clinical research. Since the first awards in 2006, the CTSAs have transformed clinical research in academic medical centers, creating new homes for translational science, integrating communities into the research process, and training a new generation of interdisciplinary clinical researchers. An external evaluation of the CTSA program has been conducted and offers constructive recommendations for ensuring that this highly valuable program is optimally leveraged and aligned with NCATS as we move forward.

To accelerate research, the CTSAs have developed innovative informatics tools, such as REDcap, a freely available tool for clinical study management and capture, and ResearchMatch, a free, secure, Web-based registry which now has more than 20,000 volunteers for research studies and enables researchers to find the “right match” to participate in studies.

In 2013, we will be launching CTSA 2.0, the next phase of this program building on the successes of the past 6 years. While CTSA 1.0 established homes for translational research, CTSA 2.0 can create neighborhoods, networks of centers with shared resources to accelerate research on rare diseases and new therapeutics. Going forward, the CTSAs can have an even broader role on translational science, supporting the entire pipeline of development from bench to bedside, bedside to practice, and beyond practice to public health policy.

CATALYZING INNOVATION IN THERAPEUTICS

Drug development is expensive, slow, and failure prone. Approximately 90 percent of compounds that advance to clinical testing fail to reach the market. While NCATS will not create an industrial drug development pipeline, it can experiment on the process, identifying solutions for specific problems in drug development.

For instance, of the most common concerns we heard from industry, patient groups, and the Food and Drug Administration (FDA), was the need for detecting toxicity early in the drug development process. Roughly one-third of the failures of new medications can be attributed to toxicity not predicted from preclinical (animal or in vitro) studies. NCATS is working with the Defense Advanced Research Project Agency (DARPA) and the FDA to design a chip composed of diverse human cells and tissues with read outs that can detect toxicity. This “tissue chip” should make drug safety assessments more accurate and even make them possible earlier in the translational pipeline. DARPA and NIH have committed approximately \$70 million each over 5 years and FDA will provide guidance. The first applications were received in late January 2012 and will be funded this year with partial support from the NIH common fund.

Aside from predicting toxicity, NCATS will be working on another innovation to speed medication development. Repositioning drugs that have not been approved (drug rescue) and drugs that are already approved (drug repurposing) are probably the most rapid and cost effective approaches to new therapies. As industry holds many of the assets and data required for efficient rescue and repurposing, many institutes at NIH have been interested in working with companies to access specific compounds. Rather than creating 26 different approaches, NCATS is working with industry to provide a single, comprehensive mechanism with several companies for drug rescuing. This will permit investigators and small businesses to apply for NIH funding to conduct research on new indications using compounds from industry-provided drug collections.

NCATS is also innovating the process of drug repurposing. Through the NCATS Pharmaceutical Collection, we have developed a comprehensive database of 3,800 approved and investigational drugs to permit NCATS to screen all existing medications for novel effects that might be therapeutic for a new indication. With this approach, we discovered that a drug approved for rheumatoid arthritis could be a novel treatment for leukemia. Rather than requiring 6–8 years for the usual preclinical research and development, we moved this approved compound into a leukemia trial (in a CTSA institution) within 9 months. Continued funding of this program in fiscal year 2013 will contribute to the NIH effort of decreasing the time,

cost, and attrition rate in therapeutic development, to bring more promising new therapies to the public.

SUPPORT FOR RARE AND NEGLECTED DISEASES

There are more than 6,000 rare diseases, affecting an estimated 25 million Americans. Fewer than 250 of these rare diseases have treatments, according to data from the Online Inheritance in Man Database, Orphanet, and FDA. It is clear that efforts need to be directed to increasing the number of treatments either through new or repurposed drugs. The Therapeutics for Rare and Neglected Diseases (TRND) program within NCATS develops treatments for rare diseases, with 20 projects currently underway. But TRND is not a typical drug development effort—the projects are selected as experiments on the pipeline of drug development. That is, each project is an attempt to re-engineer the process in addition to addressing a medical need. For instance, a project on sickle cell disease has introduced a new class of molecules not previously considered as medications for any disease. Moreover, the study of rare diseases, including many single gene disorders (Niemann-Pick Type C and Hereditary Inclusion Body Myopathy), is also giving us new insights into fundamental biology. This process, sometimes called reverse translation because it moves from “bedside to bench,” is one of the ways that NCATS is reinforcing rather than reducing NIH’s commitment to basic research.

INVESTING IN PEOPLE

NCATS fosters the training of clinicians and researchers in an environment of innovation and collaboration, encouraging the next generation of leaders in translational sciences. For example, the CTSA’s are currently supporting more than 900 trainees across a wide array of disciplines. NCATS will promote novel training mechanisms, such as drug development apprenticeships for early-stage investigators, and explore cross-training of physicians and scientists between industry and academia.

CONCLUSION

The creation of NCATS offers an exciting new opportunity for accelerating the development of new and more effective therapeutics and diagnostics; namely by approaching the process of translation as a scientific challenge. By encouraging biomedical researchers across the Nation to experiment with new and innovative ways of improving these processes, our best and brightest can meet today’s challenges head on. Moreover, the development of new tools and methodologies enable all sectors to participate in this arena, maximizing the likelihood of ensuring much needed products are actually available to those who need it the most—patients.

PREPARED STATEMENT OF JAMES F. BATTEY, JR., M.D., PH.D., DIRECTOR, NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Mr. Chairman and members of the subcommittee: I am pleased to present the President’s budget request for the National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health (NIH). The fiscal year 2013 NIDCD budget of \$417,297,000 includes an increase of \$1,519,000 over the comparable fiscal year 2012 level of \$415,778,000.

The NIDCD conducts and supports research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language. Our Institute focuses on disorders that affect the quality of life of millions of Americans in their homes, workplaces, and communities. The physical, emotional, and economic impact for individuals living with these disorders is tremendous. NIDCD continues to make investments to improve our understanding of the underlying causes of communication disorders, as well as their treatment and prevention. It is a time of extraordinary promise, and I am excited to be able to share with you some of NIDCD’s ongoing research and planned activities addressing communication disorders.

EARLY EXPERIENCE SHAPES SALT PREFERENCE

Even though we know that too much salt is bad for our health, many of us still consume too much of it. In a typical diet, a lot of salt comes from starchy foods, such as breads and cereals. Too much salt can cause high blood pressure, or hypertension. Although hypertension itself usually has no symptoms, it can cause serious health problems such as stroke, heart failure, heart attack, and kidney failure. NIDCD-supported scientists determined that babies whose diets contain starchy,

salty foods will develop a preference for salty taste by as early as 6 months of age, as compared to babies who have not been given salty foods. During a preference test, the babies accustomed to saltier diets consumed 55 percent more salt than their unexposed peers. Salt preference endures into the preschool years, when children exposed to a salty diet as babies are more likely to consume plain salt. This research identifies a potential role for early dietary experiences in shaping taste preferences that could influence salt consumption in our adult years. If these results can be repeated in a larger study population, it suggests that we may be able to reduce salt consumption in future generations by encouraging parents to restrict salt in their babies' early diets. Reducing salt consumption will also reduce the incidence of hypertension, thus reducing healthcare costs due to hypertension and the serious health problems it can cause.

IDENTIFICATION OF MAJOR PROTEINS INVOLVED IN HEARING

According to NIDCD statistics, 2 to 3 out of 1,000 children in the United States are born deaf or hard of hearing, with changes in genes being a major cause of hearing impairment. NIDCD-supported scientists have shown that mutations in the TMC1 and TMC2 genes cause hereditary deafness in humans and mice. Further, they discovered that the proteins encoded by TMC1 and TMC2 genes may be key components of the long-sought after mechanotransduction channel in the inner ear—the place where mechanical stimulation of sound waves is transformed into electrical signals recognized by the brain as sound. Using mice without the TMC1 and TMC2 genes, the scientists discovered the mice had a deficit in the mechanotransduction channels in their stereocilia, the sound-sensing organelles of the inner ear, while the rest of the auditory hair cell's structure and function was normal. These genes and the proteins they regulate are the strongest candidates yet in the search for the transduction channel. If these genes do indeed encode the transduction channel, they will be useful tools to screen for drugs or molecules that bind to or pass through the channel and could be used to prevent damage to hair cells.

KEEP NOISE DOWN ON THE FARM

Farming is loud work. Squealing pigs, grinding combines, whirring power tools, and roaring vehicles can add up to a lot of noise. Prevention and treatment of noise-induced hearing loss (NIHL) is a priority for the NIDCD. NIDCD's campaign "It's a Noisy Planet. Protect their Hearing" promotes early education of elementary and middle-school children about NIHL and how to prevent it. The NIDCD has introduced new materials for parents of children who live and work on a farm to help them develop healthy hearing habits and protect their hearing for life. The NIDCD hopes that these materials will help protect individuals who live and work on a farm from developing NIHL. Preventing NIHL will improve quality of life for the millions exposed to noise, and decrease overall healthcare costs.

SALIVA IS EFFECTIVE IN SCREENING FOR CYTOMEGALOVIRUS INFECTION IN NEWBORNS

In June, NIDCD-supported scientists reported that swabbing a newborn's mouth for saliva can be used to quickly and effectively screen for cytomegalovirus (CMV) infection, a leading cause of progressive hearing loss in children. Scientists at the University of Alabama at Birmingham (UAB) determined that saliva correctly identified every baby born with the infection when liquid samples were used, and 97.4 percent of babies when the samples were dried. Most babies infected with CMV don't show symptoms at birth. NIDCD has placed a high priority on developing diagnostic tools to screen babies for congenital CMV infection, so that those who test positive can be monitored for possible hearing loss. These children can be provided with appropriate intervention as soon as possible. Because of this research, we know that testing saliva is an effective way to identify children at risk for hearing loss due to CMV.

HIV-EXPOSED CHILDREN AT HIGH RISK OF LANGUAGE DELAY

Children who do not use language well may not do well in school and may also have difficulty communicating with their peers and establishing friendships. A recent study funded by the NIDCD and seven other NIH Institutes found that 35 percent of a group of school-age children born to women with an HIV infection during pregnancy have difficulty understanding spoken words and expressing themselves verbally. These data should encourage those caring for children exposed to HIV in the womb to provide early treatment for language impairments.

PREPARED STATEMENT OF LINDA S. BIRNBAUM, PH.D., D.A.B.T., A.T.S., DIRECTOR,
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). The fiscal year 2013 NIEHS budget of \$684,030,000 includes a decrease of \$725,000 less than the comparable fiscal year 2012 level of \$684,755,000.

INTRODUCTION

As the Dutch philosopher Desiderius Erasmus so succinctly put it: Prevention is better than cure. In most instances, disease is a result of a combination of age, genetics, and environment. But unlike age and genetics, environment is something that we can affect in order to prevent illness. As an environmental public health institute, the NIEHS is entrusted with the mission to prevent human suffering and illness by creating and sharing the knowledge necessary for understanding the role of the environment in disease, and thereby enable people to lead healthier lives. NIEHS continually strives to lead public health prevention efforts by providing research science and translation to inform decisions and policies at the individual, community, national, and global levels that prevent hazardous environmental exposures and thus reduce disease and disability. Many of the most challenging diseases—and most costly in terms of both human suffering and economic resources—are being shown to have strong environmental components. Diseases such as cardiovascular disease and stroke, that cause 1 in 3 deaths in America each year, have been associated with exposure to environmental agents such as air pollution and secondhand smoke. An estimated nearly 70 percent of Americans older than the age of 20 are overweight or obese; for children the figure is more than 30 percent. New research, including studies funded by the NIEHS, shows that obesity and its common companion diabetes are complex disorders that are affected not just by food consumption and physical exertion but also by environmental factors including exposures to environmental contaminants during early life. Greater understanding of the role of such exposures and concomitant efforts to prevent them could dramatically change the trend of this increasing public health epidemic. And the list goes on. Strong associations have been shown between exposure of pregnant mothers to chemicals, including polybrominated diphenyl ethers added to products as flame retardants, and a range of neurodevelopmental disorders, learning disabilities, and behavioral effects in their children. NIEHS continues to commit significant efforts to increasing our understanding of these health effects and how they might be prevented. On a global level, the problem of respiratory illnesses resulting from exposure to indoor air pollution represents an area ripe for intervention. Toxic smoke from burning biofuels in cookstoves kills nearly 2 million people each year, largely women and children, according to the World Health Organization. NIEHS is part of the Global Alliance for Clean Cookstoves, a public-private initiative working to eliminate exposure to harmful cookstove smoke. This is a tractable prevention problem with a potentially huge payoff in public health.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES STRATEGIC PLANNING

Looking at this long list of environmentally related diseases raises the question, "How can one Institute have an impact on research and disease prevention in all these areas?" To answer this question, NIEHS is striving to maximize its impact and leadership in the environmental health sciences through a comprehensive and inclusive strategic planning process focused on identifying key strategic goals for the next 5 years. Through this process, NIEHS hopes to achieve its vision of providing a catalyst for leading the field of environmental health sciences in applying state-of-the-art biomedical research to the most important issues surrounding environmental impacts on health.

Six broad-based themes of this plan have been established, through ongoing dialogue with research scientists and stakeholder groups. "Fundamental Research" investigates basic biological pathways of how our bodies function, to set the stage for asking more in-depth questions about the effects of the environment on biological systems. "Exposure Research" focuses on the study of environmental exposures themselves, internal and external to the body. And since NIEHS recognizes that information is only effective if it can be translated into sound decisions, "Translational Science" is identified as a key theme covering research that moves a basic science observation into a public health or medical application. NIEHS also affirms its commitment to "Health Disparities and Global Environmental Health" in recognition of the fact that individuals and communities that are socioeconomically disadvantaged

also tend to suffer inequalities in both health and environmental burdens. Through “Training and Education,” NIEHS recognizes the need to develop the next generation of top-notch, innovative, and dedicated environmental health scientists and professionals. Finally, to fulfill its mission and statutory mandate to disseminate information, NIEHS is committed to developing a full range of research translation and communication tools and creative stakeholder partnerships. This “Communications and Engagement” theme is vital for realizing the Institute’s mission to promote public health and prevent environmentally related disease and disability. Two cross-cutting themes, “Collaborative and Integrative Approaches” and “Knowledge Management” will be implemented across the other themes to ensure the success of the goals throughout the strategic plan.

RECENT ACCOMPLISHMENTS

The NIEHS strategic plan highlights areas of leadership that will build on an impressive list of recent research accomplishments. For example, NIEHS-funded researchers recently published the first study documenting how exposure to perfluorinated compounds (PFCs), widely used in manufactured products such as nonstick cookware, was associated with lowered immune response to vaccinations in children. Other recent research funded by NIEHS has shown that even moderate air pollution, at levels generally considered safe under current Federal regulations, increases the risk of stroke by 34 percent.

NIEHS is also committed to helping those impacted by environmental exposures. In the aftermath of the Deepwater Horizon disaster, many questions remain about the long-term impact on the health of gulf coast residents and communities. NIEHS is leading a trans-NIH effort to create a network of community and university partnerships that seeks to identify personal and community health effects stemming from the Deepwater Horizon oil spill and to enhance community resiliency to potential disasters. The 5-year, \$25.2 million program will support population-based and laboratory research, which will ultimately develop the scientific evidence base needed to promote health and well-being for people living along the gulf coast who are at greatest risk for potential adverse physical, psychological, and behavioral health effects. In addition, research will seek to develop new strategies to enhance capacity to respond to future disasters and prevent or minimize adverse health effects arising from them. Once completed, research findings from the Deepwater Horizon Research Consortia should contribute to the evidence base needed to improve preparedness and response aimed at minimizing disaster-related health impacts.

Ultimately, NIEHS remains committed to its overall mission to discover how the environment affects people’s health, in order to promote healthier lives.

PREPARED STATEMENT OF JOSEPHINE P. BRIGGS, M.D., DIRECTOR, NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Mr. Chairman and members of the subcommittee: As the Director of the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health (NIH), I am pleased to present the President’s fiscal year 2013 budget request for NCCAM. The fiscal year 2013 budget includes \$127,930,000, which is \$26,000 more than the comparable fiscal year 2012 level of \$127,904,000.

The landscape of our healthcare system is changing in many important ways. Among them is a clear trend toward incorporation of complementary health practices, which often have origins outside of conventional medicine, into integrative approaches to care. There are a number of factors—including consumer demand and emerging scientific evidence—driving these changes. Nonetheless, there are compelling needs of the public, healthcare providers, and policymakers for good scientific evidence on the safety and potential benefit of these complementary and integrative approaches. Using the highest standards of scientific rigor, NCCAM is committed to developing evidence about practices that are being integrated into healthcare. We are particularly interested in those cases where there is scientific opportunity and/or important public health need.

TRENDS IN COMPLEMENTARY AND INTEGRATIVE HEALTHCARE

National surveys conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention show that nearly 40 percent of Americans report using one or more practices such as acupuncture, massage, yoga, meditation, spinal manipulation, dietary supplements, or herbal medicines to help manage their health and wellness. Similarly, data show that healthcare systems and providers are incorporating such interventions. For example, an American Hos-

pital Association survey conducted in 2007 showed that 37 percent of hospitals offered complementary modalities; and a national study reported last year by the NCHS reported widespread availability of complementary approaches in hospice settings. Other data from the Departments of Defense (DOD) and Veterans Affairs (VA) show increasing use of complementary modalities in their populations. According to the VA, 89 percent of their facilities offered complementary therapies in 2011. Both the DOD and VA have integrated complementary modalities into the care of patients with post-traumatic stress and sleep disorders, and to improve treatment of pain.

REDUCING PAIN AND IMPROVING SYMPTOM MANAGEMENT

One area of urgent public health need is better strategies for managing chronic pain. According to the Institute of Medicine, chronic pain affects an estimated 116 million Americans, and costs the Nation approximately \$635 billion each year. Chronic pain is the most frequently cited reason for which Americans use complementary health practices. For many individuals suffering from chronic pain, conventional approaches provide incomplete relief. Furthermore, pharmacological treatment with opioids or anti-inflammatory drugs can have significant adverse effects. There is now emerging evidence, much of it from NCCAM-supported studies, that some nonpharmacological interventions, such as massage, spinal manipulation, yoga, meditation, and acupuncture, may be helpful in treating chronic pain. Additional scientific evidence is needed to better understand these findings, and the optimal use and safety of these integrative approaches.

To this end, NCCAM is supporting a growing portfolio of studies on the use of nonpharmacological interventions for the management of chronic pain, including back and neck pain and pain associated with osteoarthritis, fibromyalgia, and headaches. In addition, we are supporting research to better understand the biological mechanisms by which complementary modalities may contribute to management of pain and other symptoms. For example, we recently funded Centers of Excellence for Research on Complementary and Alternative Medicine that use advanced functional and structural neuroimaging technologies to study pain. NCCAM is also providing leadership to a working group within the trans-NIH Pain Consortium to develop standards for research on chronic low back pain. Finally, in the next year, NCCAM plans to focus its intramural research program on understanding the role of the brain in chronic pain syndromes. The program will be highly collaborative with other intramural neuroscience programs on the NIH campus.

ADVANCING RESEARCH ON NATURAL PRODUCTS

NCCAM remains strongly committed to developing better evidence and information resources on the safety and efficacy of commonly used natural products. The Center is targeting investment in research in this arena on understanding the biological mechanisms of these products, thus creating the translational foundation for subsequent human studies.

In addition, research examining issues of safety is of great public health importance, given the widespread availability and use of these products by the public. In this regard, one area of specific need is rigorous scientific information about interactions of these products with drugs or with other natural products. This spring, NCCAM will lead a workshop, cosponsored by the NIH Office of Dietary Supplements and the National Cancer Institute, with researchers from a variety of fields to discuss ways to improve the methodologies needed to study herb-drug interactions. Workshop recommendations will help guide NCCAM's research agenda.

BUILDING AND DISSEMINATING RIGOROUS EVIDENCE

Researchers studying the effectiveness and safety of healthcare approaches already in widespread use face methodological challenges, challenges that are not unique to NCCAM's mission. To develop better methods of studying health outcomes in real-world settings, NCCAM is leading an NIH Common Fund Initiative, the Health Care Systems Research Collaboratory. The Collaboratory will develop innovative research partnerships with healthcare delivery organizations to maximize the potential use of electronic health information. NCCAM is also exploring possible collaborations with the DOD and the VA, aiming to leverage the data being gathered on the use of complementary and integrative practices in their healthcare systems. Additionally, NCCAM is providing leadership and support to the trans-NIH Patient-Reported Outcomes Measurement Information System (PROMIS), which will provide clinicians and researchers with more efficient and reliable means for gathering data on a variety of patient-reported measures of health and well-being.

NCCAM continues to provide reliable, objective, and evidence-based information on the usefulness and safety of complementary health practices to the public and healthcare providers. For example, NCCAM publishes the Clinical Digest (nccam.nih.gov/health/providers/digest), a monthly e-newsletter that summarizes the state of the science on complementary health practices and clinical guidelines. Additionally, NCCAM provides an online resource (nccam.nih.gov/health/providers) that enables healthcare providers to make informed recommendations.

CONCLUSION

Strong consumer use of complementary health practices, and growing integration of these practices into a variety of conventional healthcare settings are important trends in U.S. healthcare. While there is emerging evidence of promise for some, there are many important unanswered questions about effectiveness and safety. NCCAM remains committed to building the scientific evidence needed by consumers, providers, and health policy makers to make informed decisions about the use of complementary and integrative health practices.

PREPARED STATEMENT OF ROGER I. GLASS, M.D., PH.D., DIRECTOR, FOGARTY INTERNATIONAL CENTER

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the Fogarty International Center (FIC) of the National Institutes of Health (NIH). The fiscal year 2013 FIC budget of \$69,758,000 includes an increase of \$219,000 more than the comparable fiscal year 2012 level of \$69,539,000.

These are exciting times for global health. New HIV prevention strategies and the use of mobile technologies to extend the reach of health interventions are just two examples of research into emerging opportunities that can transform our efforts to improve health around the world. These are also examples of advances that can make a significant impact on health here at home as well as abroad. As populations in both the developed and developing world are vulnerable to existing and emerging infectious agents, as well as the growing noncommunicable disease (NCD) epidemic, there is no longer a "them" in global health, only an "us" (Global Health Council).

To most effectively address this shared burden of disease, U.S. scientists can only benefit from the unique insights and collaboration of skilled research partners around the world. At the NIH and within the U.S. Government, FIC plays a unique role by supporting the development of global health research expertise in the United States and abroad, and by fostering the international partnerships that extend the frontiers of science, accelerate discovery, and enable the United States to continue to lead in addressing the world's most pressing health challenges.

STRENGTHENING SUSTAINABLE RESEARCH CAPACITY

For over two decades, Fogarty has supported the long-term training of thousands of scientists worldwide. These scientists provide unique insights and perspectives on how to best combat global health challenges, and often contribute to groundbreaking research advances in collaboration with U.S. partners.

As the largest international commitment by any one country to fight a specific disease, the President's Emergency Plan for AIDS Relief (PEPFAR) relies on trained scientists to provide an evidence base for the new and effective strategies that have enabled PEPFAR programs and policies to make significant contributions to the progress toward an AIDS-free generation. For example, with support from Fogarty's longstanding HIV/AIDS research training program, Fogarty-supported researchers have provided evidence that a new, simpler, and shorter treatment regimen of antibiotics can prevent those infected with the tuberculosis (TB) bacterium—particularly those who also have HIV—from developing full-blown TB. In addition, Fogarty-supported researchers and trainees have also helped demonstrate: the effectiveness of anti-retroviral therapies in stopping mother-to-child transmission of the HIV virus; that male circumcision reduces HIV transmission to HIV-negative female partners; and a reduction in HIV transmission among women using microbicides that incorporate anti-retrovirals.

In response to the increased global burden of NCDs, Fogarty's NCD-Lifespan research training program supports partnerships between U.S. and low- and middle-income country (LMIC) institutions to build NCDs research capacity. By focusing on early childhood exposures and the genetic, environmental, and lifestyle risk factors that can contribute to later onset of disease, NCD-Lifespan projects are creating a cadre of investigators and institutions able to conduct research relevant to local and

global epidemics in areas such as cancer, stroke, mental illness, and metabolic disorders. In Ghana, for example, Fogarty is supporting the development of a Cardiovascular Research Training Institute as a partnership between New York University and the University of Ghana, to train investigators to conduct research on preventing and treating hypertension, diabetes, stroke, and chronic kidney disease. The resulting cadre of investigators will contribute research and expertise to the global effort to reduce cardiovascular disease morbidity and mortality.

With respect to identification of innovative, sustainable, and cost-effective strategies to fulfill its mission, Fogarty recognizes that information and communication technologies, mobile technologies, and distance learning can transform the way in which health and health research training can be conducted in the 21st century—particularly in resource-poor and remote settings. More than 50 Fogarty-supported projects have incorporated distance learning activities, which provide an innovative and cost-effective way to connect health research students in the developing world with state-of-the-art content on the other side of the globe.

NEW INVESTIGATORS, NEW IDEAS

Over the last decade, American university campuses have seen a soaring interest in global health among students and faculty from diverse fields, placing U.S. universities in an excellent position to help generate solutions to complex global health challenges. Fogarty's International Clinical Research Scholars and Fellows program and International Research Scientist Development Awards capitalize on this groundswell of interest to invest in future American leaders in global health research. These programs are investing in the next generation of talented American scientists, who will develop the skills and sensitivities to conduct research in international settings, and engage talented local researchers who can help to address complex health challenges that affect populations in the United States and abroad. Former Scholars and Fellows have developed innovative solutions to concrete global health problems. For example, in Zambia, Dr. Krista Pfaendler developed and implemented an effective and low-cost cervical cancer screening program using digital cameras for cervical photography and acetic acid (vinegar) for visual inspection.

In 2010, Fogarty piloted a 1-year program to support postdoctoral investigators in U.S. universities to carry out innovative, multidisciplinary team research in global health. With support from this program, scientists developed point-of-care telemedicine units built with \$2 microscopes that can be attached to a cell phone, enabling diagnosis of infectious diseases, such as malaria and HIV, in remote settings. Because of their ease of use, effectiveness, cost-effectiveness, and the ability for quick diagnosis, these microscopes have the potential to revolutionize care in resource-poor settings. The next generation of this program, Framework Innovations, will support U.S. and developing country institutions as they develop interdisciplinary postdoctoral research training programs in global health and enable young investigators to develop and test concrete and innovative health products, processes, and policies that respond practically and cost-effectively to critical health needs.

ADVANCING TRANSLATIONAL SCIENCE

Innovative strategies are needed to translate biomedical discoveries into new therapies, diagnostics, and prevention tools. Supported by Fogarty's International Cooperative Biodiversity Groups Program, United States and international scientists conduct discovery research on potential health applications of molecules—from plants, animals, and micro-organisms—and initiate partnerships with companies interested in developing these molecules for potential new drugs or diagnostics. This public-private partnership model has led to four active patents in the areas of cancer, parasitic diseases, and malaria.

CONCLUSION

As the world continues to become more interdependent, international scientific partnerships will play a critical role in building bridges between countries and scientists in the interest of advancing the health of our country and our globe. Fogarty invests in the best and brightest minds and catalyzes long-term, productive research collaborations. Working in partnership with the rest of the NIH, Fogarty's unique programs will continue to push the frontiers of science and enable scientists in the United States and abroad to work together to successfully tackle the world's most pressing and complex health challenges.

PREPARED STATEMENT OF PATRICIA A. GRADY, PH.D., RN, FAAN, DIRECTOR,
NATIONAL INSTITUTE OF NURSING RESEARCH

Mr. Chairman and members of the subcommittee: I am pleased to present the President's fiscal year 2013 budget request for the National Institute of Nursing Research (NINR) of the National Institutes of Health (NIH). The fiscal year 2013 NINR budget of \$144,153,000, includes a decrease of \$444,000 less than the comparable fiscal year 2012 level of \$144,597,000.

INTRODUCTION

I appreciate the opportunity to share with you a brief summary of some of the recent activities and future scientific directions of NINR. NINR supports clinical and basic research to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, enhance palliative and end-of-life care, and train the next generation of scientists. In doing so, NINR promotes and improves the health of individuals, families, and communities across the lifespan, in a variety of clinical settings and within diverse populations. NINR's emphasis on clinical research and training places NINR in a position to make major contributions to developing the evidence base for science-driven practice through innovative treatment and behavioral research.

Over the past year, we have commemorated NINR's 25th anniversary at NIH through a series of scientific outreach events that culminated in October 2011 with the release of NINR's new Strategic Plan: Bringing Science to Life. As NINR looks ahead to the next 25 years, the Institute is well-positioned to continue to advance rigorous science, develop and support evidence-based science-driven interventions across the lifespan, develop future leaders in nursing science, and contribute to improving the Nation's health and national healthcare system.

ADVANCING THE QUALITY OF LIFE: SYMPTOM MANAGEMENT

With the aging of a major sector of the Nation and advances in treatment of formerly fatal diseases, we are faced with a population that is living with multiple chronic conditions. The challenge of treating and managing these multiple conditions and their associated symptoms is one that confronts nearly all health practitioners, especially nurses involved with chronic illness management. NINR has invested deeply in the area of symptom management, from funding basic research on pain in our Intramural Research Program (IRP) to our extramural support for psychosocial and nutritional interventions to improve symptoms of chronic heart failure. Further, recognizing that chronic illness strikes across the lifespan, NINR also supports research aimed at helping children and adolescents manage their own chronic conditions and their symptoms more effectively to improve their quality of life. Finally, NINR initiated a call for research on the interconnections of diabetes and asthma, both on the rise in the United States; this research is focused on early life exposures that are associated with both conditions, as well as interventions that target the management of each disease and their synergisms.

HEALTH PROMOTION AND DISEASE PREVENTION

NINR is also heavily committed to health promotion and disease prevention. Nurses are often in unique positions as the health providers with the most frequent interactions with individuals and their support networks, and are therefore well-poised to help develop interventions that promote health and prevent disease. In one example, NINR currently supports an innovative community-based program in urban Pennsylvania that trains male Latino lay health advisors who provide their peers information on community support resources, including healthcare resources. NINR also is leading a funding opportunity focused on developing healthy habits in children and adolescents that lead to lifelong sustainable healthy behaviors that prevent disease and disability. Finally, in line with our focus on health promotion and disease prevention across the lifespan, NINR supported a research project that developed a successful program to guide mothers of very preterm infants in correctly feeding their vulnerable infants.

INVESTING IN NURSE SCIENTISTS

NINR is strongly committed to the development of future health scientists, with a specific focus on the training of nurse scientists. Along with extramural research grants and fellowships that support pre- and postdoctoral students and junior and senior researchers, NINR offers a number of intramural training opportunities to develop nurse scientists. This year, we are proud to once again offer the NINR Summer Genetics Institute, a month-long, intensive course in genetics for nurse sci-

entists at all career levels. The course is designed to increase research in genetics among graduate students and faculty in nursing, and expand the knowledge base among clinicians for genetics in clinical practice. NINR also sponsors the Methodologies Boot Camp, a 1-week intensive research training course at NIH that focuses on applying state-of-the-art methodologies to studies of symptom management, including pain, fatigue, and sleep.

END OF LIFE AND PALLIATIVE CARE

With advances in treatment for chronic diseases and the aging of our population, we as a society are facing new challenges in understanding the complexities of decisionmaking issues surrounding palliative and end-of-life care for those with advanced illness. As the lead NIH Institute for end-of-life research, NINR is committed to supporting research that leads to science-driven practices in palliative care that assists individuals, families, caregivers, and healthcare professionals in alleviating symptoms and planning for end-of-life decisions. In August 2011, NINR convened a 3-day National Summit on, "The Science of Compassion: Future Directions in End-of-Life and Palliative Care." The Summit, co-sponsored by partners across NIH, examined the state of research and clinical practice in end-of-life and palliative care and, with almost 1,000 registrants, provided an opportunity for scientists, healthcare professionals, and public advocates to come together to catalyze and shape the future research agenda for this critical scientific area. NINR also supports, along with the NIH Office of the Director, a palliative care research cooperative to develop an enhanced evidence base for palliative care by facilitating multi-site research studies and clinical trials.

INVESTING IN INNOVATION

NINR supports innovations that advance patient care, help lower the cost of healthcare, and take advantage of the advances in real-time personalized information on patients that guide healthcare today. For example, NINR supported two critical phases of the development of a novel "lab-on-a-chip" device for rapidly detecting HIV. The technique has proved highly successful, and the research team has gone on to refine and clinically test this microfluid-based lab-on-a-chip—or mCHIP—in real-life settings, with studies demonstrating that the mCHIP can accurately, rapidly, and cost-effectively detect clinically relevant infectious diseases in resource-limited settings. Other NINR-supported researchers have developed a novel, automated medication dispenser that reminds patients when to take medication, monitors dosage, and reduces treatment errors. The new dispenser will be the first on the market that can deliver not only all common forms of drugs but also biologically derived injectables.

CONCLUSION

Nursing science has a central role in developing the evidence-base for science-driven practices in healthcare. NINR's research agenda has guided and will continue to guide the advances in this field of health research through the implementation of our new Strategic Plan. NINR looks forward to continuing its support of innovative nursing science focused on some of the most important health and healthcare related issues of today.

PREPARED STATEMENT OF ERIC D. GREEN, M.D., PH.D., DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Human Genome Research Institute (NHGRI) of the National Institutes of Health (NIH). The fiscal year 2013 NHGRI budget of \$511,370,000 includes a decrease of \$893,000 less than the comparable fiscal year 2012 level of \$512,263,000.

It is an extraordinary time for the field of genomics. Through recent scientific advances and technological developments, we are gaining a deeper understanding for how the human genome plays a central role in health and disease, enabling investigators across the biomedical research spectrum to pursue new avenues for translating this knowledge into clinical applications. NHGRI, guided by an ambitious vision for genomics research that the Institute published in February 2011, is poised to lead a research agenda in fiscal year 2013 that will focus not only on basic genome biology and the genomic underpinnings of disease but will also seek to develop strategies for applying genomics to advance medical science and, ultimately, to improve the effectiveness of healthcare.

ENSURING A STRONG FOUNDATION

The unprecedented decreases in the cost of DNA sequencing—resulting from NHGRI-stimulated technology development coupled with myriad innovations by the NHGRI Large-Scale Genome Sequencing Centers—have fundamentally changed how genomic data is now generated as part of biomedical research. Whereas sequencing that first human genome during the Human Genome Project cost upwards of a \$1 billion, sequencing a human genome using recently developed technologies will soon cost \$1,000 (or less).

The recent renewal of the program supporting the NHGRI Large-Scale Genome Sequencing Centers ensures the productive continuation of flagship initiatives such as The Cancer Genome Atlas (TCGA) in addition to special projects with specialists focusing on specific disorders, such as Alzheimer's disease. These centers will continue to develop innovative methodologies and information management systems, which will inevitably lead to further reductions in the cost of genome sequencing. With such reductions will come the opportunity to sequence the tens of thousands of individual genomes required to understand the small genetic differences that cumulatively confer risk for common diseases, such as diabetes and heart disease. Furthermore, the accessibility of low-cost DNA sequencing technologies will be essential for making genome sequencing a routine part of clinical care.

To facilitate the utilization of genomic tools and information for exploring biological questions and ultimately improving clinical care, the NHGRI Centers of Excellence in Genomic Science will conduct interdisciplinary research and training initiatives focused on the production, analysis, and utilization of genomic data. From these efforts, new insights into the complexity of human genome function are emerging, and these in turn are benefiting the research community at large. Similarly, the human-centric ENCyclopedia of DNA Elements (ENCODE) project and the companion model organism ENCODE project (modENCODE) will continue to build a "knowledge base" that details the functional genomic elements underlying biological processes in humans as well as organisms that serve as important models for studying human biology.

To complement the requisite understanding of normal genome function established by these projects, tools for defining the genetic contributions to human disease are being developed. NHGRI continues to lead efforts within the international 1000 Genomes project to build a deep catalog of genomic variants among different human populations; in turn, this information will be used to identify the subsets of rare and common variants that confer risk for (or protection from) specific diseases or adverse drug responses. Fiscal year 2013 will also see the key maturation of the Human Heredity and Health in Africa (H3Africa) initiative, an NIH Common Fund project managed by NHGRI. The increased knowledge generated about genomic variation and the complex interactions between environmental and genetic factors in African populations will enhance understanding of disease predispositions and drug responses for all human populations.

If genomics is to be a powerful contributor to studies being performed across the biomedical research community, researchers must be able to process and analyze the massive amounts of genomic data that they can now readily produce. NHGRI will pursue the establishment of pioneering approaches for data management and analysis via the development and refinement of bioinformatic tools, resources, and standards.

TRANSLATING THE POTENTIAL

The Genome Sequencing Program continues to be a prominent and vibrant part of the Institute's research portfolio. Looking ahead, it will play an increased role in translating genomic-based capabilities to understand disease biology. The Program's renewal in fiscal year 2012 included not only continued support for medical sequencing projects but also a charge to conduct collaborative research projects with other investigators to broaden the application of genome sequencing as a tool for unraveling the genomic basis of human disease. The prototype for the latter is TCGA, a collaboration with the National Cancer Institute to identify the genomic basis of many different forms of human cancer.

The renewal of NHGRI's Genome Sequencing Program also included establishment of new Mendelian Disorders Genome Centers focused on rare, single-gene (called Mendelian) diseases. These new centers will seek to establish the genetic basis for thousands of rare disorders (affecting millions of Americans) for which the genetic defects remain unknown. Recent advances in genome sequencing offer the hope that the genetic underpinnings for most of these rare diseases can be identified through focused research efforts that were not possible or affordable with previous genome sequencing technologies.

PREPARING FOR GENOMIC MEDICINE

To capitalize on its growing foundation of basic and translational research, NHGRI recently launched the Clinical Sequencing Exploratory Research projects, a new component of the Institute's Genome Sequencing Program. The new projects will investigate how to utilize genomic knowledge in medical settings and begin to explore how healthcare professionals can routinely use genome sequence information for patient care. A related effort, the Electronic Medical Records and Genomics (eMERGE) Network, is pursuing how patients' genomic information can be linked to disease characteristics and symptoms in their electronic medical records, providing the ability to explore associations with disease pathologies and eventually to improve patient care.

Key to the ultimate success in all of these endeavors will be continued attention to the societal implications of advancing genomic technologies and understanding. Deliberate, ongoing engagement by laboratory, clinical, and social scientists and scholars in ethics, law, and philosophy with the public must remain a priority.

Through its portfolio of basic and translational research, the Institute is pushing forward the boundaries of our knowledge and defining the issues that must be addressed before genomics is routinely deployed as a standard element in medical care. NHGRI is leading this charge by funding ambitious research programs to understand the structure and function of genomes more fully, to use genomics as a central tool for understanding the biology of disease, and to establish the path for the implementation of genomic medicine. In all of these pursuits, the Institute maintains a laser-like focus on its ultimate mission—to improve human health through genomics research.

PREPARED STATEMENT OF JUDITH H. GREENBERG, PH.D., ACTING DIRECTOR,
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget for the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health (NIH). The fiscal year 2013 budget of \$2,378,835,000 includes a decrease of \$48,354,000 less than the comparable fiscal year 2012 level of \$2,427,189,000.

This year, in 2012, the National Institute of General Medical Sciences (NIGMS) celebrates its 50-year anniversary as NIH's "basic research institute." Since 1962, NIGMS has continuously supported highly creative people committed to building a broad and deep foundation of discovery. The findings are used and applied by scientists everywhere, leading to new diagnostics, new therapies, and new ways to prevent a wide range of diseases.

MODEL SYSTEMS ILLUMINATE HUMAN HEALTH

Laboratory-animal versions of disease are a staple of basic biomedical and behavioral research. Because fruit flies, worms, mice, and other animals are easy and relatively inexpensive to work with—and have most of the same genes and many of the same behaviors as we do—they are valuable tools for biomedical discovery. Sometimes, though, results with animal models do not hold up in human studies, in part because organisms studied in the laboratory lack the genetic diversity of people. NIGMS has addressed this problem through its support of the Collaborative Cross, a large-scale mouse-breeding project that significantly expands the genetic diversity of mice. This project has made its resources widely available to scientists everywhere—helping to fast-track important discoveries about genetics and human disease.

Other recent studies with model systems, in this case worms, have pointed to new information about a group of neurological diseases that have a common molecular defect: the inability of normal cellular proteins to fold themselves into their proper three-dimensional shapes. Misfolded proteins are implicated in Alzheimer's, Parkinson's, and Huntington's diseases, amyotrophic lateral sclerosis, cancer, cystic fibrosis, and type 2 diabetes. The recent work identified new genes and signaling pathways that keep proteins folded properly and prevent toxic clumping. The researchers also extended their findings by identifying small molecules that appear to repair misfolded proteins.

ALL SYSTEMS GO

While animal models offer key clues to understanding human disease, other studies that investigate large, interacting systems are an essential avenue for learning about health and disease. Systems biology approaches, which promote a more thor-

ough grasp of the intricate and dynamic workings of how molecular and cellular parts interact to make a whole, is a robust area of NIGMS-funded biomedical research.

Human behavior is one example of an enormously complicated system—not just for an individual but also between individuals and within and between populations. Systems biology research employing mathematical models can draw connections among a vast number of inputs, uncovering new connections and making new predictions. NIGMS has joined forces with the NIH Office of Behavioral and Social Sciences Research to identify opportunities, challenges, and gaps in knowledge needed to develop useful models of social behavior. This past fall, NIGMS issued a call for funding research that models social behavior. The new program has generated substantial interest in the research community, and the Institute is looking forward to the results that are likely to have broad application.

Another scientific area of great complexity, even though the subject of study is microscopic, is the interactions between viruses and their hosts. For many years, NIGMS has funded the AIDS-Related Structural Biology Program to obtain the three-dimensional structures of HIV proteins. Representing the culmination of hundreds of studies, researchers have just published a map of nearly 500 physical interactions between components of HIV and those in human cells. The research provides a gold mine for further studies into new drugs and vaccines against HIV.

ACCELERATING THE PACE OF DISCOVERY

As our world has flattened due to increased human travel and expanded commercial trade among many international partners, a number of new diseases have emerged and infected people around the world. To help the Nation and the world understand and prepare for contagious outbreaks, NIGMS funds the Models of Infectious Disease Agent Study (MIDAS). This international effort continues to add new research expertise to increase its capacity to simulate disease spread, evaluate different intervention strategies, and help inform public health officials and policymakers. In 2011, MIDAS scientists used whole-genome sequencing to trace the path of the E. coli outbreak that made thousands of people ill and killed more than 50 people in Germany and France. The project demonstrates the power of modeling and is one of the first uses of genetic detective work to study the dynamics of a food-borne outbreak.

The NIGMS investment accelerates the pace of discovery through its support of chemistry projects that enable biologists to study cells and organisms using state-of-the-art chemical tools; help clarify the chemical reactions that underlie human metabolism; and provide new strategies for drug development. NIGMS-supported chemists recently made two new discoveries that should enhance the manufacture of key drugs. In the first study, scientists made significant progress toward a simpler, more efficient way to synthesize Taxol, an important cancer drug used routinely to treat ovarian, breast, lung, liver, and other cancers. In a second study, NIGMS-funded chemists unveiled the working parts of the commonly used anti-fungal medicine amphotericin B, nicknamed by physicians “ampho-terrible” for its harsh side effects. The new work opens up possibilities for designing similar anti-fungal medicines that are just as effective but easier on the body.

INVESTING IN THE FUTURE OF DISCOVERY

The Institute believes that a strong biomedical research workforce is essential for the tandem goals of improving health and maintaining global competitiveness. In 2011, NIGMS published “Investing in the Future: the NIGMS Strategic Plan for Biomedical and Behavioral Research Training.” Implementation of this plan is now in full swing. Going forward, NIGMS has articulated clearly that research training is a partnership between the NIH and the academic community and continues to engage actively with its full range of stakeholders. Key foci include the importance of excellent mentoring, a continuing emphasis on diversity, and the need to recognize a full menu of career options beyond academic research for newly trained scientists.

NIGMS has also recently established a new organizational component, the Division of Training, Workforce Development, and Diversity, which integrates training, diversity, and capacity-building activities across Institute programs. This new component also oversees the Institutional Development Award (IDeA) program that broadens the geographic distribution of NIH funding. A new component of this effort is the IDeA Program Infrastructure for Clinical and Translational Research initiative, which encourages applications from IDeA States to develop infrastructure and capacity to conduct clinical and translational research on diseases that affect medi-

cally underserved populations and/or diseases prevalent in these 23 States and territories traditionally underfunded by the NIH.

EXTENDING THE REACH OF BASIC RESEARCH

Within the clinical realm, NIGMS continues to support the NIH Pharmacogenetics Research Network (PGRN), now in its 12th year of funding. This endeavor has yielded a bounty of medically relevant knowledge, including how genetic information can help predict how heart drugs, cancer medicines, nicotine patches, and a range of other treatments are likely to work in a particular person. One PGRN project is now partnering with the Electronic Medical Records and Genomics (eMERGE) Consortium to test samples from people whose electronic medical records are also available to the researchers. The goal is to demonstrate that DNA differences can be useful for decisionmaking about drug type and dosage, and ultimately to improve medication safety and efficacy.

PREPARED STATEMENT OF ALAN E. GUTTMACHER, M.D., DIRECTOR, EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Mr. Chairman and members of the subcommittee: I am pleased to present the fiscal year 2013 President's budget request for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of \$1,320,600,000. This reflects an increase of \$775,000 more than the comparable fiscal year 2012 level of \$1,319,825,000.

50 YEARS OF CONTRIBUTIONS TO HEALTH

This year marks the 50th anniversary of the founding of the NICHD. Thanks to continuing congressional support and the unwavering dedication of our scientists and stakeholders, NICHD research has changed the lives of women, children, families, and those individuals with disabilities worldwide. Since the NICHD was established in the early 1960s, research supported by the Institute contributed to a 50 percent drop in sudden infant death syndrome (SIDS), and a 70-percent drop in respiratory distress syndrome, both leading causes of the Nation's infant mortality rate. Transmission of HIV from infected mother to fetus dropped from 25 percent to less than 1 percent in the past 15 years. Discovery of an early biological marker of pregnancy led to the development of what is now the standard pregnancy test. The incidence of Haemophilus influenzae type b (Hib) meningitis, once the leading cause of acquired intellectual disability, has dropped more than 90 percent with the development of the Hib vaccine by NICHD scientists. Beyond these past contributions to public health, our anniversary presents a unique opportunity to catalyze scientific advances.

NEW ADVANCES CONTINUE THE MOMENTUM

The NICHD's basic research, conducted on the NIH campus and supported at academic institutions nationwide, adds to scientific knowledge and enables clinical researchers to develop and test new treatments. For example, in type 1 diabetes, the immune system destroys the body's insulin-producing cells that help control blood glucose levels. Infertility researchers funded by the NICHD found a way to convert endometrial stem cells into insulin-producing cells and transplant them into mice to control diabetes. These findings suggest that ultimately, a woman's own, readily available, endometrial stem cells could be used to develop insulin-producing islet cells, minimizing the chance of rejection posed by using tissues or cells from another person.

Research shows promise for developing new treatments for uterine fibroids. These noncancerous tumors, 3 to 4 times more common in African American than white women, are often associated with chronic pain, infertility, and preterm labor. Currently, few treatment options exist except surgical removal of the uterus (hysterectomy). A recent NICHD-sponsored analysis concluded that the economic costs of the poor health outcomes, treatment, and management of fibroids in the U.S. may reach \$34 billion annually. Other NICHD-supported researchers found that treatment with vitamin D reduced the size of uterine fibroids in laboratory rats predisposed to developing the tumors, suggesting that differential rates of vitamin D deficiency could help explain the health disparities in fibroid formation. Another approach, using a drug to shrink the tumors, has shown promise in preliminary clinical studies.

New technologies and tools are allowing the research community to move science along faster than ever. For example, a NICHD-supported physiatrist is combining

bioengineering with a technique called “targeted muscle reinnervation,” using nerves that remain after amputation to control assistive devices; this has enabled researchers to link an individual’s brain impulses to a computer in a prosthesis that directs motors to move the limb. The NICHD Small Business Innovation Research (SBIR) program has supported development of emerging technologies to address mounting concerns about the effects of concussions. Scientists have created a device mounted inside a football helmet to measure the impact of a collision. This new tool has already helped to quantify the impact of concussions for college football players, determine how head injuries may differ for football players at different positions, and can be used to design more protective helmets.

Scientists at the NIH’s Autism Centers of Excellence are taking advantage of new insights into brain structure and function in their Infant Brain Imaging Study. Using a special imaging technique, they tracked the brain development of infants and toddlers who have an older sibling with an autism spectrum disorder (ASD), and thus, are at increased risk of developing ASD themselves. The researchers found distinctly different patterns of brain development in the younger siblings who were later diagnosed with ASD compared to those who weren’t. These findings represent the earliest age (6 to 24 months) at which such biomarkers for ASD have been identified.

It is especially gratifying when scientific advances like these are put into practice. Last year, I reported on a major new study supported by the NICHD demonstrating that fetal surgery to correct myelomeningocele (spina bifida) greatly reduced the risk of death and doubled the chances of children being able to walk, compared to the standard practice of postnatal surgery. Over the past year, the NICHD has convened a series of meetings with numerous leading professional societies to ensure sufficient and consistent training and guidelines for performing this highly complex procedure as it becomes available in various sites around the country.

In late 2011, an NICHD-supported analysis of more than 5 million medical records showed that pregnant women assaulted by an intimate partner are at increased risk of giving birth to infants at lower birth weights. Babies born at low birth weights are at higher risk for SIDS, heart and breathing problems, and learning disabilities. The American College of Obstetricians and Gynecologists used this information in developing physician training materials for screening patients for intimate partner violence.

Since 2002, the NICHD has led the NIH’s implementation of the Best Pharmaceuticals for Children Act, supporting pharmacokinetic research and new clinical trials on drugs not previously tested for pediatric use. Due in large part to the NICHD’s Pediatric Trials Network, data on pediatric safety, dosing, and efficacy for several common drugs were sent to the Food and Drug Administration this year so that the drugs’ labels can be changed, and the children potentially benefiting from these therapeutics can be treated appropriately.

LOOKING AHEAD: SCIENTIFIC VISIONING

As exciting as these advances are, we know that the promise of improving the Nation’s health depends on enlightened management of the research enterprise. The NICHD has just concluded a “visioning” process to help us focus over the next 10 years on the best ways to achieve scientific goals, enhance prevention, and continue to improve the Nation’s health. After in-depth consultation with more than 700 experts from around the country, white papers covering nine major areas of our science were made available online (<http://www.nichd.nih.gov/vision>), and a scientific commentary summarizing NICHD’s overall vision will appear in a major medical journal later this year. Now the NICHD looks to the future, where we will work with our research partners to detail how genes, the environment, and behaviors interact, starting before birth, to affect health outcomes. We plan to determine all the causes of preterm birth, devise new treatments to maximize gynecologic health, and improve the health and functioning of individuals with intellectual, developmental, or physical differences. Collaborative efforts to strengthen transdisciplinary research and enhance the ways that we conduct science will be essential to this future.

CONCLUSION

Whether they work at the NIH or receive grants at academic institutions across the country, NICHD-supported scientists are an invaluable national resource. In the past year alone, two long-time NICHD grantees were among only seven researchers named by President Obama as recipients of the National Medal of Science. And, to honor her work encouraging young women from the inner city to engage in scientific research careers, a third NICHD grantee was recently awarded the Presidential

Award for Excellence in Science, Mathematics, and Engineering Mentoring. It is with the help of exceptional individuals such as these, and your support, that we will embark on the next 50 years of the NICHD's "Research for a Lifetime."

PREPARED STATEMENT OF STEPHEN I. KATZ, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH). The fiscal year 2013 NIAMS budget of \$535,610,000 includes an increase of \$462,000 more than the comparable fiscal year 2012 level of \$535,148,000.

INTRODUCTION

As the primary Federal agency for supporting medical research on diseases of the bones, joints, muscles, and skin, NIAMS touches the lives of nearly every American. Training the basic and clinical scientists who carry out this research, and disseminating information on research progress in these diseases, are two other important components of the NIAMS mission.

USING SCIENCE TO INFORM HEALTHCARE DECISIONS

Over the past two decades, the NIH Study of Osteoporotic Fractures (SOF) has provided information that healthcare providers are using to assess people's bone health. SOF's finding that bone mineral density (BMD) relates closely to fracture risk, for example, contributed to Medicare's decision to pay for numerous people to get their BMD measured every 2 years. Many started taking bone-preserving drugs because of their results, and the rate of hip fractures dropped nearly 25 percent among female beneficiaries. New, longer-term data from SOF could refine the screening guidance: women at the highest risk of osteoporosis might benefit from annual exams, while frequent measurements may be unnecessary for others. In fact, women with the lowest risk could be tested much less frequently unless other aspects of their health change.

As multiple treatments become available for various conditions, research is needed to help clinicians decide which options are best for their patients. Studies of adults who have rheumatoid arthritis (RA) suggest that aggressive treatment is more beneficial than waiting until the disease progresses. A group of rheumatologists tested whether a similar approach would reduce the disability and healthcare costs of juvenile idiopathic arthritis (JIA). They compared two therapies and determined that early treatment with either strategy increased the likelihood that the joint-destroying processes would stop.

Many diseases within the NIAMS mission involve pain, fatigue, and other difficult-to-measure symptoms. The ability to quantify changes in these parameters could enhance clinical outcomes research and, ultimately, clinical practice. NIAMS is one of several NIH components engaged in the Patient-Reported Outcomes Measurement Information System (PROMIS) Initiative to develop such a tool. In addition to managing PROMIS on behalf of NIH, NIAMS is encouraging researchers to use the resource in ongoing clinical studies of rheumatic, musculoskeletal, and skin diseases.

For the past decade, researchers have been monitoring the health of people who have low back pain due to intervertebral disk herniation, lumbar spinal stenosis, or degenerative spondylolisthesis. Early findings showed that, in general, most surgical patients fared better than patients who received nonoperative care, although many patients got better without surgery. Recent data show that the cost-effectiveness of surgery for low back pain due to these disorders—4 years after an operation—is comparable to that of other common treatments for nonmusculoskeletal conditions.

Community engagement is a key component for translating interventions into healthcare and integrating lifestyle changes into daily living. To address the well-documented disparities in medical knowledge and research participation, NIAMS will continue its Multicultural Outreach Initiative to improve access to health information for underserved minority populations. Fiscal year 2013 plans include field testing program materials and creating an electronic toolkit to facilitate their dissemination.

INVESTING IN BASIC RESEARCH

Itch is an often difficult and sometimes debilitating symptom of many skin diseases and other disorders within the NIAMS mission. Poor knowledge of the mechanisms underlying chronic itch has hampered the development of pharmacologic treatments. In fiscal year 2013, NIAMS will encourage basic and translational studies in this area.

NIAMS maintains a considerable investment into the genetic and cellular basis of osteoarthritis (OA), with the goal of identifying potential targets for therapies that halt tissue degeneration. Even after researchers develop treatments to stop or reverse OA progression, however, some patients will require total joint replacement. With support from the American Recovery and Reinvestment Act of 2009, researchers made a surprising discovery about the lubricating layer that forms around metal-on-metal hip implants. Instead of cell-based fluid made by the patient, the lubricant is a synthetic material produced through friction. This finding could lead to longer-lasting materials which, in turn, could improve the surgeries' success and reduce their long-term costs.

With the advent of new laboratory and data mining tools, investigators are making connections among biologic processes and organ systems that previously were viewed independently. For example, researchers are learning that inflammation, which plays an important role in RA and other autoimmune joint diseases, is involved in OA onset and osteoarthritic joint degeneration. Others are exploring how normally harmless microorganisms can lead to RA by causing the immune system to attack healthy tissue.

The technologic advances related to genome-wide analyses have enabled investigators to identify a genetic mutation that causes a rare childhood disease characterized predominantly by inflammation and fat loss. The disorder, named chronic atypical neutrophilic dermatosis with lipodystrophy and elevated temperature (CANDLE), may actually represent a spectrum of diseases that have been described in the literature under a variety of names. More importantly, since no treatment for this disease exists, the findings may have uncovered a possible target for future therapies.

ADVANCING TRANSLATIONAL SCIENCES

NIAMS supports several large programs to encourage teams of translational researchers. In fiscal year 2013, it again will partner with other NIH Institutes to fund applications for the Wellstone Muscular Dystrophy Cooperative Research Centers program. The Centers have facilitated numerous basic discoveries and animal tests since their establishment in 2003. A group of investigators that includes Wellstone researchers recently published preclinical data about small molecules that target the defective RNA that causes myotonic dystrophy type 1. The cell-culture and mouse-model findings have the potential to benefit people who have myotonic dystrophy type 1; their promise also extends to other conditions that might be amenable to RNA-targeted therapies.

NIAMS strengthened its Small Business Innovation Research (SBIR) program in recent years by inviting eligible companies to propose studies on specific topics that complement the Institute's other grants. Results from the targeted efforts include a cell-derived human skin substitute for use in consumer product testing, drug discovery, and toxicity screening. NIAMS will continue to look for opportunities that could benefit from an SBIR focus and will solicit applications as areas are identified.

CONCLUSION

The advances described above are just a few of the contributions that NIAMS-funded investigators have made to save and improve millions of American lives. Collectively, the Institute's research, training, and health information programs have significantly advanced our understanding of how to treat or prevent many common, chronic, costly diseases. Looking forward, this progress will serve as a strong foundation for the future, as the burden that these conditions place on individuals and society is reduced and, over time, eliminated.

PREPARED STATEMENT OF STORY C. LANDIS, PH.D., DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). The fiscal year 2013 NINDS budget of \$1,624,707,000 includes an increase of \$278,000 more than the

comparable fiscal year 2012 level of \$1,624,429,000. The NINDS mission is to reduce the burden of neurological diseases through research. NIH research has improved the lives of many people with neurological disorders directly and by providing the foundation for private sector research. The American Heart Association (AHA) reported that the stroke death rate decreased by 34.8 percent from 1998 to 2008. Better treatments are available for multiple sclerosis, epilepsy, Parkinson's, and other diseases, and genetics research has led to tests that significantly reduce the time to obtain the correct diagnosis for many rare disorders. Moreover, basic science is driving remarkable opportunities for progress. Paradoxically, however, industry is significantly reducing their investment in research on brain disorders because of the challenges brain diseases present. NINDS supports a spectrum of basic, translational, and clinical research to complement and encourage private sector efforts. Because gaps in basic understanding of the normal brain or disease are most often the cause when progress against neurological disease is not forthcoming, the Institute continues to invest more than one-half of its resources in basic research, for which the NIH role is especially crucial.

ACCELERATING DISCOVERY

Last year, for the first time, researchers provided a molecular diagnosis for a family's inherited disease using whole genome sequencing (WGS). The disease was a type of Charcot Marie Tooth disease, a disorder that affects the body's nerves. This year WGS provided not only a molecular diagnosis but also immediate therapeutic benefit. In this study, twin children had been diagnosed with dopa-responsive dystonia, a movement disorder that reflects a deficiency of the neurotransmitter dopamine. The children's health problems persisted despite treatment with the drug l-dopa, which replenishes dopamine and is usually effective. Once WGS identified the specific gene defect, it became apparent that the neurotransmitter serotonin was also deficient. Boosting serotonin with a readily available drug dramatically improved the children's health. Dozens of studies are now underway using these "next generation" sequencing methods in common and rare neurological diseases. A new "Center without Walls," for example, is bringing the best researchers together, regardless of geography, to apply the new genetics technologies to epilepsy.

Next-generation sequencing is just one of several technologies that are transforming basic and clinical neuroscience. Optogenetics allows precise control of nerve cells' activity by light. Induced pluripotent stem cell (iPSC) methods derive nerve cells from skin cells of patients affected by disease, to enable studies of disease and screening of drugs in a culture dish. NINDS supports extensive iPSC research, including consortia in ALS, Parkinson's, and Huntington's disease. Brain imaging now reveals structure, activity, and chemistry of the living brain in health and disease. Recently, for example, brain imaging provided insights about traumatic brain injuries (TBI) in the military, the lingering effects of concussions in young athletes and new understanding of autism. The NIH Human Connectome Project is an ambitious imaging effort to map the wiring diagram of the entire human brain. NIH encourages sharing of data from the Connectome project, gene studies, iPSC methods, and other research that is producing extraordinary amounts of useful information. A notable recent effort to promote data sharing is a TBI database created jointly by the NIH and the Department of Defense.

TRANSLATING DISCOVERY TO HEALTH

NINDS has a long history of translating scientific advances into better medicine. Rare disease studies, bold new therapeutic strategies, and technology development are examples of translational research in which NINDS plays a key role. Several NINDS programs support translational research. The Anticonvulsant Screening Program (ASP) has contributed to the development of eight epilepsy drugs now on the market. Following an external review completed this year, the ASP will refocus on what most concerns the epilepsy community today—drugs to address treatment-resistant epilepsy and to modify the course and development of the underlying disease. Recent activities in the NINDS Neural Prosthesis Program, which pioneered this entire field, include collaboration with Defense Advanced Research Projects Agency (DARPA) to enhance brain control of an advanced prosthetic arm, and development of an ultrathin flexible brain implant that could one day be used to treat epileptic seizures and other disorders. To exploit opportunities across all neurological disorders, the Cooperative Program in Translational Research, begun in 2002, supports teams of academic and small business investigators to carry out pre-clinical therapy development. NINDS is now funding two Phase II clinical trials of therapies developed in this program. NINDS is also leading an NIH Blueprint Grant

Challenge to develop truly novel drugs that will transform the treatment of nervous system diseases.

Because candidate therapies for many disorders are emerging, in 2011 NINDS launched the NeuroNext clinical network at 25 sites across the United States. NeuroNext will remove roadblocks to the crucial early stage clinical testing of novel therapies and reduce from years to months the time to move new therapies into testing in patients. NeuroNext will test biomarkers for spinal muscular atrophy (SMA) in its first clinical study to prepare for trials of candidate therapies for SMA.

NINDS phase III, multi-center clinical trials continue to advance public health. The Neurological Emergency Treatment Trials (NETT) network completed the Rapid Anticonvulsant Medication Prior to Arrival (RAMPART) trial well ahead of schedule, showing that paramedics in the field can safely deliver the drug midazolam into muscle using an autoinjector (like an EpiPen) and stop continuous seizures faster than the usual intravenous treatment. These results inform responses to common continuous seizures and seizures caused by industrial accidents or nerve agents. NETT trials of stroke and TBI emergency treatments are underway. Also this year, the Stenting vs. Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMPRISS) clinical trial showed that patients at high risk for a second stroke who received intensive medical treatment had fewer strokes and deaths than patients who received a stent in blood vessels that supply the brain in addition to the medical treatment. Follow up is continuing to compare longer-term benefits.

With the concern about dementia as our population ages, it is worth noting that stroke is a major contributor to dementia, highlighting the complex relationships among various types of dementia. Not only do the 7 million U.S. stroke survivors have an increased likelihood of cognitive problems, and perhaps also 13 million who have had “silent strokes” but also vascular problems that cause stroke are also associated with Alzheimer’s disease. Signs that a stroke has occurred are often found in the brains of Alzheimer’s patients, and beta-amyloid, a key protein in Alzheimer’s pathology, may stimulate the formation of blood clots, which can cause stroke. Furthermore, last year the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study, which is following more than 30,000 people, reported that high blood pressure and other known risk factors for stroke increase the risk of cognitive problems, even among people who have never had a stroke. Research suggests that there is a dementia spectrum from pure vascular dementia to pure Alzheimer’s disease, with most patients having contributions from both. Recognition of intersections not only between Alzheimer’s disease and stroke but also Alzheimer’s disease with TBI, Parkinson’s, frontotemporal dementia, and other disorders may provide leads toward better prevention and treatment of all dementias.

Hundreds of neurological disorders affect patients, families, and society. The aging population, concern about the long lasting effects of TBI, and reduced private sector investment are among several factors that underscore the importance of NINDS funded research. Although neurological disorders present enormous challenges, progress in neuroscience and other areas of research provides exceptional opportunities for the future.

PREPARED STATEMENT OF DONALD A.B. LINDBERG, M.D., DIRECTOR, NATIONAL LIBRARY OF MEDICINE

Mr. Chairman and members of the subcommittee: I am pleased to present the President’s budget request for the National Library of Medicine (NLM) of the National Institutes of Health (NIH). The fiscal year 2013 NLM budget of \$372,651,000 includes an increase of \$7,608,000 more than the comparable fiscal year 2012 level of \$365,043,000. Funds have been included to allow the National Center for Biotechnology Information (NCBI) to meet the challenges of collecting, organizing, analyzing, and disseminating the deluge of data emanating from research in molecular biology and genomics.

As the world’s largest biomedical library and the producer of internationally trusted electronic information services, NLM delivers trillions of bytes of scientific data and health information to millions of users every day. Many searches that begin in Google or a mobile “app” actually retrieve information from an NLM Web site. After 175 years, NLM is a key link in the chain that makes biomedical research results—DNA sequences, clinical trials data, toxicology and environmental health data, published articles, and consumer health information—readily available to scientists, health professionals, and the public. A leader in biomedical informatics and information technology, NLM also conducts and supports leading-edge research and devel-

opment in electronic health records, clinical decision support, information retrieval, imaging, computational biology, telecommunications, and disaster response.

NLM's programs and services directly support NIH's four key initiatives in basic research, technology, translational science, and research training. The Library organizes and provides access to the published medical literature and massive amounts of scientific data from high throughput sequencing; assembles data about small molecules to support research and therapeutic discovery; provides the world's largest clinical trials registry and results database; and is the definitive source of published evidence for healthcare decisions. Research supported or conducted by NLM underpins today's electronic health record systems. The Library has been the principal funder of university-based informatics research training for 40 years, supporting the development of today's leaders in informatics research and health information technology. NLM's databases and its partnership with the Nation's health sciences libraries deliver research results wherever they can fuel discovery and support health decisionmaking.

RESEARCH INFORMATION RESOURCES

NLM's PubMed/MEDLINE database is the world's gateway to research results published in the biomedical literature, linking to full-text articles in PubMed Central, including those deposited under the NIH Public Access Policy, and on publishers' Web sites, as well as connecting to vast collections of scientific data. Through its NCBI, NLM is a hub for the international exchange and use of molecular biology and genomic information, with many databases fundamental to the identification of important associations between genes and disease and to the translation of new knowledge into better diagnoses and treatments. Resources such as dbGaP, the Genetic Testing Registry (GTR) and the ClinVar database create a bridge between basic research and clinical applications.

NLM also stands at the center of international exchange of data about clinical research studies. NLM's Lister Hill National Center for Biomedical Communications builds ClinicalTrials.gov, the world's most comprehensive clinical trials database, including registration data for more than 117,000 clinical studies with sites in 178 countries. ClinicalTrials.gov has novel and flexible mechanisms that enable submission of summary results data for clinical trials subject to the Food and Drug Administration Amendments Act of 2007. To date, summary results are available for more than 5,000 completed trials of FDA-approved drugs, biological products, and devices—providing a new and growing source of evidence on efficacy and comparative effectiveness. NLM is a primary source for results of comparative effectiveness research, providing access to evidence on best practices to improve patient safety and healthcare quality. In 2011, the Library greatly expanded its collection of full-text guidelines, evidence summaries, and systematic reviews from authoritative agencies and organizations around the world.

HEALTH DATA STANDARDS AND ELECTRONIC HEALTH RECORDS

Electronic health records (EHRs) with advanced decision-support capabilities and connections to relevant health information will be essential to achieving precision medicine and helping Americans manage their own health. For 40 years, NLM has supported seminal research on electronic patient records, clinical decision support, and health information exchange, including concepts and methods now reflected in EHR products and personal health record tools, such as Microsoft Health Vault. As the HHS coordinating body for clinical terminology standards, NLM works closely with the Office of the National Coordinator for Health Information Technology to facilitate adoption and "meaningful use" of EHRs. NLM supports, develops, and disseminates several key data standards now required for U.S. health information exchange. While actively engaged in research on Next Generation EHRs, NLM also produces tools, frequently used subsets of large terminologies, and mappings to help EHR developers and users implement health data standards right now. NLM's MedlinePlus Connect is used in multiple EHR products to provide high quality health information relevant to a patient's specific health conditions, medications, and tests, as present in his or her EHR.

INFORMATION SERVICES FOR THE PUBLIC

This EHR connection builds upon NLM's extensive information services for patients, families and the public. The Library's MedlinePlus Web site provides integrated access to high quality consumer health information produced by all NIH components and HHS agencies, other Federal departments, and authoritative private organizations. It serves as a gateway to specialized NLM information sources for consumers, such as the Genetic Home Reference and the Household Products Data-

base. Available in English and Spanish, with selected information in 40 other languages, MedlinePlus averages well over 750,000 visits per day. Mobile MedlinePlus, also in both English and Spanish, reaches the large and rapidly growing mobile Internet audience.

The NIH MedlinePlus magazine, in English and Spanish, is an outreach effort made possible with support from many parts of NIH and the Friends of the NLM. Distributed free to the public via physician offices, community health centers, libraries and other locations, the magazine reaches a readership of up to 5 million nationwide. Each issue focuses on the latest research results, clinical trials and guidelines from the 27 NIH Institutes and Centers.

To be of greatest use to the widest audience, NLM's information services must be known and readily accessible. The Library's outreach program, with a special emphasis on reaching underserved populations, relies heavily on the more than 6,300-member National Network of Libraries of Medicine (NN/LM). The NN/LM is a network of academic health sciences libraries, hospital libraries, public libraries and community-based organizations working to bring the message about NLM's free, high-quality health information resources to communities across the Nation.

DISASTER INFORMATION MANAGEMENT

Through its Disaster Information Management Resource Center, NLM builds on proven emergency backup and response mechanisms within the NN/LM to promote effective use of libraries and information specialists in disaster preparedness and response. NLM conducts research on new methods for sharing health information in emergencies as its contribution to the Bethesda Hospital Emergency Preparedness Partnership, a model of private-public hospital collaboration for coordinated disaster planning. NLM works with the Pan American Health Organization (PAHO) and the Latin American Network for Disaster and Health Information to promote capacity-building in disaster information management. In addition, NLM responds to specific disasters worldwide with specialized information resources appropriate to the need, including a recently launched Disaster Information Apps and Mobile Web Sites page.

In summary, NLM's information services and research programs serve the Nation and the world by supporting scientific discovery, clinical research, education, healthcare delivery, public health response, and the empowerment of people to improve personal health. The Library is committed to the innovative use of computing and communications to enhance public access to the results of biomedical research.

PREPARED STATEMENT OF RODERIC I. PETTIGREW, PH.D., M.D., DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health. The fiscal year 2013 NIBIB budget of \$336,896,000 is \$1,058,000 less than the comparable fiscal year 2012 level of \$337,954,000.

The mission of NIBIB is to improve human health by leading the development and accelerating the application of biomedical technologies. NIBIB invests resources in scientific and technological research opportunities at the convergence of the physical, quantitative and life sciences, and in training the next generation of researchers. The Institute is at the forefront of translating scientific advances into engineered medical solutions. Ultimately, NIBIB seeks to realize innovations that address healthcare challenges, reduce disease mortality and morbidity, and enhance quality of life. To accomplish this goal, NIBIB continues to fund bold and far-reaching projects that facilitate discovery and translate basic science into better healthcare.

DISCOVERY SCIENCE AND TECHNOLOGIES TO EMPOWER PATIENTS

Neurostimulation Research in Paraplegics: Recovery of Voluntary Motion, Bladder, and Sexual Function.—Through the NIBIB Rehabilitation Engineering program, researchers from the University of California, Los Angeles, have developed a high-density electrode array technology for epidural stimulation of the spinal cord. The first patient, the victim of a car accident that left him completely paralyzed from the chest down, received electrical stimulator implants in his lower back. Over a 1-year period, he received daily electrode stimulating sessions with specific tasks and movements being performed, which is known as locomotor training. The procedure resulted in independent standing, some voluntary leg control, and regained bladder,

bowel, and sexual function. It is believed that the epidural stimulation and locomotor training have two distinct roles. The stimulation appears to switch on intact circuits in the spinal cord, while the training relays specific information about body and limb positions. The investigators have applied this technology to three patients with complete spinal cord injury. All patients are able to stand and voluntarily control both legs in the presence of epidural stimulation.

Wireless Tongue Drive System Could Provide Independence to Paralyzed Patients.—Assistive technologies (ATs) have been available to control devices used for daily living such as powered wheelchairs and computers. However, many of these devices have limited commands, cause rapid muscle fatigue, or interfere with the user's basic functions. NIBIB-funded researchers from the Georgia Institute of Technology have developed a tongue-operated AT called the Tongue Drive System (TDS) that is unobtrusive, wearable, wireless, and can substitute for many arm and hand functions. The core TDS technology exploits the fact that even a person with severe paralysis that impairs breathing and speech can still move their tongue and therefore, can fully utilize this extraordinary system. The device consists of a headset, a compact computer, and a tiny magnet attached to the tongue. Tongue movements change the magnetic field around the mouth. These changes are detected by magnetic sensors in the headset, relayed to the computer, and translated into the commands of the user. The system allows users to control various devices and perform numerous tasks such as drive their wheelchairs, operate their computers, and generally control their environment in an independent fashion. The TDS can be linked to currently available technologies such as a smart phone, to control household appliances, lights, locks, heating/air conditioning, as well as prosthetic arms or legs. This remarkable technology could offer paralyzed individuals an unprecedented level of independence for leading active, productive lives.

TECHNOLOGIES TO ACCELERATE THERAPEUTICS DEVELOPMENT

Multi-Layered Nanoparticles for Specific Delivery of Drugs to Tumors.—An important area of investigation supported by NIBIB is targeted drug delivery, e.g., to cancer cells and not the surrounding normal tissue. One group of investigators has created multilayered nanoparticles that can be delivered systemically (by venous injection) but act only at the site of the tumor due to the specific chemical properties of each layer and their interaction with the specific biochemistry of tumor cells. The properties of the outer surface layer were designed to provide a surface that promotes distribution of particles throughout the body and shields the drug while preventing binding to healthy tissues. This outer "stealth" layer is also pH-sensitive and is shed in the acidic environment of tumors exposing the toxic load of the nanoparticle. At the site of a tumor, the shed surface layer reveals a charged nanoparticle layer, which contains the anti-cancer agent and is readily taken up by tumor cells. The investigators have demonstrated that this concept for tumor targeting is applicable to a broad range of cancers and compatible with various therapies designed to be triggered by acidic tumor tissue. Because particles can be designed with layers that can be shed in specific environments, the cancer drug can be exposed and delivered directly to the tumor, which makes this emerging technology an extremely promising cancer drug delivery technique.

Nanoscale Theranostics: Delivering Treatment and Monitoring Efficacy Simultaneously.—Recent advances in nanoscience have spurred new developments in the field of theranostics (the combination of both therapeutic and diagnostic functions in a single system). These integrated systems have been shown to selectively transport therapeutic agents to target tissues while simultaneously monitoring biological responses to the delivered therapy. The current challenge is to develop systems or "platforms" that allow the optimization of the function of each of the combined molecular components that target the disease site, deliver the therapy, and allow for imaging of the results immediately. Researchers recently developed a nanoscale delivery platform known as polymer-caged nanobins (PCNs). The surface of PCNs can be chemically modified to attach a variety of molecules in order to target specific cells or tissues. The platform is liposome based, which allows for a simplified loading and encapsulation of a range of therapeutic drugs. To allow monitoring of the response to therapy, the PCN shell contains magnetic resonance imaging (MRI) contrast agents, which provide images of the drug targets as well as real time images of the response to the drug, e.g., reduction in tumor size. This type of theranostic can make the treatment of numerous diseases safer and more successful because the prescribed regimens can be adjusted in real time during treatment.

ACCELERATING EARLY DIAGNOSIS AT THE POINT-OF-CARE

Handheld Nuclear Magnetic Resonance for Rapid Point-of-Care Diagnostics.—One of the major challenges in medicine is the rapid and accurate measurement of proteins that are biomarkers of a specific disease, or pathogens in biological samples. Magnetic particles which target biomarkers are attractive candidates for such biosensing applications because most biological samples do not have any background magnetization that would interfere with detection. A handheld micro-nuclear magnetic resonance (NMR) device, which can detect such particles, has recently been developed for rapid approximately one-half hour analysis of a variety of biologics, from bacteria identification in small fluid samples to protein markers of cancer. The device employs magnetic particles that bind to targets of interest, creating a signal detectable by the micro-NMR. Also known as diagnostic magnetic resonance (DMR), this powerful biosensor technology offers unique advantages, such as robust signal amplification, broad applicability to profile different types of targets (DNA, proteins, metabolites, and cells), minimal sample preparation, ability to perform measurements in turbid media, and high-throughput capacity. Importantly, the low cost and ability to use the device at the point-of-care could make important contributions to the battle against serious public health issues such as tuberculosis and HIV in underserved populations. In an early study of patients with unknown solid masses, the diagnosis of cancer was made at the bedside in approximately one-half hour and with higher accuracy than with the traditional method of tissue biopsy which requires two days for final results.

NEW INVESTIGATORS, NEW IDEAS

National Institute of Biomedical Imaging and Bioengineering Design by Biomedical Undergraduate Teams Challenge.—The Design by Biomedical Undergraduate Teams (DEBUT) challenge is a new National Institute of Biomedical Imaging and Bioengineering (NIBIB) program opened to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. The main goals of the challenge are:

- to provide undergraduate students experience in working in teams to identify unmet clinical needs, and design, build and debug solutions for open-ended problems;
- to generate novel, innovative tools to improve healthcare, consistent with NIBIB's mission; and
- to highlight and acknowledge the contributions and accomplishments of undergraduate students.

Entries have been solicited in three categories:

- Diagnostic devices and methods;
- Therapeutic devices and methods; and
- Technologies to aid underserved populations and individuals with disabilities.

The winning student team in each category will receive a \$10,000 prize at the NIBIB DEBUT Award Ceremony during the annual conference of the Biomedical Engineering Society.

 PREPARED STATEMENT OF JOHN RUFFIN, PH.D., DIRECTOR, NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute on Minority Health and Health Disparities (NIMHD) of the National Institutes of Health. The fiscal year 2013 NIMHD budget of \$279,389,000 includes an increase of \$3,278,000 more than the comparable fiscal year 2012 level of \$276,111,000.

INTRODUCTION

Millions of Americans from racial and ethnic minority, rural and low-income populations continue to be burdened by disparities in health status and healthcare, despite recent scientific and medical advances to improve the quality of health in this nation. Evidence-based research has shown that these disparities result from the interaction of multiple chronic influences, such as social, environmental, behavioral, and biological factors. Traditionally, research emphasis has been on examining the biology of health disparities. In recent years, the impact of social factors has become more evident in having a strong causal linkage to health disparities. For example, the role of the social and physical environment, the effect of poor housing circumstances, and the difficulties of accessing transportation to obtain timely needed medical care, are all important factors. Therefore, the elimination of health dispari-

ties requires a coordinated and integrated approach across multiple disciplines to understand and solve the underlying biological and nonbiological evolution of health disparities. NIMHD has been at the forefront leading scientific research and building bridges to eliminate health disparities while working with public and private sector partners.

INNOVATION IN RESEARCH

NIMHD administers a portfolio of programs aimed at approaching health disparities from many angles, embodied in the principal goals of research, research capacity building, and outreach. Through research, the NIMHD seeks to understand the development and progression of diseases and conditions disproportionately affecting underserved populations, and to develop evidence-based strategies to improve prevention, diagnosis, and treatment methods. The Centers of Excellence (CoE) Program continues to be a powerful force for encouraging large-scale, transdisciplinary research. CoE researchers have analyzed associations between insulin resistance and other markers of disease in a sample of Mexican-American adolescents from a severely disadvantaged community on the Texas-Mexico border. This study found that approximately 50 percent of their sample (mean age, 16 years old) were overweight or obese, and more participants were obese than overweight. Participants (27 percent) in this sample had insulin resistance, a strong predictor of diabetes, and two biomarkers, low high-density lipoprotein cholesterol and high waist circumference, were strongly linked to insulin resistance. These findings emphasize the need to address insulin resistance at least as early as adolescence to prevent adverse economic, social, and health consequences. Another group found evidence that supports the hypothesis that the loss of function of a molecule that promotes cell adhesion contributes to the development of the aggressive breast cancer commonly found in African-American women. NIMHD COE researchers have also discovered that moral beliefs and lack of awareness contribute to low rates of cervical cancer screening in young Asian-American women.

TOWARD DIVERSITY IN THE WORKFORCE

Building the capacity of individuals, institutions, and communities to conduct research and undertake training, with the goal of strengthening the diversity of the science and medical workforce, are crucial to improving the quality of healthcare of America's underserved populations. The Research Endowment, Research Centers in Minority Institutions (RCMI), and the Building Research Infrastructure and Capacity (BRIC) Programs are the pillar of the NIMHD support for building a national enterprise of academic institutions with the physical and intellectual capability to be leaders in health disparities research. At the University of Texas Brownsville, NIMHD funding has helped to leverage resources for the creation of a new college, the College of Biomedical Sciences and Health Professions, and establish a new degree program in biomedical sciences.

NIMHD continues to recruit an average of 250 new candidates into its Loan Repayment Program annually, adding to the diversity of individuals from health disparity populations in the science and health professions workforce. Many of these scholars are engaged in behavioral, social sciences, prevention, health services, and community-oriented research exploring the various social determinants of health. Some of the innovative research projects include studying text messaging to improve depression treatment adherence in low-income patients, creating web-based treatment programs for substance use in American Indian and Alaska Natives, and examining how perceived discrimination and health system distrust affect behavior and decisionmaking related to cervical cancer prevention in rural and minority women.

ENGAGING COMMUNITIES

Harnessing the power and insights of diverse communities is another important factor because health disparity populations often encounter cultural or environmental barriers to improved health. Outreach efforts remain at the core of the NIMHD's commitment to engage communities in the research process, and equally important, to translate research findings into culturally and linguistically appropriate tools and programs to educate and empower affected communities and their healthcare providers. The Community-Based Participatory Research (CBPR) Initiative supports research that engages communities in the research process as equal partners with scientists. This engagement is valuable in helping communities sustain healthy behaviors over the long-term. For example, one project at Wake Forest University trained members of Latino soccer teams in North Carolina to discuss HIV-prevention behaviors with fellow players. After 18 months, men in the inter-

vention group were significantly more likely to report consistent condom use and HIV testing than those in a control group. Grantees at Saint Louis University are increasing fruit and vegetable consumption by local black men by producing community gardens. These plots have provided more than 1,800 pounds of fresh produce to 150 families, and residents showed decreases in hypertension and body mass index.

A FUTURE OF SUSTAINABLE COMMITMENT

NIMHD seeks to ensure that the investment and progress that has been made toward eliminating health disparities is not lost. It will continue to identify opportunities to sustain effective programs and initiatives by forging and strengthening partnerships across all sectors, while accelerating the pace of research, policy, practice, and community interventions to address pervasive barriers and emerging issues impeding the elimination of health disparities. It will also be imperative to establish an effective system of coordination for these inter and intra-agency activities. Enhanced understanding of the social determinants of health and how where we live, work, and play influence health outcomes are among the priorities that must be aggressively advanced through innovative approaches. While the issues are many, NIMHD is confident that the infrastructure it has built throughout the Nation is up to the challenge, and it is poised to support and create sustainable interventions that will move the country closer to eliminating health disparities. Ensuring that all Americans have an equal chance at healthy life is not an option. NIMHD remains committed to achieving health equity for underserved communities.

PREPARED STATEMENT OF SUSAN B. SHURIN, M.D., ACTING DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH). The fiscal year 2013 NHLBI budget of \$3,076,067,000 includes an increase of \$709,000 more than the comparable fiscal year 2012 level of \$3,075,358,000.

The NHLBI leads research and education programs to discover and apply knowledge to improve health by preventing and treating heart, lung, and blood diseases. I appreciate the opportunity to highlight just a few examples of our success in doing so and some of our most promising research programs that will enable further advances.

CHRONIC DISEASE RISK REDUCTION

Cardiovascular diseases (CVD) and pulmonary conditions are among the leading causes of disability and death around the world. Although their prevention and treatment have improved dramatically, without further progress they will continue to impose an increasing health burden as our population ages. A recent meta-analysis of lifetime risk for CVD underscored the availability of lifelong opportunities for CVD prevention. The Institute is funding a clinical trial to examine diet and exercise interventions to improve neurocognition in patients with CVD risk factors who have cognitive impairment. Effective ways to help people lose weight and sustain weight loss were identified in an NHLBI-supported study reported in November 2011; multiple ongoing projects are addressing ways to help children and adults in a wide range of circumstances improve their health through weight control and physical activity.

The NHLBI continues to focus upon understanding CVD risk in vulnerable populations. The Jackson Heart Study is addressing the biological, behavioral, and psychosocial factors that account for the high burden of CVD in African Americans. The Hispanic Community Health Study—Study of Latinos is addressing the factors involved in the prevalence and development of CVD in Hispanic populations in the United States. Both studies are expected to be renewed in fiscal year 2013. A new program planned for fiscal year 2013 will foster development of effective and sustainable public health interventions to reduce CVD morbidity and mortality in high-risk rural populations.

INTERPRETING THE HUMAN GENOME IN HEALTH AND DISEASE

Data from the NHLBI's substantial investment in whole exome sequencing of participants in its long-term cohort studies is paying off: data are now being deposited in dbGaP, the informatics resource at the National Library of Medicine, for use by

investigators around the world. The return on this investment will provide valuable new diagnostics and treatments for the next decade.

The NHLBI has led multiple global consortia in sharing data and encouraging analysis of large genomic data sets linked to phenotype. One such consortium identified 16 genetic loci important for control of blood pressure that are now being explored by other NHLBI-supported investigators as new approaches to control blood pressure. Still other NHLBI-supported studies are revealing the genetic and environmental causes of chronic obstructive pulmonary disease (COPD), asthma, abnormalities of heart rhythm, and factors that affect the severity of hemoglobin disorders such as sickle cell disease.

NEW THERAPIES FOR HEART, LUNG, AND BLOOD DISORDERS

The NHLBI supports development of improved therapies for heart disease through resources such as the Cardiac Translational Research Implementation Program (C-TRIP) and their assessment in clinical trials through Institute-initiated programs such as the Pediatric Heart Network (now completing a trial in Marfan's syndrome) and multiple studies of genetics and clinical management of congenital heart disease), the Heart Failure Network (conducting studies of cellular and drug therapies of heart failure), and the Cardiothoracic Surgical Trials Network (conducting comparative studies of surgical approaches).

Several NHLBI programs are advancing translation of basic scientific knowledge into new therapies. The Centers for Advanced Diagnostics and Experimental Therapeutics in Lung Diseases (CADET) will accelerate the development of agents for diagnosing and treating lung diseases. Investigators are partnering with other NIH programs such as Therapeutics for Rare and Neglected Diseases (TRND) to do early-stage translational work that will be followed by NHLBI-supported clinical trials.

GENE AND CELLULAR THERAPIES

NHLBI-supported scientists recently reported success in treating hemophilia B, an inherited bleeding disorder, in several patients with a single infusion of a gene therapy that durably boosted the production of the missing clotting factor. If confirmed in other patients, this approach may allow patients to minimize or discontinue expensive treatment with replacement clotting factor.

Encouraging results from studies that use gene therapies in animal models for other diseases offer promise for the treatment of human disease. For example, a unique genetic approach of replacing the single mutated amino acid in mice cured their sickle cell disease. A new form of gene therapy for heart failure improved heart function in pigs without apparent toxicity.

Bone marrow transplantation has been standard clinical therapy for certain diseases since the 1960s. The NHLBI is the primary Institute supporting the Bone Marrow Transplant (BMT) Clinical Trials Network (CTN), with strong support from the NCI. A BMT CTN finding that use of mobilized peripheral blood stem cells rather than bone marrow substantially lowers the risk of graft-versus-host disease (an often fatal complication of BMT) has already affected practice and should lessen complications of BMT.

The NHLBI is supporting resources such as the Production Assistance for Cellular Therapies program to facilitate laboratory and clinical studies of cellular therapies to enhance healing after tissue damage caused by myocardial infarction and some forms of lung disease. Use of mesenchymal stem cells to repair tissue without scarring is being tested in early-stage human trials, with some very encouraging results.

RARE DISEASES

The NHLBI supports infrastructures—registries, clinical trial networks, and biorepositories—to enable research on rare diseases and on risk factors for more common diseases. For example, both sporadic and Marfan-associated thoracic aortic disease may have a common pathway, and a genetic cause of aortic aneurysms may be more prevalent than previously thought. The NHLBI is a leader in conducting clinical trials in pulmonary hypertension and idiopathic pulmonary fibrosis. Linkage of genetic and clinical data with a biorepository is enabling identification of factors influencing the development of congenital heart disease.

Following promising studies in mice, the NHLBI is now completing a study of losartan, an FDA-approved antihypertensive drug, in Marfan syndrome. The NHLBI supported a clinical trial that showed rapamycin (Sirolimus) stabilized lung function, reduced symptoms, and improved quality of life in patients with lymphangioleiomyomatosis (LAM), a progressive cystic lung disease in women. NHLBI partnerships with patient advocacy organizations in the conduct of both trials facilitated their rapid enrollment and completion.

Sickle cell disease remains an area of intensive focus for the NHLBI. A trial recently demonstrated that hydroxyurea, known to be an effective treatment for adults, is also safe and effective in very young children. In fiscal year 2013, the NHLBI plans to initiate Excellence in Hemoglobinopathy Research Awards to promote multidisciplinary basic and translational research and facilitate collaboration with clinical hematologists. The NHLBI has played a major role in a Department of Health and Human Services (HHS)-wide initiative to coordinate the research and healthcare delivery efforts of six HHS components to reduce the health burdens of hemoglobinopathies (sickle cell disease and thalassemia). The NHLBI is developing clinical practice guidelines to ensure that providers know the components of high-quality, evidence-based care for sickle cell disease.

HEMOVIGILANCE

The NHLBI supports multiple studies, and works closely with the FDA, to ensure appropriate monitoring of the blood supply against potential threats. In 2010 and 2011, an NHLBI-led interagency group demonstrated that a xenotropic murine retrovirus (XMRV), which had been reported to be associated with chronic fatigue syndrome in some patients, did not pose a risk to the safety of the blood supply. NHLBI leadership ensured that this and other important health questions were quickly resolved.

PREPARED STATEMENT OF PAUL A. SIEVING, M.D., PH.D., DIRECTOR, NATIONAL EYE INSTITUTE

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Eye Institute (NEI) of the National Institutes of Health (NIH). The fiscal year 2013 NEI budget of \$693,015,000 includes a decrease of \$8,861,000 less than the comparable fiscal year 2012 level of \$701,876,000. As the Director of the NEI, it is my privilege to report on the many research opportunities that exist to reduce the burden of eye disease.

CLINICAL/TRANSLATIONAL RESEARCH

Gene Therapy.—In 2008, NEI-supported investigators reported results from a landmark phase I clinical trial of gene therapy in three patients with a blinding, early onset retinal disease, Leber congenital amaurosis (LCA), which is caused by a defect of the RPE65 gene. Treatment, consisting of injecting a viral vector to deliver normal copies of the RPE65 gene, was well tolerated, and there was objective evidence of modest visual improvement in all three study subjects. To date, 15 participants have been treated and all have experienced visual improvements. Recently published clinical trial results find that increasing the dose with a second injection safely expands the area of retina exposed to the treatment (RPE65-AAV). Responsiveness of light-sensitive photoreceptor cells near injection sites increased after treatment. Younger participants, when compared to older participants, did not experience greater visual improvements. In fact, the two participants with the greatest visual acuity gains were among the oldest in the study. The researchers speculated that the number and health of remaining photoreceptors matter more than patient age, as the rate of photoreceptor loss varies considerably among people with RPE65-deficient LCA. The finding suggests that careful evaluation of photoreceptor cell health is important in determining potential clinical trial participants. Because safety was the primary outcome of this trial, a conservative approach was taken that limited treatment to the eye with poorer vision. In the future, the researchers plan to seek further visual gains by administering three injections of RPE65-AAV and treating the better eye.

A team of NEI investigators restored vision in a canine model of X-linked retinitis pigmentosa (XLRP) using a new gene therapy vector capable of transfecting both rod and cone cells. XLRP is a severe retinal disease that affects both rod and cone photoreceptor cells. Patients with XLRP experience night blindness as children and become blind by middle age. A common form of XLRP results from mutations in the retinitis pigmentosa GTPase regulator (RPGR) gene. Treatment restored lost photoreceptor cell structure and repaired photoreceptor cell connections to other retinal neurons that send visual signals to the brain. This study provides a clearer path to clinical trials for XLRP. In addition, gene therapy trials for age-related macular degeneration (AMD), choroideremia, Leber's hereditary optic neuropathy, Stargardt macular dystrophy (SMD), and Usher syndrome were launched this past year. Clinical trials for juvenile retinoschisis, achromatopsia, and retinitis

pigmentosa are also planned. All of these trials were made possible by sustained NEI support to develop and refine gene therapy techniques.

Stem Cell Therapies.—In January 2012 Advanced Cell Technologies published preliminary results of the first-ever clinical trials of a product derived from human embryonic stem cells (hESCs). These landmark clinical trials are evaluating hESC-derived retinal pigment epithelium (RPE) cells for the treatment of Stargardt's macular dystrophy (SMD) and age-related macular degeneration (AMD). In the two treated patients, there were no adverse events and both had modest but objective improvements in vision. The RPE is a highly specialized layer of cells adjoining the retina that support photoreceptor cell function. SMD and AMD are known to result from a diseased RPE.

GENETICS

NEI created the International AMD Genetics Consortium in 2010 to identify the remaining genetic risk variants for AMD. To increase the statistical power needed to identify genes that have small, yet significant contributions to AMD, the consortium is conducting a meta-analysis on 15 Genome Wide Association Studies (GWAS) representing more than 8,000 patients with AMD and 50,000 controls. In addition to verifying known genes, the consortium identified 19 new gene variants. The genes identified in these studies function in the immune system, cholesterol transport and metabolism, and formation and maintenance of connective tissue. This study provides a nearly complete picture of genetic heritability for AMD. NEI's effort to unite the international research community to share GWAS data sets made it possible to solve a common goal in our understanding of this blinding disease.

In 2009, NEI established the NEI Glaucoma Human Genetics Collaboration (NEIGHBOR), a consortium of clinicians and geneticists at 12 institutions throughout the United States dedicated to identifying the genetics of glaucoma. NEIGHBOR collected and sequenced 6,000 DNA samples and is the largest genetics study of glaucoma. Thus far, NEIGHBOR investigators identified a risk variant in the gene *CDKNB2*. This gene is thought to play a role in the development of the optic nerve head, where retinal ganglion cell axons, which degenerate in glaucoma, converge to form the optic nerve. NEI will make GWAS data from NEIGHBOR available to the vision research community for further evaluation in 2012.

NEUROSCIENCE

In 2011, NEI awarded a grant to support Project Prakash, which combines an extraordinary scientific opportunity with a humanitarian mission. Understanding how the human brain learns to perceive objects remains a fundamental challenge in neuroscience. Project Prakash seeks to treat older children born with congenital cataracts and other eye disorders and then study how their visual function develops. Visual development normally takes place during infancy before children acquire language and can communicate what they are seeing. By treating older children who can fully communicate, Project Prakash will permit scientists to more directly address the nature of neuroplasticity and visual development. This study will also provide important clinical insights to inform visual rehabilitation. India accounts for nearly 30 percent of the world's blindness. Many are poor children with treatable congenital eye disorders, but most never receive medical attention because they live in rural areas far from urban medical centers. Tragically, it is estimated that 60 percent of India's blind children die before reaching adulthood. Project Prakash is a unique opportunity to offer humanitarian medical aid while advancing the field of neuroscience.

PREPARED STATEMENT OF MARTHA J. SOMERMAN, D.D.S., PH.D., DIRECTOR, NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute of Dental and Craniofacial Research (NIDCR) of the National Institutes of Health (NIH). The fiscal year 2013 NIDCR budget of \$408,212,000 includes a decrease of \$2,010,000 less than the comparable fiscal year 2012 level of \$410,222,000.

Science long has served as one of the Nation's most essential economic engines. From the Human Genome Project to the Internet, scientists started with basic research questions that later propelled American entrepreneurship into creating previously unimaginable new markets. So what types of research now are advancing in the Nation's laboratories and clinics that might one day propel American industry and public health to new heights? Today, I offer a brief overview of NIDCR's invest-

ment and progress in a few key areas, and suggest their potential to enhance the dental, oral, and craniofacial health of millions of Americans.

CHRONIC INFLAMMATION

A great place to start is with a promising therapeutic approach that mimics the body's own signals to control inflammation and inflammatory pain. Inflammation is part of the immune system's normal response to infections and tissue injury. Without it, tissues would not heal. At some pre-programmed point, when the threat subsides, the response turns off and inflammation is resolved. For millions of people, however, the immune system's signals get crossed and inflammation is dangerously prolonged.

An NIDCR grantee has developed promising candidate compounds based on the body's own inflammation-resolving molecules. The compounds have proven potent at reducing inflammation and inflammatory pain in animals without the adverse side effects of available analgesics. The plan is to move into human studies within the next year to evaluate their safety and efficacy in turning off the destructive inflammation occurring in periodontal disease. The hope is these compounds one day will provide a more effective approach to managing this widespread oral condition and, possibly, other chronic inflammatory conditions elsewhere in the body.

CHRONIC PAIN

The Institute of Medicine reported in 2011 that more than 116 million Americans suffer from chronic pain, with annual costs of approximately \$600 million. The profound complexity of the body's processes for perceiving and responding to pain is a key factor contributing to the current inadequacies of chronic pain control and interventions to prevent the transition from acute to chronic pain. For the most part, chronic pain conditions and their molecular underpinnings remain poorly understood. This is changing. In late 2005, NIDCR began supporting the first-ever, large longitudinal clinical study of a chronic pain condition. It focuses on temporomandibular joint and muscle disorders (TMJDs), a common group of conditions that affect the area in and around the jaw joint and often overlap with other chronic pain conditions. Preliminary findings, reported in December 2011, identified mutations in genes linked to chronic TMJD, including genes associated with stress, psychological well-being, and inflammation. Building on this work, NIDCR places a high priority on supporting research on the genetics of chronic orofacial pain, with a focus on identifying gene variants that influence pain perception, their interactions with environmental triggers, and behavioral responses to pain.

In other work, NIDCR-supported behavioral scientists are providing insight into factors influencing providers' treatment decisions for chronic pain. They found that decisions tend to be influenced by individual characteristics of patients, such as gender and race or ethnicity, which are extraneous to the pain condition itself. These results are leading to new ways of training providers, helping to focus treatment decisions on more clinically relevant factors.

ORAL CANCER

Personalized healthcare offers tremendous promise for improving the lives of people diagnosed with cancer, as well as other diseases. Among new cancer occurrences, oral and pharyngeal cancer (OPC) is the eighth most common among U.S. men and seventh among African-American men, affecting more than 30,000 people each year. Since 2009, NIDCR has invested in the Oral Cancer Genome Project, which aims to define the genetic changes driving development of oral and pharyngeal tumors. As part of this project, NIDCR-supported researchers employed next-generation sequencing technology to yield one of the most comprehensive analyses yet of the genetics underlying head and neck squamous cell carcinoma (HNSCC), the most common of OPCs. The genomics data provide evidence that HNSCC involves dozens of distinct molecular conditions, each driven by a unique pattern of gene alterations. NIDCR will support work to validate the research findings, which could help identify and reclassify these tumors based on their individual specific molecular characteristics—a key first step in establishing personalized therapies.

Another important result from the Oral Cancer Genome Project was the confirmation that head and neck tumors associated with human papillomavirus (HPV) infection have their own distinct genetic profile. HPV is associated with a subset of OPCs that increased by 225 percent from 1998 to 2004. NIDCR supports research to understand the natural history of this growing public health issue.

The Institute also supports research to improve the survival rate for HNSCC. In a significant advance, scientists in NIDCR's laboratories demonstrated that metformin, a widely used anti-diabetes drug, prevents development and progression

of oral squamous cell carcinomas in mice. NIDCR is initiating clinical studies to determine its effectiveness in humans, opening a new approach to treating this deadly cancer.

CRANIOFACIAL DEVELOPMENT

Cleft lip and cleft palate (CLP) are among the most common of all birth defects, occurring in 1 of 700 live births in the United States, or 7,000 babies per year. Treatment is expensive and difficult, requiring multiple surgeries, orthodontics, and speech therapy over a period of years. NIDCR takes a multi-pronged approach to these devastating conditions, incorporating basic research with prevention, treatment, and post-treatment research. The goal is fewer children born with CLP, better outcomes for those afflicted with the disorders, and less cost and stress for families.

Through genome-wide studies, NIDCR-supported investigators defined several genetic and environmental CLP risk factors. This work set the stage for a researcher co-funded by NIDCR and NICHD to develop a mouse model that closely mimics CLP. The same researcher demonstrated that restoring function in one molecule resulted in complete correction of a cleft lip defect in mouse embryos still developing in utero.

NIDCR-funded investigators have found that many children born with CLP have impaired cognitive functioning that goes undetected until the child is older and remediation is more difficult. Early screening for cognitive deficits in children with CLP may help them reach their full potential through timely, tailored instruction. Research on early screening technologies is underway. In addition, NIDCR continues to fund research to optimize care for children with clefting disorders, including clinical studies comparing the cost and effectiveness of intervention procedures.

NIDCR's investment in small business innovation research (SBIR) and small business technology transfer (STTR) programs is sparking economic activity and improving outcomes for people with craniofacial defects such as CLP. An NIDCR grantee developed surgical simulation software to help clinicians plan and optimize craniofacial surgery and provide a 3D prediction of patients' outcomes. Another grantee leveraged SBIR/STTR investments to patent a minimally invasive surgical instrument system to aid periodontal surgery, often needed by people with CLP.

EVIDENCE-BASED CARE

NIDCR efforts to strengthen the knowledge base for dental practice will accelerate in April 2012 with the establishment of a National Dental Practice-Based Research Network. Building on the success of precursor regional networks, the national network will leverage the power of large numbers of practitioners to propose and perform clinical studies on topics important to dentistry. Because the research is conducted in the real-world environment of dental practice, dentists are more likely to accept and adopt the findings. The expected result is nothing short of a transformation of dental practice—one that will result in more individualized and evidence-based treatment and prevention, to the benefit of millions of Americans.

PREPARED STATEMENT OF LAWRENCE A. TABAK, D.D.S., PH.D., PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the Office of the Director (OD) of the National Institutes of Health (NIH). The fiscal year 2013 OD budget of \$1,429,161,000 includes a decrease of \$28,220,000 less than the comparable fiscal year 2012 level of \$1,457,381,000.

The OD promotes and fosters NIH research and research training efforts in the prevention and treatment of disease through the policy oversight of both the extramural grant and contract award functions and the Intramural Research program. The OD stimulates specific areas of research to complement the ongoing efforts of the Institutes and Centers through the activities of several cross-cutting program offices. The OD also develops policies in response to emerging scientific opportunities employing ethical and legal considerations; provides oversight of peer review policies; coordinates information technology across the agency; and, coordinates the communication of health information to the public and scientific communities.

The fiscal year 2013 request will also support activities managed by the OD's operational offices. OD operations is comprised of several OD offices that provide advice to the NIH Director, policy direction and oversight to the NIH research community and administer centralized support services essential to the NIH mission.

The functions and initiatives of the OD's research offices, also known as Program, Projects and Activities, are described in detail as follows:

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) is the home for cross-cutting offices that support research in areas of emerging scientific opportunity, rising public health challenges, or knowledge gaps that deserve special emphasis. DPCPSI's scope expanded in fiscal year 2012 with the creation of a new Office of Research Infrastructure Programs (ORIP) which supports research resources that serve grantees across the NIH. In addition to ORIP, there are five offices that are described. The fiscal year 2013 budget for DPCPSI, Office of the Director and the Office of Strategic Coordination is \$8,116,000.

OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS

Office of Research Infrastructure Programs (ORIP) supports research infrastructure, research-related programs, and NIH's science education efforts. Within ORIP, the Division of Comparative Medicine provides scientists with essential resources—including specialized disease-model laboratory animals, research facilities, training, and other tools—that enable research funded by all NIH ICs. The Shared and High End Instrumentation programs provide support for the purchase of research equipment, ranging in cost from \$100,000 to \$2,000,000. The Animal Facilities Improvement program provides funds to modernize animal facilities that support biomedical and behavioral research. ORIP also currently monitors more than 350 construction awards that have not yet reached their 20-year milestone and 147 ARRA awards for 10 years. The ORIP budget for fiscal year 2013 is \$283,698,000. The Science Education Partnership Awards (SEPA) program encourages pre K–12 projects that support diversity in the research workforce as well as museum exhibits for students, teachers, and the public. In fiscal year 2013, the budget for SEPAs is \$20,282,000. The Office of Science Education (OSE) develops science education programs, instructional materials, and career resources that serve our Nation's science teachers, their students, and the public. The fiscal year 2013 budget for OSE is \$3,980,000.

OFFICE OF AIDS RESEARCH

The Office of AIDS Research (OAR) plays a unique role at NIH, establishing a plan for the AIDS research program. OAR coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. OAR's response to the AIDS epidemic requires a unique and complex multi-Institute, multidisciplinary, global research program. This diverse research portfolio demands an unprecedented level of scientific coordination and management of research funds to identify the highest priority areas of scientific opportunity, enhance collaboration, minimize duplication, and ensure that precious research dollars are invested effectively and efficiently, allowing NIH to pursue a united research front against the global AIDS epidemic. The fiscal year 2013 budget for OAR is \$63,802,000.

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH

The Office of Behavioral and Social Sciences Research (OBSSR) was established by the Congress to stimulate behavioral and social science research at NIH and to integrate it more fully into the NIH research enterprise. To address the contribution of behavior to health and disease, OBSSR supports the activities of the NIH Basic Behavioral and Social Science Opportunity Network, a trans-NIH initiative to expand the agency's funding of basic behavioral and social sciences research. The fiscal year 2013 budget for OBSSR is \$27,001,000.

OFFICE OF RESEARCH ON WOMEN'S HEALTH

The mission of the Office of Research on Women's Health (ORWH) is to advance NIH research on women's health. This is accomplished by catalyzing innovative research addressing the gaps in knowledge regarding diseases and conditions that affect women and in partnership with the ICs through the implementation of the NIH strategic plan for women's health and sex differences research which serves as a framework for interdisciplinary scientific approaches. ORWH promotes the recruitment, retention, reentry, and sustained advancement of women in biomedical careers and continues to lead efforts to ensure adherence to policies for the inclusion of women and minorities in NIH clinical research. The fiscal year 2013 budget for ORWH is \$42,324,000.

OFFICE OF DISEASE PREVENTION

The mission of the Office of Disease Prevention (ODP) is to foster, coordinate, and assess research in disease prevention and health promotion at the NIH. ODP collaborates with other Federal and international organizations, academic institutions, and the private sector in formulating new research initiatives and policies to improve public health. The fiscal year 2013 budget for ODP is \$6,065,000. The Office of Dietary Supplements (ODS) is within the ODP organizational structure. ODS strengthens knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public. The fiscal year 2013 budget for ODS is \$27,717,000.

OFFICE OF STRATEGIC COORDINATION AND THE COMMON FUND

Office of Strategic Coordination (OSC) leads strategic planning for and centrally manages Common Fund (CF)-supported programs. OSC works with staff across the NIH in CF program development and implementation. The NIH CF was created by the 2006 NIH Reform Act which codified the approach of the NIH Roadmap for Medical Research to support cross-cutting, trans-NIH programs that require participation by at least two NIH ICs or would otherwise benefit from strategic planning and coordination. The CF provides limited-term funding for goal-driven, coordinated research networks to generate data, solve technological problems, and/or pilot resources and tools that will stimulate the broader research community. The fiscal year 2013 budget for the Common Fund is \$544,930,000.

INTRAMURAL LOAN REPAYMENT AND SCHOLARSHIP PROGRAMS

The NIH Intramural Loan Repayment and Scholarship Programs (ILRSP) seek to recruit and retain highly qualified physicians, dentists, and other health professionals with doctoral-level degrees. These programs offer financial incentives and other benefits to attract highly qualified physicians, nurses, and scientists into careers in biomedical, behavioral, and clinical research as employees of the NIH. The Undergraduate Scholarship Programs (UGSP) offers competitive scholarships to exceptional college students from disadvantaged backgrounds that are committed to biomedical, behavioral, and social science health-related research careers at the NIH. The fiscal year 2013 budget for ILRSP is \$7,393,000.

PREPARED STATEMENT OF NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH). The fiscal year 2013 NIDA budget of \$1,054,001,000 includes an increase of \$1,887,000 more than the comparable fiscal year 2012 level of \$1,052,114,000.

The President's budget for fiscal year 2013, which has just been released, offers a timely opportunity to review NIDA's research priorities for bringing the power of science to bear on drug abuse and addiction and reducing their burden on the public's health.

A TECHNOLOGICAL REVOLUTION

The technologies of biomedical research are advancing at unprecedented rates ushering in scientific breakthroughs that are providing a deeper understanding of human genetics, chemistry, and brain circuitry. The emerging picture has the potential to transform how we prevent and treat drug abuse and addiction and its health consequences, and involves new techniques for capturing and analyzing vast and diverse datasets on everything from genetics to neuroimaging to social networks.

NIDA is poised to harness complete genome and "deep" sequencing tools and a growing portfolio of epigenetic initiatives to elucidate how biological processes and environmental factors like chronic stress and drug exposure can alter the expression of genes that influence brain organization and function and the expression (or not) of substance use disorders. For example, the recent finding in an animal model that nicotine can trigger epigenetic processes that make the brain more susceptible to the effects of cocaine could have important policy and practice implications, if it occurs also in humans.

Epigenetic research is also shedding critical new light into the mechanisms that govern the disease progression of HIV, the spread of which is closely intertwined with injection and noninjection drug-use behaviors. A cure for HIV has been elusive

because the virus is able to “hide” in a latent form in resting CD4–T cells. This allows HIV to persist for years, even with prolonged exposure to antiretroviral drugs. Understanding this “latency” effect could enable researchers to reactivate the virus and use current or future therapies to rid the body of it altogether.

The overlaying of neuroimaging data will further accelerate discovery by linking molecular and cellular data with human behavior. For example, a new functional magnetic resonance imaging (fMRI)-based approach can probe the resting brain (i.e., one not performing any specific task) to illuminate circuit-level functions that may prompt behavioral responses, including those related to diseased states or vulnerability. Individual differences found in these images could provide useful biomarkers (neural signatures) of illness risk, course, and treatment response.

The amount and diversity of data being generated by genetic, epigenetic, and imaging studies call for harmonization standards that will allow data integration across laboratories. Thus, our continuing efforts to train the next generation of addiction researchers must now take into account the urgent need for a new cadre of interdisciplinary scientists capable of developing modern analytical tools for integrating and managing large pooled data sets and for modeling and analyzing complexity.

THERAPEUTICS DEVELOPMENT

To help those already suffering from addiction, we need to expand the tools available to treat substance use disorders and their health consequences. To this end, NIDA will continue to invest in the development of addiction medications and to seek public-private partnerships with pharmaceutical companies still reluctant to play an active role due to perceived stigma and financial disincentives. Success demands both adaptable and novel approaches.

Among the “low-hanging fruit” are already-approved drugs, which NIDA is seeking to repurpose for addiction indications, saving enormous amounts of research and development time and cost. Notable in this category are: buspirone, which blocks action at the dopamine (D3) receptor (among its other effects) and may be useful in treating stimulant addiction, based on well-established findings in the animal literature; and cytosine, which acts on nicotinic receptors and has recently been shown to be about 3.5 times more effective than placebo in a smoking cessation trial.

NIDA also continues to support research to increase the effectiveness of various vaccines being tested against nicotine, cocaine, heroin, and methamphetamine. Efforts aim to increase these vaccines’ immunogenicity—that is, their ability to stimulate the production of antibodies capable of blocking a drug’s entry into the brain.

Finally, NIDA is actively pursuing a strategy that involves the use of medication combinations, an approach that has proven effective for treating many diseases (e.g., HIV, cancer) and one starting to show success with addiction. For example, the combination of lofexidine (a hypertension medication) and marinol (a synthetic form of marijuana’s THC) has shown promise in treating withdrawal symptoms (which can trigger relapse) among marijuana-addicted individuals.

IMPROVING PUBLIC HEALTHCARE: DELIVERY AND PERFORMANCE

NIDA will harness every opportunity to translate scientific knowledge to improve strategies for combating drug abuse and addiction. This commitment includes engaging physicians as “frontline” responders and providing them with tested tools, including a Web-based screening tool that generates specific clinical recommendations. The broad availability of these resources is an important step toward integrating substance abuse screening, brief intervention, and referral to treatment (SBIRT) into routine medical care, which will enable better healthcare decisions and outcomes.

NIDA will also capitalize on the Affordable Care Act to study how innovations in service delivery, organization, and financing can improve access to and use of effective prevention and treatment interventions. Because so few people access treatment, coupled with the more than \$600 billion that drug abuse and addiction cost society each year, even a marginal increase in treatment use and retention could have a sizeable public health impact—for individuals, families, and society as a whole.

To help get evidence-based treatments to providers in a variety of settings, NIDA uses collaborative research infrastructures designed to deploy proven strategies rapidly and effectively. For example, NIDA’s Criminal Justice-Drug Abuse Treatment Studies (CJ–DATS) network promotes multilevel collaborations to test proven treatment models in the criminal justice system, disproportionately affected by both drug abuse and HIV. One example, called “Seek, Test, Treat, and Retain,” expands access to HIV testing and treatment, ultimately reducing HIV spread.

STAYING AHEAD OF THE CURVE

NIDA continues to monitor drug abuse trends across different populations. Particularly worrisome are the trends pertaining to marijuana use, on the rise after about a decade of decline; the emergence of an ever-evolving array of synthetic drugs (e.g., spice and bath salts) that are sending users to emergency rooms nationwide; and the continued high rates of prescription drug abuse, which have resulted in a quadrupling in unintentional overdose deaths in this country since 1999. NIDA is addressing all these problems through both broad-based prevention efforts and targeted initiatives.

Prescription drug abuse is one such targeted area that demands a multifaceted approach. NIDA's long-term strategy to help reverse this trend includes:

- research to understand the factors that influence an individual's risk, treat those already addicted, and develop pain medications with reduced abuse potential;
- physician education to improve pain treatment while minimizing prescription drug abuse; and
- community engagement exemplified by NIDA's leadership of a multiagency effort to create a Surgeon General Call to Action to reduce prescription drug abuse among youth.

In closing, NIDA pledges to continue to tackle the emerging and significant public health needs related to drug abuse and addiction, taking advantage of unprecedented scientific opportunities to close the gaps in our knowledge and develop and disseminate more effective strategies to prevent and treat drug abuse and addiction.

PREPARED STATEMENT OF KENNETH R. WARREN, PH.D., ACTING DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Mr. Chairman and members of the subcommittee: I am pleased to present the President's budget request for the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH). The fiscal year 2013 NIAAA budget of \$457,104,000 for the NIAAA reflects a decrease of \$1,868,000 less than the comparable fiscal year 2012 level of \$458,972,000.

SCOPE OF THE PROBLEM

The Centers for Disease Control and Prevention (CDC) ranks alcohol as the third leading cause of preventable death in the United States, and the World Health Organization lists alcohol as one of the top 10 causes of Disability Adjusted Life Years in the United States. And, according to a new study by the CDC, the cost of excessive alcohol consumption in the United States reached \$223.5 billion in 2006.

On a more personal level, I would venture that each of you knows someone who has experienced an alcohol-related problem. It could be a child who has difficulty in school as a result of prenatal alcohol exposure. Perhaps you have a relative or colleague who is one of the almost 18 million people who suffer from alcohol abuse or dependence. Alternatively, your son or daughter may be one of the more than 40 percent of college students who binge drink, many of whom experience blackouts, not remembering where they were, what they did, or with whom. You may know one of the 97,000 college students to experience alcohol-related sexual assault or heard the frustration of a college student trying to study while the alcohol-fueled party raged in the room next door. Many of us also have friends that grew up in a household where alcohol was a problem; in fact, 1 in 10 children in the United States grow up under such circumstances. Clearly, alcohol related problems are not reserved for the middle-aged, nor are they only experienced by those who drink.

RESEARCH

NIAAA supported research is advancing our understanding of alcohol-related problems across the lifespan. By translating this research into new and better prevention and treatment approaches we have the ability to enhance the well-being of individuals, their families, and society-at-large.

Much of what we have learned about alcohol use and alcohol use disorders in the U.S. population comes from analyses of NIAAA's National Epidemiologic Survey on Alcohol and Related Conditions (NESARC). Beginning in 2012, the third wave of NESARC will collect DNA samples in addition to detailed information on alcohol use, alcohol use disorders, and related physical and mental disabilities from an estimated 46,000 participants. This rich resource of genetic and other data will enable future studies comparing whole genome sequences to identify interactions between environmental and genetic risk factors that are associated with harmful alcohol use

patterns and their associated disabilities. Survey data on the distribution of alcohol-related problems and treatment utilization will inform treatment delivery systems to better help those in need of services.

Research on individuals at different stages of life and at different points in the trajectory of their alcohol use and related problems underscores the importance of early identification and intervention in reducing future health problems. This is true for:

- children exposed to alcohol in utero;
- children and adolescents using alcohol and/or at high risk for alcohol-related problems; and
- individuals who exceed the low risk drinking guidelines, including those with alcohol dependence.

One of the barriers to intervening early with children with fetal alcohol spectrum disorders is identification of affected children given the wide range of physical, behavioral, and cognitive effects that may result from prenatal alcohol exposure. Ongoing studies are demonstrating the utility of fetal ultrasound and 3D facial image analysis for earlier and improved recognition of affected children. Alcohol has also been implicated in sudden infant death syndrome and stillbirth. In collaboration with National Institute of Child Health and Human Development and NIDCD, NIAAA is supporting studies to investigate this association and the role other environmental and maternal factors may play.

Children and adolescents who drink are also vulnerable to a number of adverse outcomes. These range from immediate consequences such as academic and social problems, injuries, and death, to longer-term consequences including increased risk for alcohol dependence. Nevertheless, alcohol use increases dramatically during adolescence. Given the range and severity of consequences associated with underage drinking and the prevalence of drinking and binge drinking, routine screening and intervention for alcohol use in young people is critical. Yet many pediatricians and family practitioners cite a lack of time, a lack of familiarity with screening tools, and a lack of confidence in their alcohol management skills as barriers to screening. NIAAA designed Alcohol Screening and Brief Intervention for Youth: A Practitioner's Guide to help clinicians conduct fast, effective alcohol screens and brief interventions. The guide contains a new two-question screen and presents the first youth alcohol risk estimator chart, which combines information about a patient's age and drinking frequency to give a clinician a broad indication of the patient's chances for having alcohol-related problems. Coupled with what a clinician already knows about a patient, the risk estimator can help determine the depth and content of the clinician's response. The guide outlines different levels of intervention and presents an overview of brief motivational interviewing, an interactive, youth-friendly intervention that is considered to have the best potential effectiveness for the adolescent population. Importantly, the guide has been endorsed and promoted by the American Academy of Pediatrics.

In addition to the acute consequences of underage drinking, there is increasing evidence that alcohol use during adolescence may result in enduring functional and structural changes in the brain. Studies to date, however, cannot differentiate between anomalies which resulted from adolescent alcohol exposure and those which predated it. NIAAA is embarking on a new multi-site initiative enlisting children and young adolescents before they begin to use alcohol and following them through adolescence. These studies will use advanced neuroimaging technology as well as neuropsychological and behavioral measures to assess alcohol's effects on brain development and associated cognitive, affective, and behavioral processes. NIAAA will continue to support complementary basic animal research on the effects of adolescent alcohol exposure on subsequent brain function and behavior into adulthood. Collectively these studies will provide a more complete picture of alcohol's effects on the developing brain and potentially provide insight into the association between early alcohol use and later alcohol dependence at the molecular and structural levels.

NIAAA continues to promote screening and brief intervention for adults and encourages inclusion of it in electronic health records. The primary goal is to identify and address high-risk drinking behavior early, including advising individuals who do not meet criteria for alcohol dependence. By intervening early, providers are able to offer their patients more appealing, accessible options to address their alcohol problems, options that are less resource intensive and less expensive.

For those who continue to drink excessively, especially long term, the risk of alcoholic liver disease becomes a significant concern. In fact, 40 percent of patients with severe alcoholic hepatitis, a serious and potentially treatable form of alcoholic liver disease, die within 6 months of the onset of the clinical syndrome. NIAAA has launched a new initiative to foster close collaboration between basic scientists and

clinicians expediting the translation of emerging findings into more effective treatment strategies. Of particular interest is the connection between the gut, liver, and brain and how perturbations to one organ may aggravate the disease state in another. NIAAA is supporting the integration of research to better understand the basic biological mechanisms that underlie the disease and the individual factors that contribute to disease susceptibility in clinical studies that will test new and improved strategies. The goal is to decrease the high mortality and morbidity associated with alcoholic hepatitis.

Developing effective treatments for alcohol dependence remains a high priority for NIAAA. Preliminary studies suggest that the smoking cessation drug varenicline (Chantix) could reduce drinking in alcohol-dependent smokers. NIAAA is currently conducting a larger clinical trial with alcohol dependent smokers and nonsmokers to assess safety and determine if varenicline reduces drinking in either group.

PREPARED STATEMENT OF JACK WHITESCARVER, PH.D., DIRECTOR, OFFICE OF AIDS RESEARCH

Mr. Chairman and members of the subcommittee: I am pleased to present the fiscal year 2013 President's budget request for the trans-National Institutes of Health (NIH) AIDS research program, which is \$3,074,921,000. This amount is the same as the fiscal year 2012 enacted level. It includes the total trans-NIH support for intramural and extramural research for basic, clinical, behavioral, social science, and translational research on HIV/AIDS and the wide spectrum of AIDS-associated malignancies, opportunistic infections, co-infections, and clinical complications; as well as research management support; research centers; and training.

Within the total, the Office of AIDS Research (OAR) has provided increases to high-priority prevention research in the areas of microbicides, vaccines, behavioral and social science, and treatment as prevention research, as well as to etiology and pathogenesis research that provides the essential basic science foundation not only for AIDS-related research but for other related diseases and conditions as well. In order to provide those increases, OAR has reduced and redirected funds from other areas, including natural history and epidemiology, therapeutics, and training and infrastructure support.

THE AIDS PANDEMIC

The HIV/AIDS epidemic continues to expand. UNAIDS estimates that in 2010, more than 34 million people were living with HIV/AIDS; 2.7 million were newly infected; and 1.8 million people died of AIDS-related illnesses. In the United States, the Centers for Disease Control and Prevention (CDC) estimates that more than 1.2 million people are HIV-infected; and someone is infected with HIV every 9½ minutes. AIDS disproportionately affects racial and ethnic populations, women of color, young adults, and men who have sex with men. The number of individuals aged 50 years and older living with HIV/AIDS is increasing, due in part to antiretroviral therapy, which has made it possible for many HIV-infected persons to live longer but also due to new infections in individuals older than the age of 50. The AIDS pandemic has devastating consequences around the world in virtually every sector of society. Further research to improve prevention and treatment is urgently needed. Advances in prevention and treatment also will have extensive economic benefits.

30 YEARS OF EXTRAORDINARY NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH ACCOMPLISHMENTS

HIV, the virus that causes AIDS, is one of the most complex pathogens to affect human health and challenge biomedical research. In the three decades since AIDS was first recognized, NIH has established the world's leading AIDS research program. This investment in HIV research has transformed the disease from a mysterious and uniformly fatal infection into one that can be accurately diagnosed and effectively managed with appropriate treatment. A recent study estimated that 14.4 million life-years have been gained among adults around the world since 1995 as a result of AIDS therapies developed through NIH-funded research.

NIH research has resulted in landmark advances that have led to:

- the co-discovery of HIV, the virus that causes AIDS;
- development of the first blood test for the disease, which has allowed diagnosis of infection as well as ensured the safety of the blood supply;

- the critical discovery of key targets to develop Antiretroviral Therapies (ART) and multi-drug regimens that have resulted in improved life expectancy for those with access to and who can tolerate these drugs;
- the development of treatments for many HIV-associated coinfections, comorbidities, malignancies, and clinical manifestations, with benefits for patients also suffering from those other diseases;
- groundbreaking strategies for the prevention of mother-to-child transmission, which have resulted in dramatic decreases in perinatal HIV in the United States;
- demonstration that the use of male circumcision can reduce the risk of HIV acquisition;
- the first step in proving the concept that a vaccine to prevent HIV infection is feasible; and discovery of two potent human antibodies that can stop more than 90 percent of known global HIV strains from infecting human cells in the laboratory;
- demonstration of the first proof of concept for the feasibility of a microbicide gel capable of preventing HIV transmission;
- demonstration that the use of therapy by infected individuals can dramatically reduce transmission to an uninfected partner;
- groundbreaking research regarding Pre-Exposure Prophylaxis (PrEP), examining whether the use of antiretroviral treatment regimens by some groups of high-risk uninfected individuals could reduce the risk of HIV acquisition;
- discovery that genetic variants may play a role in protecting some individuals, known as “elite controllers,” who have been exposed to HIV over an extended period, from developing symptoms and enabling them to control the infection without therapy;
- critical basic science discoveries that continue to provide the foundation for novel research; and
- progress in both basic and treatment research efforts aimed at eliminating viral reservoirs in the body, which is, for the first time, leading scientists to design and conduct research aimed at a cure.

EXTRAORDINARY OPPORTUNITIES FOR FISCAL YEAR 2013

Advances made by NIH investigators have opened doors for new and exciting research opportunities to answer key scientific questions that remain in the search for strategies to prevent and treat HIV infection both in the United States and around the world, and represent the building blocks for the development of the OAR Trans-NIH AIDS research budget:

Investing in Basic Research.—OAR will increase support for basic research that will underpin further development of critically needed vaccines and microbicides.

Encouraging New Investigators and New Ideas.—OAR will provide additional support for innovative multi-disciplinary research and international collaborations to develop novel approaches and strategies to eliminate viral reservoirs that could lead toward a cure for HIV.

Accelerating Discovery Through Technology.—OAR will increase funds to support critical studies in the area of therapeutics as a method to prevent infection, including treatment to prevent HIV infection after exposure; Pre-Exposure Prophylaxis (PrEP); a potential prevention strategy known as “test and treat,” to determine whether a community-wide testing program with treatment can decrease the overall rate of new HIV infections; and improved strategies to prevent mother-to-child transmission. A key priority is to evaluate prevention interventions that can be used in combination in different populations, including adolescents and older individuals.

Improving Disease Outcomes.—OAR will target funding for NIH research focused on developing better, less toxic treatments and investigating how genetic determinants, sex, gender, race, age, nutritional status, treatment during pregnancy, and other factors interact to affect treatment success or failure and/or disease progression. Studies will address the increased incidence of malignancies, cardiovascular and metabolic complications, and premature aging associated with long-term HIV disease and ART.

Advancing Translational Sciences.—OAR will ensure adequate resources for research on the feasibility, effectiveness, and sustainability required to scale-up interventions from a structured behavioral or clinical study to a broader “real world” setting.

GLOBAL IMPACT OF NATIONAL INSTITUTES OF HEALTH AIDS RESEARCH

Research to address the global pandemic is essential. AIDS research represents the largest component of the total NIH global research investment. Since the early days of the epidemic, NIH has maintained a strong international AIDS research portfolio that has grown to include projects in approximately 100 countries around the world. NIH AIDS research studies are designed so that the results are relevant for both the host nation and the United States. These research programs also enhance research infrastructure, and training of in-country scientists and healthcare providers. New collaborations have been designed to improve both medical and nursing education as a mechanism to build a cadre of global health leaders. Most of these grants and contracts are awarded to U.S.-based investigators to conduct research in collaboration with in-country scientists; some are awarded directly to investigators in international scientific or medical institutions.

BENEFITS OF AIDS RESEARCH TO OTHER DISEASES

It is essential to point out that AIDS research also pays extensive dividends in many other areas of biomedical research, including in the prevention, diagnosis and treatment of many other diseases. It deepens our understanding of immunology, virology, microbiology, molecular biology, and genetics. AIDS research is helping to unravel the mysteries surrounding so many other diseases because of the pace of discovery and because of the unique nature of HIV, i.e., the way the virus enters a cell, causes infection, affects every organ system, and unleashes a myriad of opportunistic infections, co-morbidities, cancers, and other complications. AIDS research continues to make discoveries that can be applied to other infectious, malignant, neurologic, autoimmune, and metabolic diseases, as well as complex issues of aging and dementia. AIDS treatment research has led to more effective drugs for multiple bacterial, mycobacterial, and fungal diseases and fostered significant improvements in drug design technologies. AIDS research has led to the development of new models to test treatments for other diseases in faster, more efficient and more inclusive clinical trials. Drugs developed to prevent and treat AIDS-associated opportunistic infections also now benefit patients undergoing cancer chemotherapy and patients receiving anti-transplant rejection therapy. AIDS research also has advanced understanding of the relationship between viruses and cancer. New investments in AIDS research will continue to fuel biomedical advances and breakthroughs that will have profound benefits far beyond the AIDS pandemic.

SUMMARY

Despite these advances, however, AIDS is not over, and serious challenges lie ahead. The HIV/AIDS pandemic will remain the most serious public health crisis of our time until better, more effective, and affordable prevention and treatment regimens are developed and universally available. NIH will continue to search for solutions to prevent, treat, and eventually cure AIDS.

Senator HARKIN. Thank you very much again, Dr. Collins, for a very provocative statement. I mean “provocative” in a good way, provoking thinking.

IMPACT OF SEQUESTRATION

Senator HARKIN. We’ll start a round of 5-minute questions now.

First, Dr. Collins, I’d like to start by asking about the threat of sequestration.

Under the Budget Control Act of 2011, funding for virtually all Federal programs face a possible across-the-board cut in January. So we could approve our appropriations bill later this year, and then find that virtually every program will be cut in January 2013.

Now CBO has estimated, as I said in my opening statement, a 7.8-percent cut. Other observers, such as the Center on Budget and Policy Priorities, think the cuts could be even larger, 9.1 percent. But for the sake of discussion, we’ll go with CBO’s numbers.

Could you just give us a thumbnail sketch of what that would mean for NIH? I mentioned earlier, I think in my statement, about the number of cuts that would come because of that it was esti-

mated that the number of grants would shrink by more than 1,600 in 2014, by more than 16,000 over a decade.

Just gives us an idea of what that would mean in terms of overall NIH performance.

Dr. COLLINS. Senator, I appreciate the question. It is a very serious one.

We also heard this estimate from the CBO, that if the sequesters were to kick in on January 2013, that NIH would expect to lose 7.8 percent of the budget, about \$2.4 billion. That would, of course, happen with the fiscal year already 3 months along. The estimate that has been put forward by an analysis would result in roughly 2,300 grants that we would not be able to award in fiscal year 2013 that we otherwise would've expected to.

That represents almost a quarter of our new and competing grants. That would result in success rates for applicants who come in with new applications or competing ones falling to historically low levels, and it would be devastating for many investigators who are seeking to continue programs that they have had funded in the past and are back for their competing renewal or who are starting things that are entirely new.

And I think the burden would hit particularly heavily upon first-time investigators who are seeking to get their programs up and going. And upon learning of something of this sort, what is already a considerable sense of anxiety in that cohort, who are our future, would only go up.

This would have across-the-board implications in terms of both basic and clinical science. We would, of course, attempt to try to prioritize those things that are most critical. But there's no question that such things as an influenza vaccine, which Dr. Fauci can tell you much more about, in terms of a universal vaccine, would be slowed down; that efforts in cancer research would be slowed down; that the common fund, also a component of the NIH budget where we have a lot of our venture capital space, we would not be able to start new programs, such as one focused on how to bring together cellphone technology and prevention in health, which is a very exciting new area.

All of those things would be put at great risk by this kind of outcome.

NATIONAL CANCER INSTITUTE BUDGET RESTRAINTS

Senator HARKIN. Thank you, Dr. Collins.

And, Dr. Varmus, even if we can avoid sequestration, the budget is likely to remain tight. You've been managing the NCI with small or no increase since your return.

What strategies have you found or do you plan that will allow you to continue to make progress against cancer with these tight budgets?

Dr. VARMUS. Thank you, Senator.

Well, we've done several things to try to cope with the tight budgets. I can't print money, so that would be the ideal solution. But we have been, for example, looking very carefully at grants that get lower-priority scores, to see if there are grants that meet certain high-priority topics to make sure those get funded. We've been reorganizing our clinical trials cooperative groups to be sure

they operate effectively and are answering deep scientific questions.

As you've heard in Mr. Shelby's opening statement, we have started a new program that emphasizes the bringing together of the scientific community to help define the great unanswered questions in cancer research, the so-called provocative questions, the initiative that solicited more than 750 applications to study these deeper questions and empower the scientific community to help us define what needs to be answered in the future.

We have the ability to act on our new conception of what the genetic underpinnings of cancer are through the collaborative project we undertake with the Genome Institute on the cancer genome atlas.

All of these things are helping us, but, of course, these strategies don't solve the underlying problem of having adequate resources to support science, which costs real money.

Senator HARKIN. Sure.

Well, I am about out. Senator Shelby, I want to make sure everybody gets at least one round of questions.

Senator Shelby.

OBESITY EPIDEMIC

Senator SHELBY. Thank you, Mr. Chairman.

More than one-third of U.S. adults, as everybody at the table knows, are obese. The Deep South, my area of the country, has the highest obesity rate in the country with 6 out of 7 States having an obese population higher than 30 percent.

Obesity is most prevalent in racial and ethnic minorities, low-income populations, and those who live in rural areas. Currently, there's a limited number of the most high-risk population involved in clinical trials and other NIH-funded research.

My question to you, Dr. Collins, is how can the NIH ensure the involvement of the communities most affected by obesity?

Dr. COLLINS. A very appropriate question, Senator, and one that we are quite concerned about as we look at those curves showing increasing longevity for our population. We worry that they might flatten out and actually go the wrong way, if we're not able to get control of this epidemic of obesity and diabetes.

NIH is deeply engaged in this effort, and I'm going to ask my colleague, Dr. Griffin Rodgers, who codirects the effort in obesity research across all of the NIH Institutes, to tell you something about that plan.

Senator SHELBY. Thank you, Dr. Rodgers.

Dr. RODGERS. Thank you, Senator.

NIH supports really a broad array of activities and basic translational and clinical research related to the issue of obesity. As you point out, this is really a complex problem, and a problem that one solution will clearly not be the issue.

As a result of this, the NIH engaged in a strategic planning exercise and just published, about a year ago, a strategic plan directed to obesity, aiming at prevention in local communities, the hardest affected. You mentioned the disparities in racial and ethnic groups, and physicians' offices, bringing into the fold a whole lot of people who were previously not—including urban planners and others.

We've enlisted a number of behaviorists to work on this problem, and we have some really healthy relationships both in the private sector as well as with foundations to tackle this major problem.

Senator SHELBY. How do you get people, and I'm one of them, I'm sure, to eat an apple instead of a cheeseburger?

A cheeseburger, sometimes we crave that. We might not crave the apple. But we all know the apple is much healthier for us. Is that correct?

Dr. RODGERS. You're absolutely right. And you raised an interesting point, something that people have described as "nudge."

Sometimes if you make the default value something that is healthy, you can achieve your objective. So instead of, "Would you like fries with that?" could it be "Would you like an apple with that?"

And I'm pleased to say that many in the food industry are beginning to consider these types of approaches.

INSTITUTIONAL DEVELOPMENT AWARDS ELIGIBILITY

Senator SHELBY. Institutional Development Awards (IDeA), in its entirety, my State of Alabama is a significant recipient of NIH funding, mainly due to research grants received by one institution, the University of Alabama (UAB), of course.

While their success provides significant benefits to both the State and the Nation through medical breakthroughs and economic investment, I'm concerned that its success puts other institutions in Alabama at a competitive disadvantage to similar schools in the IDeA area.

The goal there, I understand, is to broaden the geographic distribution of the NIH funding to institutions that have a historically low success rate. However, many institutions that could benefit are unable to compete for this funding, because the State they reside in is ineligible due to the success of just one institution.

The fiscal year 2012 bill included report language in support of revising current eligibility criteria. No update was provided in the congressional justification for fiscal year 2013.

Dr. Collins, my question to you, can you discuss the progress you've made in response to this language, if you have one?

Dr. COLLINS. Senator, I appreciate the question, and we are very much supportive of the IDeA program, and you've correctly cited it's an effort to try to make sure that institutions that are in States that don't have particularly heavy research investments are still able to compete for funds to be able to do good science.

As I understand it, Senator, the way in which the IDeA program is defined, in terms of which States are eligible, is not something that NIH has control over, but that in fact is something which is in the hands of the Congress.

We recognize that the IDeA program is not entirely in sync with the Experimental Program to Stimulate Competitive Research (EPSCoR) that the National Science Foundation (NSF) supports, which has a similar intention but a slightly different definition.

We are happy to continue to explore this, but we are unable to do so all on our own.

Senator SHELBY. Thank you.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Shelby.
Let's see, this will be Senator Brown.

STATEMENT OF SENATOR SHERROD BROWN

Senator BROWN. Thank you, Mr. Chairman.

Thank you all for being here and for your public service. All six of you are part of the reason that life expectancy is 30 years longer than it was a century ago, so thank you for that.

My first question is for Dr. Collins, and then a question for Dr. Fauci.

NATIONAL CHILDREN'S STUDY

The National Children's Study (NCS), what you're doing is impressive, following children from birth to age 21. In 2008, Case Western Reserve University School of Medicine in Cleveland, where Dr. Collins recently visited, was awarded two study center contracts to research children in Lorain and Cuyahoga counties, two urban, industrial counties that have a pretty diverse population and pretty widespread poverty.

Case Western Reserve University has worked with community partners, such as Battelle Memorial Institute, the Cuyahoga County Board of Health—that's Cleveland—and the Lorain County General Health District. They employed some 60 people for research and data collectors.

It's been brought to my attention that NIH found that the study's geographic approach is too expensive. It seems to back off that, and my understanding is that the seven original sites conducting this research are opposed to making that change.

It seems you're missing a whole cohort of children that are coming to the office rather than going to the community.

Can you explain to me what are your thoughts in reversing that direction, that decision?

Dr. COLLINS. Certainly, Senator, and thank you for the question.

We are very much invested in the success of the NCS as a critical way of assessing environmental and genetic risk factors for many disorders that affect individuals, with the goal then of ascertaining and following 100,000 kids from even prior to pregnancy, through the pregnancy, and on to age 21.

We've conducted over the last 3 or 4 years a series of Vanguard studies to try to assess what is the best way to ascertain such a large number of individuals. And what we've learned through that process, as well as the evolution of the way in which science is being conducted and the way in which healthcare is now possible to deliver, is that there may be ways to do this study which are actually at least as effective and considerably more efficient.

And as a result of that, and what we've learned from the Vanguard study, there is consideration underway that main study might be focused in a different way than knocking on doors, which had been the original plan.

Knocking on doors turns out to be very expensive, and it turns out also to be quite difficult to ascertain a sufficient number of cases, whereas working through providers—and again, geographically distributed providers—provides us a better opportunity to do this in a fashion which can actually save taxpayers' dollars.

But we're very sensitive to the issues you raise. This needs to be a study of children in this Nation that does not leave out those who, at the present time, don't have much in the way of health coverage.

And so the main study, which is still in the process of having its design worked out, will have some serious attention paid to that issue, so that we have a representative group of children, not necessarily ascertained in the original way, in terms of door-knocking but which does in fact give us the information we need to know about genetics, about environment in multiple different groups across socioeconomic status.

And I guess I would just encourage those who are concerned about the change to be part of the process that's going forward now, including a major meeting in the advisory group next month, to be sure that we're getting all the input we need to design a study that is going to give the answer that the Nation needs.

TUBERCULOSIS: PREVENTION, DETECTION, AND TREATMENT

Senator BROWN. Thank you.

One other question, Mr. Chairman.

Dr. Fauci, thank you for your work on infectious disease. As you know, March 24, this last Saturday, was World Tuberculosis Day, commemorating the day in 1882 when the cause of tuberculosis was discovered, as you know.

It's not much of a problem in this country. It's still a problem, obviously. It's not expensive to cure, as long as people take their medicines. You know all of that of course.

One million children will die of tuberculosis (TB) in the next 5 years around the country, as you also know, and more than 10 million children were orphaned just, I believe, last year alone because of TB.

Most alarming is the spread of multidrug-resistant (MDR) and now extensively drug-resistant TB (XDR-TB). The cures for MDR are there. The cure for XDR is significantly more difficult.

What are we doing? What is your Institute doing to foster the development of diagnostic drugs? What are we doing, especially to prevent, detect, and treat TB? And how do we manage the pockets, especially of XDR-TB, around the world and particularly in India and in sub-Saharan Africa?

Dr. FAUCI. Thank you for that question, Senator Brown.

This is truly a very important problem that has slipped off the radar screen, because of the victims of our success in the developed world, as you mentioned. But there are 1.8 million deaths with TB worldwide with an increasing percentage being MDR and XDR TB.

To your question, what we have been doing over the past several years, most intensively over the past 5 to 10 years at NIH, has been to try and bring the science of tuberculosis into the 21st century. All of the advances in molecular biology, in sequencing and drug targeting, have really not been applied as robustly as it should have been to tuberculosis.

So, we are engaging in rather intense partnerships, with industry and public-private partnerships, for the screening and development of drugs for what we call point-of-care diagnostics. One of the real tragedies about tuberculosis is we're using the same diagnostic

test that was used a century ago, namely looking into the microscope to look for, in a very insensitive way, the tubercle bacillus without even knowing just by looking at it whether it's sensitive or resistant to the common drugs.

We've now been involved in developing point-of-care diagnosis that can tell you within a couple of hours, for example, not only is it TB but is it going to be MDR TB.

We are now on the way to developing a vaccine. It's curious that we have a vaccine for TB that's been around again for a century that doesn't work on respiratory TB at all, which is the most common form of spread.

So, these are all the kinds of things that we've accelerated intensively over the last several years in both the control and, hopefully, it sounds maybe pie in the sky but people are starting to think about it now, is major control and in some countries even elimination of TB.

So we're very excited about the efforts, and we will continue to make them a high priority.

Senator BROWN. Thank you.

Thanks, Mr. Chairman.

Senator HARKIN. Senator Moran.

Senator MORAN. Chairman, thank you very much.

Doctors, welcome. One of the first visits that I made after becoming a member of the United States Senate was to the University of Kansas, where I saw research, basic research in pharmacology, pharmaceutical drugs being developed. And this research seems to me to be so beneficial.

And, particularly, I would highlight an example of collaboration between the University of Kansas, NCI, and the Leukemia and Lymphoma Society. And it seems to me, if we're going to get the best opportunities out of our investment, it is this public-private collaboration that's going to make a significant difference.

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES ROLE AND RESPONSIBILITY

And I want to talk, at least in this round of questions, about the National Center for Advancing Translational Science (NCATS).

How do we turn medical discoveries into life-saving treatments and cures? And my assumption is that's the goal of this new center. Is there a problem? Does that not occur adequately today in the absence of NCATS? So in other words, what role will NCATS play in improving the circumstance, if there is a problem to overcome?

What are the impediments toward getting that basic research and pharmacology into those drugs that save and cure and treat? And is there any incompatibility with what the private sector, what drug companies are doing, and with what NCATS is attempting to accomplish?

And then finally, perhaps this is for Dr. Varmus, but what will be the relationship between NCI and NCATS in this process?

Dr. COLLINS. Thank you, Senator Moran, for a very interesting set of questions, and one that is very much on the minds of many of us as we try to make sure the deluge of basic science discoveries that are pouring out of laboratories move as quickly as possible into their translational and clinical benefits.

You mentioned this relationship between Kansas and NCATS, and the Leukemia and Lymphoma Society.

Senator MORAN. I did it to give you a heads up as to my question, so you could anticipate it.

Dr. COLLINS. We're very excited about this particular program, because it's already now enrolling patients into a clinical trial.

I'm going to ask Dr. Insel, who is now the Acting Director of NCATS, to address some of the questions you've posed about what we aim to accomplish with this newest part of NIH.

Dr. INSEL. Thank you. It's an honor to be able to tell you a little bit about this.

I think the first thing to be clear about is that all 27 Institutes and Centers at the NIH have an investment in this kind of translation going from fundamental discoveries to making changes in health. That's what we do.

What this new entity will do, and as the chairman said before, this new entity is essentially just putting under one roof many programs that were already there.

But this is an attempt to develop the tools and to develop some new procedures that make it easier for the other 26 Institutes and Centers to succeed.

So this is a great example. This is a case in which we were interested in taking a compound that was already available in the pharmaceutical industry but not being used very much, one that was developed for rheumatoid arthritis, and developing a process by which we could screen all of the drugs that were out there, to see whether they might hit new targets that might be helpful for a disease that no one had ever considered before.

In this case, a drug for rheumatoid arthritis turned out to be very helpful for a particular form of leukemia. And then we could go to our colleagues in Kansas, who have one of the NCATS centers, the Clinical and Translational Science Awards, and get them to begin to develop this, working with the Leukemia and Lymphoma Society to have this partnership to potentially develop a new treatment for this form of leukemia.

Senator MORAN. I appreciate that story very much. It was very impressive, again, for me to see in the laboratory.

Why does that research not take place elsewhere? Why is NIH such an important component in bringing these, as you say, in this case, a drug that existed but not, I assume, thought of to be used for another purpose?

Is it the NCI that is necessary to get us to move in the directions of this new thought, these new opportunities?

Dr. INSEL. Well again, I would want to make clear that I think the NCI and many other Institutes have a stake in doing just this. The question is whether you want to do it 26 times or you want to do it once.

So in the case of developing, for instance, a procedure to move compounds from the pharmaceutical industry into academic settings, we all do that at all the Institutes to some extent. It's a bit of an impediment. It gets complicated.

There are templates that can be developed that will make that much easier doing it once instead of doing it multiple times. And there are tools that we need.

In this case, this was a particular repository that was developed by the folks at NCATS that collected in one place all the medications that were out there, so we could do a single screen instead of having to break it up into many different attempts.

So NCATS is really an enabler, essentially. We sometimes call it a catalyst for innovation. It's a way of putting under one roof many of the tools that all of us need to get things done faster.

Senator MORAN. Thank you very much, Doctor. Thank you.

Dr. Varmus.

Dr. VARMUS. Well, let me just add one or two words here.

As you pointed out, Senator, the categorical institutes have a deep investment in translational research activities, and the NCI is no exception to that, with well more than \$1 billion a year being invested in these topics.

In the case of chronic lymphocytic leukemia, we have a major program to look at the basic genetics. It's a disease that is a smoldering disease which becomes acute, and we have very few treatments when the disease enters its acute phase.

The intramural program of the NCI came to the chemical genome screening center to help find drugs that might be repurposed, drugs that the company might have little interest in, because it's off-patent, and we were fortunate to have this drug turn up.

Now this trial we see as emblematic of what NCI might be involved in, in working with NCATS. In this case, as you've heard, the trial is being sponsored by the Leukemia and Lymphoma Society. But I think this is a good example of how the interaction between the NCATS and individual institutes like ours might be very beneficial.

Senator MORAN. Thank you all very much.

Senator HARKIN. Thank you, Senator Moran.

Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman and Ranking Member. Thank you for holding this hearing today, and I want to thank the panel for being here.

I'm going to focus my questions with Dr. Collins and Dr. Varmus.

I'm a cancer survivor. I survived clear-cell sarcoma about 15 years ago. Thank you for all your work and all you do in the cancer area, and every other area, for that matter.

PANCREATIC CANCER

I want to ask about pancreatic cancer. As I understand it, it's the most lethal of the common cancers. It's the fourth-leading cause of cancer death. This year, more than 43,000 Americans will be diagnosed with pancreatic cancer, most of whom will die within 1 year of their diagnosis, because the disease is usually too far advanced by the time it's discovered.

And I know in this subcommittee, we're careful to avoid trying to tie the hands of scientists by directing too precisely the appropriated money, on how it should be spent. But I'm troubled that while survival rates of many cancers are steadily improving, one of the most lethal forms of cancer, pancreatic cancer, remains at about 6 percent.

And I look at the model for breast cancer. I'm not sure that's the best model, but I do look at that model and some of the focus there.

I'm wondering if NIH would consider using that breast-cancer model to try to go after pancreatic cancer.

Dr. VARMUS. Thank you for that, Senator.

As someone who has lost several friends to this disease over the last decade and who has worked in my own laboratory on this disease, I appreciate the devastation the disease causes and the difficulty of trying to make headway against it.

Indeed, of the cancers that we work on, I'd say progress has been relatively small in the clinical arena, as you point out.

But there is a great deal of reason for optimism in this domain.

First of all, we have a much larger number of investigators working on the disease, and we have some scientific opportunities that are very dramatic that I'd like to outline for you very briefly. As a result of both factors over the course of the last decade, the amount of money that the NCI spends on this disease, despite the flattening of our budget, has gone up 300 percent.

The model that you alluded to of breast cancer is useful, because one of the things that's been a factor in increasing our attention and increasing our spending on this disease has been the role of advocacy groups, such as the Lustgarten Foundation and several others, that have helped to incentivize NCI-supported investigators to work on this very difficult problem.

There's been a number of dramatic changes in our view of this disease in the last few years, one as a result of being able to take DNA from tumors and examine the underlying damage in the genomes of those cells, to try to understand the disease more profoundly.

One of the consequences of that analysis has been to perceive that pancreatic cancer does not arise in a matter of months. It rises over the course of one or two decades. And that's an important fact, because we know now that there is quite a large window of opportunity for detecting the disease earlier than we have seen heretofore. And that's, of course, a major factor in this disease, the symptoms appear very late when the disease has often spread. And unlike certain other cancers that manifest themselves on the skin or with symptoms at an early stage, it's been difficult to diagnose this disease at an early phase.

Second, we've been able to understand the relationship between the tumor itself and the cells that surround it that make the disease somewhat impermeable to some of the therapies that have been used for other cancers. And there are new ways to try to make the surrounding material more permeable to cancers.

Furthermore, there's been a number of mouse models of the disease that were previously difficult to create that are now being used to try to understand the physiology of the disease and to test treatments in animal models.

All those things give me considerable optimism for the future.

PRIORITIZING CANCER FUNDING

Senator PRYOR. Well, does that mean, though, that you're going to prioritize it in terms of funding and try to invest more there?

Dr. VARMUS. It is prioritized, Senator. And I mentioned earlier that, in this period of budgetary constraint, the NCI has been paying special attention to grants that might in the past have been un-

funded because they fell below what we used to call a pay line. And now we examine quite a number of grants that get priority scores that are perhaps less high and look at them for the diseases that fall in certain categories where we made less progress in therapeutics, neuroblastoma, lung cancer, pancreatic cancer, ovarian cancer, and others. And we frequently fund grants that scores may have been a little less than others but nevertheless represent high-priority areas for us.

Senator PRYOR. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Pryor.

Senator Cochran.

INSTITUTIONAL DEVELOPMENT AWARD PROGRAM FUNDING

Senator COCHRAN. Mr. Chairman, thank you very much.

Let me ask about a program that is designed to help ensure a broader base of financial support to research institutions and those who are in university settings, and who are engaged in research that has unique applications and importance to the medical community and the life of the citizens of our country.

This is done through a program called the Institutional Development Award (IDeA), and the whole point is to broaden the geographic distribution of NIH funding in biomedical and behavioral research programs.

In my State, we have seen some very important strides made in these programs. There are 23 other States in the same boat as my State of Mississippi.

The bill that we have provided funding in directed that certain areas be undertaken for research and review. The Centers of Biomedical Research Excellence (COBRE), which is a Competitive Grant Program, received an increase of \$45.9 million through this program. But NIH said that they're not going to be able to use the funds, and so this year's bill reduces funding by about \$50 million.

I'm asking, what do we need to do, use different wording, put a star by the provision in the bill that these are funds that are intended to be used and for the purposes that the Congress stated? Who wants to take that on and explain what's going on to me?

Dr. COLLINS. Senator, I appreciate that question and clearly the IDeA program is one that NIH is proud of. And before you came in, Senator Shelby was asking whether Alabama could be added to the club, because, clearly, the 23 States that are eligible for this program depend on the opportunity to be able to compete for NIH dollars, and lots of good science gets done as a result.

I want to reassure you that the dollars that were allocated to the IDeA program in fiscal year 2012, the year that we're currently in, are going to be utilized and are going to be utilized, I think, quite effectively. We are going to follow the Congress's instructions here in terms of how to make the most of this additional allocate of almost \$50 million, which for the IDeA programs represents a 22-percent increase in that program in fiscal year 2012 compared to fiscal year 2011.

So, we will be funding both COBRE program that you referred to. Also, as we were asked to do, the new Center for Clinical and Translational Science is part of the IDeA program, and that process is already very much underway, and we will make sure that

we do everything you would want us to, in terms of reviewing and choosing the very most competitive programs to award those dollars to.

Going forward in fiscal year 2013, you will notice that the dollars do not stay at that same level. We are certainly very enthusiastic about IDeA, but at the same time, we have so many pressures on so many other parts of the program that the President's budget reflects that, in terms of decisions that were made in putting together that fiscal year 2013 budget.

But again, I do want to reassure you, as far as fiscal year 2012, we are going to spend those dollars in a very, I think, aggressively innovative way and to the benefit of the IDeA States.

Senator COCHRAN. Thank you very much.

And thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

I just might add on that IDeA program, I was not one of those States either. But I'm not clamoring for Iowa to be one, because while I understand the interest of States to find funding for a lot of different things, I think Senator Shelby said it in his opening statement: We want the best science rewarded.

If it's not in Iowa, then it's someplace else. But it's got to be the best science.

We're not in the business of just spreading money around. We're in the business of trying to take the limited budget that we have and reward the best science that's out there. And we count of all of you and your advisory boards and others to tell us what that best science is. I just want to make that statement.

Senator COCHRAN. Could I have the opportunity of asking the witness whether they think this is wisely invested money or not? I think the suggestion of the question that the chairman has asked suggests that they may be funding in this program just because a Senator on this subcommittee, vice chairman of the full committee, asked for it.

Senator HARKIN. No, I just want to——

Senator COCHRAN. That's not the purpose of the question. The question was on the merits of the program, if it was justified and if the funding level and the language and all was consistent with what the department and the witnesses here thought would be an appropriate investment.

H5N1 RESEARCH

Senator HARKIN. Well, I sure hope so. I hope that is what they will do.

Dr. Fauci, over the past few months, there has been quite a controversy regarding NIH-funded research related to H5N1 flu virus. You remember, you've been here before in the past on this?

Dr. FAUCI. Yes.

Senator HARKIN. A great flare up a few years ago from Southeast Asia, concerned about what was going to happen when it got here.

Fortunately, we found out that it wasn't very transmissible to humans. But recent research has shown that it's possible to genetically alter the virus so that it could spread from human to human.

In December, the National Science Advisory Board on Biosecurity said that this research was a "grave concern to public health." It

asked two journals, "Nature" and "Science", to withhold some parts of the research results to reduce the risk that bioterrorists and others could misuse this information.

On the other side, however, many leading flu researchers disagree and believe the full results should be published.

As of now, a final decision on publication is still pending. There's also a voluntary moratorium among flu experts on some of the research.

You have said that you support this research. I want to know why, and what did NIH hope to learn? Is it worth the danger that a lab-made virus could be released into the world, either intentionally or by accident? And do you think the full results of this research should be published?

Dr. FAUCI. Okay. Thank you for that question, Mr. Chairman.

First of all, the issue of H5N1 and why we do the research, there is no question that influenza, in general, the potential for pandemic influenza and, in this case, specifically, the H5N1, is a clear and present danger because we still have smoldering infections with major outbreaks in chickenpox and, occasionally, a jump from a chicken species to the human species.

As you said correctly, this is not easily transmissible from human to human, and certainly not transmissible easily from chicken to human. The problem is that, as you look in the wild, you see that viruses, as they always do, evolve. And the critical question that really spurs this research is what are those factors that go into the evolution of a virus to what we call "species adapt." In this case, adapt to the human in a way that would make it transmissible. This is an absolutely, unequivocal, critically important question to ask.

So in that case, the research is really very important. We have a major program for decades that studies what we call transmissibility in species adaptability that has made us much better prepared from year to year and on the rare occasion where you get a pandemic to be able to predict and be prepared for, to respond to a pandemic. That's issue number one.

The papers in question, we're doing something that is an important approach toward understanding this phenomenon that is a real and present danger in the wild. And what they did is that they tried to characterize exactly how a virus would look if it did develop the capability of, in this case, mammal.

You use the words human transmissibility. I want to underscore that this was transmissibility from ferret-to-ferret, which is a good but imperfect model for human influenza. So there is a misperception there that this is now transmissible in human.

There was also a misperception in the information that was given out to the public that when you made a virus transmissible from a ferret to a ferret by aerosol transmission, which is the way humans transmit virus from one to another, that actually those ferrets died with high degree of mortality. And that turns out to be not the case.

So where we are now, today, is that we had a determination. We are very careful about the balance between the scientific need to know for the public health good and safety and security. We take that very, very seriously.

When it became clear that this could be what we dual-use research of concern that could possibly be used for nefarious purposes, we put it before an advisory committee that made the recommendation on the basis of the information that they had that the research was important to perform, but that perhaps parts of it, the details, might not be readily available to everyone.

WHO called a meeting, and when they looked at the data and some additional data, and some clarification, they came to a conclusion that was a little bit different. They said, in the big picture of things, the real and present danger of this happening in the wild really outweighs the possible risks of there being bioterrorists.

So, we have a disparity now of recommendations.

Tomorrow, the NIH/HHS is reconvening the National Science Advisory Board for Biosecurity, which is a nongovernment, outside group that would advise the Government, and we are the ones that originally said that we should hold back.

So we're looking forward to tomorrow and Friday when this group will reconvene and look at additional data, because there has been considerably more information that has been gathered since the original determination to hold back some of the data.

Senator HARKIN. Well, I'll look forward to that, too. In the next couple of days?

Link for Recommendations follows: http://oba.od.nih.gov/oba/biosecurity/PDF/03302012_NSABB_Recommendations.pdf.

Dr. FAUCI. Yes, Sir.

Senator HARKIN. That's very timely.

I have a follow-up on that, on H5N1, in my next round, but my time is up.

Senator Shelby.

DOWN SYNDROME

Senator SHELBY. In the area Down syndrome, Dr. Collins, I support the goal of the NCATS to invest in research that moves a potential therapy from development to market as you do. As you continue to develop aspects of the new center, this may be an opportunity to focus on conditions where comorbidities are so pervasive that research will help both the population in question and those suffering from such comorbidities.

For example, 50 percent of those born with Down syndrome, also are born with a congenital heart defect, and more than 50 percent of those with Down syndrome will suffer from the early onset of Alzheimer's disease. Yet it's extremely rare for a person with Down syndrome to suffer from a solid tumor cancer, heart attack, or stroke.

Can you discuss how NCATS will focus on diseases, such as Down syndrome, whose research could benefit many in populations?

Dr. COLLINS. Thank you for the question, Senator. I'm trained as a medical geneticist, and so Down syndrome is certainly one of the conditions that, in my clinical years, I spent a lot of time wrestling with, in terms of trying to give the best advice to children and their parents about this disorder.

As you know, this is caused by an extra copy of an entire chromosome, chromosome 21, which means that genes that are nor-

mally present in two copies are present in three. Even though it's one of the smaller chromosomes, there's still a lot of genes on that chromosome.

And it's been a big question for research to figure out which of those are the ones that are so dose-sensitive, because most of the time, if you have 50 percent more of something, it's not going to cause a lot of trouble. But, apparently, on that chromosome are some genes that do have that potential.

It's the National Institute of Child Health and Human Development (NICHD), whose Director, Dr. Alan Guttmacher, is here, who has the lead in Down syndrome research. They have put together a research protocol and a plan over the course of the last few years, and now formed a consortium bringing together NIH and other organizations to be sure we are looking at what the opportunities and gaps are.

There is some exciting research going on in terms of the mouse model of Down syndrome and even some therapeutic interventions using neuropeptides that seem to show promise in that mouse model.

In terms of the role of NCATS, again, as you heard from Dr. Insel, NCATS does not have as its goal to focus on specific disorders. That's the role of the other 26 Institutes.

NCATS aims to provide resources and to attack those bottlenecks that are slowing down everybody, and to try to see whether we could do better in terms of, when you have an idea about a therapeutic, how do you get it to the point of a clinical approval in less than 14 years and with a failure rate that's less than 99 percent? That's really what NCATS is all about.

So, NCATS should be an important addition to the landscape. But again, I think the lead efforts in Down syndrome will continue to be at NICHD.

INTERAGENCY COLLABORATIONS AND CYSTIC FIBROSIS

Senator SHELBY. Thank you.

Dr. Collins, this is a very important time, as you said, in the history of drug development. We continue to see the benefits from mapping the human genome when specific treatments for genetic diseases are being developed to target smaller and smaller populations.

This aspect of personalized medicine holds promise to treat or to cure rare diseases that plague millions of Americans.

In January, the Food and Drug Administration (FDA) approved a groundbreaking new drug for cystic fibrosis. This drug treats the underlying genetic cause of cystic fibrosis in the 1,200 people who are affected by a particular genetic mutation. This breakthrough treatment has led to tremendous health gains for those who take the drug, and may lead to the development of an innovative new class of drugs for a much larger portion of the cystic fibrosis population.

Collaboration between the NIH and the FDA has the potential, I believe, to move genetic breakthroughs more quickly through the development process and into the hands of patients by ensuring that the FDA has the tools it needs to review and to regulate the genetic treatment.

What are your thoughts on this?

Dr. COLLINS. Well, Senator, I think what you've pointed to is a really exciting development for cystic fibrosis but also a very important point you're making about the need for close collaboration between NIH and FDA, the private sector, and advocacy organizations, such as the Cystic Fibrosis Foundation, who played a big role in this recent advance in cystic fibrosis.

And if you'll permit me, I will tell you what a personal delight it was, having been part of the team that discovered that gene in 1989, to see at this point the use of that information coming forward with the drug Kalydeco.

Senator SHELBY. What can that mean to the people with cystic fibrosis?

Dr. COLLINS. So for the roughly 1,300 individuals in the country who have this specific mutation in the cystic fibrosis gene called G551D, which is unfortunately only about 4 percent of cystic fibrosis sufferers, this drug causes that defective protein to rev itself up. And the clinical results, as published in the New England Journal last year, are truly dramatic in terms of improvement in lung function, gain in weight, because cystic fibrosis is often associated with weight loss. And also, you can see the biomarker for cystic fibrosis, the sweat chloride, returning to normal in kids who are taking this drug.

Again, this special this evening that NOVA is putting on will give you a couple of examples of how that has played out.

So that is really gratifying. But you're right. We need to be sure that we can replicate that many times over.

Dr. Margaret A. Hamburg, the Commissioner of the FDA, and I have formed a joint leadership council between our senior leaders, and many of the NIH representatives who are sitting here at the table are on that council. She has also brought her Center Directors into that same place.

We have resolved together to identify the areas that are most in need of this kind of collaboration and are working quite intensively to try to do that.

Senator HARKIN. Thank you very much, Senator Shelby.

Senator Mikulski.

Senator MIKULSKI. Good morning, everybody. I'm so sorry I couldn't be here for all of your testimony. I was at the DOD on military medicine, and of course, as you know, a lot of that is right across the street from NIH, and we won't talk about the traffic jam.

Senator HARKIN. But thank you for helping with that, too.

NATIONAL INSTITUTES OF HEALTH PRIORITIES

Senator MIKULSKI. And I was effusive with Senator Inouye.

But, Dr. Collins, and to all of you, I've known you for so many years, and I just want to welcome you and let you know how glad I am to see you and how much you are appreciated. We ask you to do a lot. We hope that we have the adequate resources, and at the same time, we are deeply troubled that, as Federal employees are under attack, they seem to forget that you are the Federal employees we need and we turn to in the national interest.

I'll come back to that, because I wonder how all of that harassment, hazing, the cute one-liners in town hall meetings against Federal employees are affecting morale, recruitment, and retention, because, I think, from what I hear, standing in a bagel line or something, or a broccoli line, in Rockville, that I hear it.

But let me get right to my question. Many of you we have turned to at a time of national emergency, and I think of Dr. Fauci, when an obscure virus was beginning to kill young men in our community and escalated in our country and even into a global crisis, AIDS; when we had the anthrax scare here, et cetera.

We came together, and we really moved on a national agenda, and this then goes to, picking up on Senator Shelby, the acceleration of drugs.

Now, Dr. Varmus, you and I have talked about these things. We don't want industrial policy visits at NIH. We don't want to pick winners and losers, et cetera.

But we have compelling needs. We have the orphan drug, you know, the rare disease constellation and then we have those areas that relate to chronic illness or the impending or arriving epidemic of Alzheimer's.

And my question to you is looking at both your Center for Translational Medicine and so on, how can we look at what are compelling national needs, those that we know will impact significant parts of our population, use a significant amount of our cost for the treatment of these, some so long range, like Alzheimer's, some immediate, like diabetes, Dr. Rodgers?

One, do you think it is a valid thing to do? How can we work with you to do that? What are the right resources? And how do we avoid the industrial policy syndrome, which we certainly don't want to get into, because you do need lots of latitude for discovery.

Dr. COLLINS. Well, thank you, Senator, and by the way, congratulations to the Senator from NIH on this recent milestone of recently being recognized as the longest-serving woman in Congress. We were all cheering for that.

Senator MIKULSKI. Thank you. It was moving from the bagel line to the broccoli line.

Dr. COLLINS. Your question is a very important one. How do we in fact decide how to set priorities is what I think you're asking, and of course that's not only—

Senator MIKULSKI. And also how to accelerate?

Dr. COLLINS. And how do we speed up the process of going from basic science to therapeutics?

Maybe just as an example, because it is timely, I would mention what you just mentioned, the situation with Alzheimer's disease. So talk about a public health circumstance of enormous concern. Here we have a diagram showing the prevalence of Alzheimer's disease currently at 5.1 million, expected to rise almost to 12 million over the course of the next few years, if nothing is done about it, and with the cost going through the roof. So here is an area of potential, very serious significance.

And also, I'm happy to say, a situation where the science of Alzheimer's disease has come across quite quickly in just the last year or two, putting us in a position to be able to push that therapeutic agenda harder. And yet for many companies, diseases affecting the

CNS are not seen at the present time as being particularly commercially attractive.

Senator MIKULSKI. Do you want to say what CNS means?

Dr. COLLINS. CNS, central nervous system. I'm sorry. Brain diseases.

I'm going to ask Dr. Hodes, who is the head of the National Institute of Aging, to just say a word about the science that propels us to be particularly excited about Alzheimer's, again as an example of the exhortation you're providing us about what we need to pay attention to.

Dr. HODES. Thank you. I'd be happy to do so.

As we've seen emphasized, the byproduct of the extended longevity in the American and world population has really been the increased threat posed by diseases of late life, and Alzheimer's is certainly prominent among them.

So there's no question, as there has been for a number of years, about the public health importance and imperative. As Dr. Collins notes, what is most exciting to us all is the advance in science that really creates an opportunity, justification for optimism, that didn't exist before.

Earlier, Dr. Collins presented an example of a drug through repurposing, in this case Bexarotene, a drug that had been used to treat a kind of skin cancer, which when tested for its effect on some of the underlying processes of Alzheimer's disease in a mouse model showed absolutely dramatic effects.

Another kind of advance that has been featured, just in the past few months, has been the use of induced pluripotent stem cells and particularly the translation from a skin fibroblast from an individual with or without Alzheimer's disease into neuronal cells in a tissue culture dish, which reflect many of the underlying biochemical abnormalities of Alzheimer's disease.

The potential here for screening now in cells and tissue culture tens, hundreds, thousands of compounds, to see whether they will have an effect that provides a suggestion of which might ultimately be translated, is just one of the many examples that we are poised to capitalize upon at this time.

Senator MIKULSKI. Dr. Hodes, if I could jump in?

This is so exciting to hear. But I held a hearing 3 years ago on the issues of Alzheimer's, with my colleague Senator Bond, who was tremendously interested in this as well as arthritis. And we heard then, 3 years ago, well, we are on the brink of big breakthroughs.

So I had a legislative framework to take a look at that. I was stymied in this institution, okay? I was stymied in this institution on taking a look at this. And I won't go through my legislation. This is not about me. It's about people, which is why we're all in this.

And my question is, 3 years later, I've given up on legislation. I mean, I'm going to move my legislation. Maybe it'll happen; maybe it won't.

But I'm asking, administratively, and through the executive branch, where we have a body of knowledge and a variety of studies that are breakthrough possibilities that meet compelling human need and big budget busters, how can we move these through this process and get them into the hands of clinicians?

I've now heard about promising science, and I'm going to continue to support it, but the promise of science needs to have deliverables.

Dr. HODES. If I may, Mr. Chairman? I know we're over time.

Senator MIKULSKI. Do you mind, Mr. Chairman?

Senator HARKIN. We're over time, but go ahead and respond, please.

Dr. HODES. So with regard to Alzheimer's, recognizing the exceptional scientific opportunity and public health need, in the fiscal year 2013 budget, the President's budget proposes an additional \$80 million for Alzheimer's disease research, over and above the regular NIH appropriation, as a recognition of that exceptional opportunity.

But I think your question is broader than that.

Senator MIKULSKI. It's much broader.

Dr. HODES. And that is how do we, at a time where resources are in fact constrained, make decisions about how to set the priorities to the way that benefits the public in the greatest way? That is our toughest challenge. That's what we sit around the table with the Institute Directors on Thursdays and try to wrestle it. That's what all 27 of the Institute and Center Directors are charged with, in terms of surveying the landscape, trying to see where the gaps are. What we don't want to do is be overly top down.

Senator MIKULSKI. You haven't answered my question.

Dr. HODES. I thought I was getting there, but maybe I—

Senator MIKULSKI. I feel the pressures of time, Doctor. And I don't mean to be interruptive or whatever. But I know you're working hard on it. But do you have an answer to my question?

And if not, it's not a hostile or aggressive question. I just feel the demands of time on our population, the frustrations that families and patients have. You meet with advocacy groups. You're well-known for your accessibility.

Do you have an answer on how we can do this without industrial policy?

Dr. HODES. Senator, I share your frustration and your passion, believe me. The reason I went into research was because of the concerns that we weren't going fast enough in finding answers for people who need them desperately.

I think what NIH is trying to do, in answer to your question, is to be sure we are looking at every possible means of promoting science rapidly. We are trying to figure out how to work with the private sector in circumstances where we can do things together.

But for circumstances where clearly things are hung up, like the bottlenecks we're now trying to tackle with this new NCATS, we are jumping out there in a fairly aggressive way, in fact, in a way that some have said was too aggressive.

But we accept that concern, because of our impatience, just like yours, to take this science that's happening right now and turn it into treatments and cures for those millions of people who are waiting for those hopes to come true.

Senator MIKULSKI. I know my time is up. Well, I want to thank you for your science. I want to thank you for your dedication and for your compassion and your humanitarianism.

Senator HARKIN. Thank you.

NEW INVESTIGATORS

Senator Moran.

Senator MORAN. Mr. Chairman, thank you. Doctors, let me just join, perhaps, the Senator from Maryland, and I was thinking about the—I think most of us spend our lives trying to create hope for other people. I hope that you take great satisfaction in the noble calling that you're pursuing in your lives and know that you are providing hope. In my view, it's the mission of the NIH to provide hope for Americans and really for people around the world that we find cures and treatments.

And so I commend you for choosing a profession, a career, a path, that I think matters so much in changing the world.

Somewhat in that regard, obviously bringing new talent and professionalism, scientists, researchers, and medical practitioners to the arena to provide that hope, I've said numerous times that one of the problems with reduced funding at NIH, or flat-funding that results in less actual money available for research, one of the reasons that that's so troublesome to me is that we're sending a message to the next generation, the potential researchers, scientists, physicians, that the certainty of their career path or the value of what they do is not recognized.

And while I say that, I don't have any basis other than perhaps common sense to say that that would be the case, and I would be interested in knowing if you can, either anecdotally or scientifically, tell me that that's a valid point to make to the American taxpayer, the merit of making certain that funding continues in a stable manner.

And one perhaps less philosophical question, I would like to hear, Dr. Insel, if there is a—this is a question that comes to me just knowing of your center. What's going on that will be helpful to our returning veterans related to mental health? And is there a relationship between what you do and the Department of Veterans Affairs (VA)?

Dr. COLLINS. I'll take the first part of your question, and then ask Dr. Insel to jump right in.

Certainly, for a new investigator who has recently gone through extensive research training and is now starting up their own independent research program in one of our Nation's great universities or institutes, this is a somewhat scary time. They can see what's happened in terms of the likelihood of being funded if you send your best ideas to NIH, which traditionally during the last 40 years has been in the range of 25 to 35 percent, and which last year, the last year we have full numbers for, fell to 17 percent.

That means that an awful lot of that effort comes away without support. And, therefore, those investigators spend even more of their time writing, revising, resubmitting, hoping that they will actually make that cut and be able to get started.

And certainly, if I had to pick one thing that I would say would be most healthy for the American biomedical research future, it would be stability. The feast or famine just doesn't work in this circumstance. You want to give investigators the confidence that if they have good ideas, and if they work hard, and if they produce publications that change the direction of a particular field, they

make insights, they make breakthroughs, they take risks, that there is a career there. And it's difficult when things are bouncing around, as they currently are, for particularly early stage investigators to have the confidence that there's a pathway for them.

That trickles down, and others who are sort of earlier in their decisionmaking hear about it and begin to wonder whether this is a career that they want to invest themselves in.

That's not happening in other countries, but that's happening, certainly, in the United States.

RECRUITMENT OF SCIENTISTS

Senator MORAN. Is there an opportunity for that talent that we're trying to retain in the United States? Is there a movement abroad? Would research scientists in the United States conduct their research elsewhere or pursue—are we competing, I guess is the word, in a global economy, for the best talent?

Dr. COLLINS. We are, and, of course, we have greatly benefited over the years in being able to recruit talent from other countries, and we continue to.

In many instances, those individuals would come and be trained in our country and then would stay and become part of this remarkable innovative community.

It is less likely now that those individuals will stay. It's easier, in many ways, to go back to their countries, where there's more support now plus perhaps they see the environment here as not as friendly.

So, yes, that dynamics have certainly changed.

POST-TRAUMATIC STRESS DISORDER

Dr. INSEL. So very quickly, with my day job hat on, from NIMH, we're particularly concerned about the needs of returning veterans. Estimates are somewhere north of 300,000 who will develop post-traumatic stress disorder (PTSD) or a related disorder that will require some kind of care in the community or potentially through the VA.

We work closely with the VA, but our largest single project currently is actually with the DOD, working with the Pentagon on a massive project now with more than 30,000 soldiers involved, to look at soldiers, with active-duty soldiers, and following them through their service to figure out what we can do to make sure that they don't develop PTSD, traumatic brain injury, or other problems.

That was really generated by the increase in suicide that was reported by the Army, and we've been charged with trying to turn those numbers around.

Senator HARKIN. Thank you, Senator Moran.

Dr. Fauci, I said I have a follow up on H5N1, and that's not true. I have a follow-up question but not necessarily on H5N1, except to say I just wonder if we've been kind of lulled into a state of complacency on this. And we know viruses mutate all the time. If this does mutate into a form that is transmissible, it could be devastating.

Dr. FAUCI. Right.

Senator HARKIN. And hopefully, we're prepared for that.

Dr. FAUCI. Right.

IMMUNOTHERAPY ADVANCEMENTS

Senator HARKIN. But what I want to ask you about was a question that you've responded to previously before this subcommittee and it has to do with food allergies. We talked about this a lot in the past.

I've been told that small trials involving immunotherapy have been very encouraging in treating children who have peanut, egg, and/or milk allergies. As I understand what happens, these kids are given small amounts, and then larger and larger amounts.

Again, I guess for some children with very severe cases, this isn't enough, so they're given both that plus a drug.

From what I understand, what's needed now are phase II trials for these treatments, as well as studies that could explain how they're working.

So, again, what's happening in this area? Why does immunotherapy work for some and not for others? And how are you proceeding with the phase II trials?

Dr. FAUCI. Okay. Thank you for that question.

We have, as I've told you and this subcommittee before, over the last several years, dramatically increased the resources that we have put in on food allergy. Having said that, we started off at a low number. So at a time when the NIH budget has been flat, we have been progressively increasing by a considerable number of factors.

We still are not where we want to be, but within that realm, answer to one of your specific questions, it is unclear at present why some people respond to this early desensitization by giving small amounts of what would ultimately be desensitizing antigen—in this case, it would be peanut or chocolate or something like that.

Phase II trials are, as you know, the next stage after you show that a particular intervention is safe in a phase I to go in and get more information from a phase II. We are very much right now involved in making that next step to go to phase II trials and some of those interventions. But it is not in a situation where we are having a large enough trial to definitively answer the questions, but that is the next stage that we're going.

So we're right at the point and we are working with a number of the societies. In fact, I just met less than 2 weeks ago with our food allergy constituency groups to discuss how we might continue in an arena of constrained resources to push this agenda, particularly in the arena of clinical trials.

Senator HARKIN. If you don't have the figure now, maybe you could just transmit it to us later on, just how much is this going to cost.

Dr. FAUCI. Right. Okay. I don't have the exact number now, but clinical trials in general, particularly when you get to phase II and phase IIB, which involves several hundreds of people, it costs a considerable amount of money.

And that's really been one of the constraints that we have, because the total budget for food allergy, although it's accelerated greatly over the last few years, is still, relatively speaking, when

you compare it to other things, rather small, which we're trying to do something about.

ALZHEIMER'S RESEARCH

Senator HARKIN. Thank you, Dr. Fauci.

I still have a minute and a half. I want to get Dr. Hodes into this area of Alzheimer's research. The President, as Dr. Collins has said a couple of times in his opening statement, again, has proposed \$80 million for NIH research specific on Alzheimer's.

And where he's getting the money? He's taking it from the Prevention and Public Health Fund (PPHF), Senator, that we put into the Affordable Care Act.

I just, again, in a friendly atmosphere, want you to know that that won't happen. That is not going to happen. I will make absolutely certain that not one more nickel is taken out of the PPHF for anything outside than what it was intended for. Just as I will not go after NIH to get money for the PPHF, we're not going to take money out of that fund and put it into NIH.

Now, again, if you're wondering why I'm so upset about this, it's because this President put in his budget to take \$4.5 billion out of that fund. And the Congress, in extending the unemployment insurance to the end of the year and that tax cut on Social Security, while they pay for it, they took the money out of the PPHF.

So I'm very upset about that. I'm very upset with the President and his people at the Office of Management and Budget (OMB) for what they did on that, and then to come and say, now we're going to take another \$80 million. I know that sounds like a small amount but, still, after you've taken \$5 billion out, and now they're just going to start nickel and diming us?

So, I just want you to know, I'm a strong supporter of Alzheimer's research, but this \$80 million isn't happening. NIH has the flexibility to direct a larger share of its funding to Alzheimer's research within its own budget, assuming two things. One, there are enough scientific opportunities to warrant an increase, and, second, researchers submit enough high-quality applications.

So, again, I know all of the data and statistics on what's happening on Alzheimer's in the future. It's something we have to pay more attention to. We need more research into that area. How much more, I don't know. That's up to you. You're the experts in this area.

But this subcommittee will be more than supportive of efforts by the NIH to focus more on this, given those two conditions that I mentioned, into Alzheimer's research.

And I don't know if you have a response to that, Dr. Hodes or not, I'm not asking for a response. I just want you to know what's happening here.

Senator Shelby.

NATIONAL INSTITUTES OF HEALTH MERITOCRACY MODEL

Senator SHELBY. Thank you, Senator Harkin.

The NIH has a highly competitive, two-tiered, independent peer-review process that ensures support of the most promising science and the most productive scientists. The fiscal year 2013 budget pro-

poses to alter this system by capping the amount of awards one principle investigator can receive at \$1.5 million.

And while I suspect you will state this proposal will only scrutinize large guarantees and not mandate a strict dollar-level cap, I'm concerned that there's a larger issue with this proposal; that is, a disincentive to success.

This proposal limits the amount of rewards one investigator can receive through the peer-review process and does not let science dictate funding decisions.

Dr. COLLINS, what will make a researcher strive for the next discovery when they're limited in the awards that they can receive? Could you explain?

Dr. COLLINS. Senator, I appreciate the question very much, and we are, at NIH, proud of being what we would call ourselves a meritocracy; that is, you get supported by NIH because of the strength of your science.

Senator SHELBY. Right. Well, that's a strength of NIH, isn't it?

Dr. COLLINS. It is. And we aim to maintain that.

This circumstance is born of the particularly difficult constraints that we now see in front of us, where there is no magical solution to the several pressures.

I mentioned earlier that the ability of early stage investigators who are just getting started to get funded is clearly putting them under considerable stress.

We debated over many months whether in fact there were levers that NIH might be willing to try to pull in this circumstance to be sure that we were supporting the best science in a way that might require a little bit more scrutiny in certain circumstances.

And you're right in your comment. What we are not proposing is a cap on an individual investigator's support at \$1.5 million, not at all. It is just that if an investigator has already achieved that amount of funding and comes in asking for more, that particular grant is going to get a little bit more scrutiny to be sure that this is in fact the best use of the taxpayers' dollars.

That's what we're aiming to try to do. This has been, in some ways, piloted by National Institute of General Medical Sciences (NIGMS). They have been doing this already for several years, and even at a lower cap, at \$750,000.

And most of the time, when they look at the application, they said, this is great science, we should fund it. We've looked at it a little bit more closely now. We want to be sure that this investigator can actually manage three or four projects as opposed to one, and we think they can, and let's go ahead and see what they can do.

Senator SHELBY. So you're not saying you're going to cap it?

Dr. COLLINS. No.

Senator SHELBY. You're going to measure it and see what happens.

Dr. COLLINS. We're going to look at it a little more closely and see what happens.

Now only about 6 percent of our investigators are at that level, so this is not going to clog the system. And it will be the decision of our advisory councils, who are themselves very invested in the

meritocracy model, who will decide whether, in fact, this is the right place to go.

REPLICATING RESULTS

Senator SHELBY. In December, the Wall Street Journal ran a front-page article entitled, "Scientists' Elusive Goal: Reproducing Study Results." I'm sure you saw that.

The article described a phenomenon in which most biomedical study results, including those funded by the NIH, that appear in top peer-reviewed journals cannot be reproduced or replicated.

The article cited a Bayer study, describing how it had halted 64 percent of its early drug target projects because in-house experiments failed to match claims made in the publications.

This is a great concern, Dr. Collins. I don't want to ever discourage scientific inquiry, and I know you don't, or basic biomedical research. But I think we on this subcommittee, we need to know why so many published results in peer-reviewed publications are unable to be successfully reproduced.

When the NIH requests \$30 billion or more in taxpayer dollars for biomedical research, which I think is not enough, shouldn't reproducibility, replication of these studies, be a part of the foundation by which the research is judged? And how can NIH address this problem? Is that a concern to you?

Dr. COLLINS. It certainly is, Senator. And that Wall Street Journal article also I think raised many ripples of concern, because of the numbers that Bayer was citing.

Well, first of all, we know that investigators who are doing cutting-edge science are working in areas where you're at the edge of what's possible.

Senator SHELBY. We know you're experimenting and you're hoping. I understand.

Dr. COLLINS. Exactly. And so it is not surprising that in that circumstance you may come up occasionally with results that others can't seem to replicate but—

Senator SHELBY. What about that kind of percentage?

Dr. COLLINS. Well, the percentages quoted by Bayer were certainly deeply troubling.

Senator SHELBY. What about at NIH? What kind of percentages do you have there?

Dr. COLLINS. I think it would depend on exactly how the question was phrased. So certainly—

Senator SHELBY. What do you mean by that?

Dr. COLLINS. Well, when somebody is publishing a paper saying that we have determined that it is exactly 24.3 percent of individuals who have a particular problem when it turns out it's really 31 percent or 17 percent. Well, was that a confirmation or not? You see the issue in terms of the precision.

Bayer as a company is trying to make drugs. They want to tolerate no imprecision before they invest hundreds of millions of dollars. So, some of this is along those lines.

Senator SHELBY. Okay.

Dr. COLLINS. Some of it is, frankly, the fact that when you try to repeat an experiment, you may not do it exactly the same way. And both answers could be right, the original investigator and the

person who tries to reproduce it, but they actually didn't quite do the same experiment. And that is always a possibility when you look at a conflict of this sort.

But you know what the good news is? It's that science is self-correcting, that over the course of time, any result that matters is going to be looked at by other investigators, in the private sector, in the public sector. And if it is not correct, you will discover that relatively soon. And if it is correct, others will know that and will build upon it.

So despite the concerns here, which I think are quite real, I think we can be confident that our overall scientific foundation is strong.

Senator SHELBY. Thank you. Thank you, Mr. Chairman.

Senator HARKIN. Great response.

Senator Mikulski.

FEDERAL EMPLOYEES: RECRUITMENT AND RETENTION

Senator MIKULSKI. I know the hour is growing late, and I want to note Senator Harkin's concern about prevention.

And when we did the Affordable Care Act, this was going to be one of the lynchpins of our bill, both prevention and quality initiatives, so that we can both save lives, improve lives, as well as save money.

That is why we looked at chronic conditions. That is why you'll hear me talk so much about them. The epidemic that we know is a chronic condition. Hopefully, one day we can manage Alzheimer's the way we manage diabetes, that we know that it is there, but we can handle it.

Unfortunately, the prevention money has been used as a bank to fund other things, and this is what has Senator Harkin so concerned and, quite frankly, myself.

And I think we need to look at the Alzheimer's funding. We need to talk about where else we can look to that, because it would be a sad day in our country where one important need and one important paradigm shift and focus is pitted against each other. So we look forward to working together to solve this problem and to move ahead.

But I want to talk about Federal employees in your NIH. Of course, I am deeply concerned about the continual attack. Not only do we have to look at how we are going to fund Federal employees, their pay, their pensions, the pay freeze but also this ongoing hazing, harassment, snarky comments, throwaway one-liners, and so on.

Now that's how I feel. Could you tell me, Dr. Collins, how that impacts your recruitment and retention? Or have I just got a soft heart towards Federal employees?

Dr. COLLINS. We thank you for your soft heart, Senator. It means a lot.

But this is a very serious issue in terms of morale. For individuals like the 18,000 who work at NIH, to read about themselves in the comments of individuals who've never met anybody who works at NIH and who talk about these being employees who are simply overpaid and contributing little is deeply hurtful.

I am so proud to stand at the helm of an organization with such incredibly dedicated people, some of whom you see here at this table with me, and all of those, in terms of senior scientific positions, who could easily be employed at much better financial rates in other parts of the public and private sectors, and who are doing this work because of their hopes of making a difference, because of their public spirit, because of their determination to make the world a better place.

To have that kind of dedication characterized in the way that seems to be done in a sweeping way by people talking about Federal employees as if they are somehow a parasite upon the public is really deeply hurtful.

And of course, that is translated into decisions in terms of ways in which Federal employees are being treated in terms of financial aspects, which I think our employees are ready to actually tighten their belts and take whatever needs to be done in an honorable fair-minded way, as far as helping out with the difficulties our Government faces.

But why gang up on them? Why try to single them out?

Senator MIKULSKI. Here is my question in line with that. Since all of the activities that have been going on, particularly around pensions, extended pay freezes, and so on, do you see an upsurge in requests for retirement?

Dr. COLLINS. I don't know if I have statistics on exactly—

Senator MIKULSKI. I am not only talking about the Ph.D.'s, but we're talking about the lab people, the ones who run that fire department. I mean, there is a lot of support staff that goes on to enable the scientist to be the scientist.

Dr. COLLINS. Indeed. And we depend on those people critically or we couldn't do our work. I don't know whether there is an actual statistical indication of an upsurge in retirements, but certainly as an indicator of general morale, I would not be surprised if that is the case.

And when it comes to your other question about hiring people, the kinds of hires that I am trying to be involved in generally are the high-level senior scientists, and this question comes up, "Is this a good time to come and work for the Federal Government? All the things we are reading about in the paper makes it sounds as if we're not going to be considered as the leaders we hoped to be." It is a serious issue.

Senator MIKULSKI. So my colleague from the other side asked excellent questions about, you know, the issues about the availability of scientists, are they going elsewhere to do research, should we change our immigration policy, give every new Ph.D. a green card? Those are subjects of debate. But we are losing out on ourselves, aren't we?

Dr. COLLINS. We are. Even for the people that grew up here and want to stay here. They are not necessarily being well-received, as they should be for their dedicated service.

Senator MIKULSKI. Right. And as I look at the table, I note the longevity and the incredible service, Dr. Hodes, we've known. Dr. Fauci I have known from more than 25 years—20 years.

Dr. COLLINS. I bet its 25 or 30 years.

Senator MIKULSKI. I bet that.

And Dr. Varmus was at NIH, left for Memorial Sloan-Kettering Cancer Center, came back to head a new Institute. This says something about mission-driven. But I think we need to correct it.

Now, I want to be clear, I don't have my coat on as symbolic defiance of the pay freeze.

But I think we need to not only look at how we can manage our Government in a more frugal way, but I think we need to stop this bashing of our Federal employees, and, like you said, take note of what we ask them to do. Everybody is against the Federal employees until they want them and need them.

Dr. COLLINS. Thank you, Senator.

Senator MIKULSKI. Thank you very much.

NATIONAL INSTITUTES OF HEALTH FUNDING

Senator HARKIN. Thank you, Senator Mikulski.

I just want to clear up—maybe I misspoke or I may have left a wrong impression when I said that we won't take money from the prevention fund for NIH; we won't take from the NIH for the prevention fund.

That is not necessarily true. It depends on what it is being used for.

For example, Dr. Rodgers, we have the NIH fund for the diabetes prevention program. In fact, I included \$10 million from the PPHF for that, because that is a proven intervention. It has been proven to prevent and to delay the onset of type 2 diabetes.

The research for that, however, was funded both by NIH and CDC collaboratively. So once they have funded the adequate research, and they have proven interventions, that is where we're more than willing—I am more than happy to get money out for the prevention aspects of that.

What I was talking about on Alzheimer's is that the research for Alzheimer's should not come from the PPHF. If your research leads to some proven preventative measures, which we hope it does, then that is the point at which then we step in with the PPHF. Do you see what I'm saying?

So I just want to kind of clear that up. That's why the \$80 million is not going to happen from us. If you've got a proven prevention strategy that has been proven through research, fine. That's what the Prevention and Public Health Fund is for. I just want to clear that up.

BIOLOGY OF AGING

But one other question, Dr. Hodes, on Alzheimer's. As to the question about the biology of aging, when we think of Alzheimer's, cancer, congestive heart failure as distinct diseases, one thing they have in common, it comes with aging. And so if we can learn more about the aging process, we think that might give us more insight into this.

The NIA took the lead in establishing a group to coordinate efforts across the NIH on understanding the role aging plays in susceptibility to age-related diseases.

Can you just tell us a little bit more about the current activities of this interest group and why is it important?

Dr. HODES. Thank you for that question, and I would be happy to.

Just as you described, aging is clearly a risk factor for many of the changes, diseases, conditions that occur as the years go by. And there is increasing evidence that there are identifiable, underlying biological processes that occur with aging that may be of interest not only in their own purely scientific right, but because they give clues as to points of intervention to affect many of the conditions with aging.

With this in mind, with increasing evidence, exciting studies such as a recent demonstration that in experimental animals, small numbers of cells which can be identified as senescent—they behave abnormally; they secrete abnormal proteins; but they are in very small numbers—went through very ingenious genetic manipulations. They are removed from a live animal, a mouse model. The mouse does better. The mouse has reversed many of the conditions that occur with aging, as an example of the way that intervening at this basic level may have broad implications.

Based on this kind of conviction, there has been over the past several months discussions beginning with a number of us at the table here as Institute Directors, a support of an interest group that brings together those who may have primary affiliations with various disease organ-centered Institutes and Centers, but in common have reason to believe that the underlying aging process is relevant to all of us.

This interest group now has sponsored and will continue a series of lectures, of journal clubs. But most importantly, it creates a new forum for looking at ways in which common support from across the NIH toward problems that are appropriately targeted for the benefit of all us based on the condition of aging will benefit—and it is truly an exciting time and a revolutionary kind of expansion in the way this consciousness now has progressed across NIH.

So we're very excited by it. We think it has great promise for making our research more efficient, more targeted to serve all.

Senator HARKIN. Very good.

I have agreed to permit this room to be used by the National Alliance on Aging after this hearing for a press conference on that subject.

There was one other thing I wanted to bring up here. I have a lot of things I would like to bring up here, as a matter of fact.

I am down to 15 seconds. Do you have another question that you want to ask?

Senator Mikulski.

Senator MIKULSKI. I think that's it.

Senator HARKIN. Do you want anything else?

I'll tell you what, I'll submit it in writing. It is a longer question. I'll submit it in writing. We're getting close to the noon hour anyway. It has to do with the tension between more grants for less money, fewer grants for more money. We kind of touched on that in the beginning. I would like to delve into that a little bit more, and I'll do it with a written question, just how you're looking at that tension that is going on, because we want to increase the grants but decreasing the amount of money, what does that do?

Anyway, I am conflicted by it. I don't know what the right answer is. So I'll write it to you.

Anything else that anybody wanted to bring up for the record that we not have asked or you wanted to follow up for any clarification purposes or anything like that? Anyone at all?

ADDITIONAL COMMITTEE QUESTIONS

Well, listen, our thanks to all of you for your great leadership at the NIH, and we're going to do our best to make sure that our budget is not only not decreased, but we hopefully increase it a little bit, but things are tight around here, as you know.

Senator SHELBY. Especially in the area of biomedical research.

[The following questions were not asked at the hearing but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

NUMBER OF NEW GRANTS

Question. Dr. Collins, you noted in your opening statement that the number of new and competing research grants in the President's budget would rise from 8,743 in fiscal year 2012 to 9,415 in fiscal year 2013, an increase of 672. That's encouraging. But to achieve this increase, the value of individual grants would drop slightly. As you explained, noncompeting grants would be cut by 1 percent.

This raises a fundamental dilemma for National Institutes of Health (NIH), one that is likely to persist as long as budgets remain tight. And that is: Is it better to award more grants for less money or fewer grants for the same (or more) money?

The President's budget seems to have opted for the former approach. More grants mean a higher success rate, plus more opportunities for young researchers to win their first award. But of course there are also disadvantages when the average value of each grant drops. Some argue that it makes more sense to simply fund the best science, and if that means fewer grants, then so be it.

Please comment on this tension and why the President's budget puts an emphasis on increasing the number of grants.

Answer. NIH uses its Research Project Grants (RPG) to support the most meritorious research applications identified by a rigorous peer-review process to have the highest potential for advancing biomedical knowledge and public health. The total number of competing RPG estimated in the President's fiscal year 2013 budget request is expected to increase to 9,415 compared to the 8,743 funded by the fiscal year 2012 enacted level. A tight budget environment prompts a delicate balancing of needs to fund adequately new individual projects, support the maximum number of new research opportunities, and sustain existing grants. In order to maximize resources for investigator-initiated grants, NIH plans to follow grants management policies in fiscal year 2013 that discontinue outyear inflationary allowances for most grants. In the short term, NIH plans to reduce noncompeting continuation grants by 1 percent less than the fiscal year 2012 level, and negotiate the budgets of competing grants to avoid growth in the average award size. In the future, sound fiscal management requires that we continue to carefully consider the number, cost, and duration of new RPGs in order to minimize negative impact on existing programs.

Accompanying these policies for maximizing resources in fiscal year 2013 for new investigator-initiated grants is our continued commitment to award grants to new investigators at rates equal to those of established investigators. Also, NIH will establish a new process for additional scrutiny of awards to any principal investigator with existing grants of \$1.5 million or more in total costs by an Institute or Center's Advisory Council. The purpose of this policy is to promote the award of NIH research grants to as many distinct principal investigators as possible.

These policies will work in concert to ensure that pursuit of new research questions, the lifeblood for cutting-edge science, is maintained. Science advancement includes both the production of new knowledge and new scientists. New scientists, however, must have a reasonable expectation that they will be able to successfully compete for their own research grants at the end of their prolonged period of training if they are to be retained as members of the biomedical research workforce. NIH has strategically chosen in fiscal year 2013 to support a larger number of new re-

search project grants by sustaining support for noncompeting continuations at 99 percent of their competing levels. This approach balances NIH's commitment to its ongoing research portfolio with the need to stimulate new research ideas and priorities in this time of limited resources.

NATIONAL CHILDREN'S STUDY

Question. Dr. Collins, NIH, Centers for Disease Control and the Environmental Protection Agency spent a combined \$54.7 million on the National Children's Study (NCS) from fiscal year 2000 through fiscal year 2006. From fiscal year 2007 through fiscal year 2012, the Congress appropriated another \$937 million for the NCS, bringing the total to almost \$1 billion. What has this nearly \$1 billion achieved so far?

Answer. NIH has shown the feasibility of performing an NCS by designing and testing varied scientific approaches and demonstrating how to conduct a study of this size and scientific and logistical complexity in a fiscally sound manner.

In addition to comparing different enrollment strategies to develop a scientifically valid and fiscally responsible methodology to enroll 100,000 children in the Main Study, the NCS has enrolled more than 3,000 children to date in the Vanguard Study. In addition, we have developed innovative approaches to research methodology and developed broadly useful research tools.

Examples include:

—New informatics approaches including:

- The capacity to capture systematically the operational, logistical, and cost data for an ongoing study;
- A comprehensive approach to harmonize the terminology for neonatal medicine, including the deposition of hundreds of terms that researchers around the world can use into the National Cancer Institute Enterprise Vocabulary Services;
- Development of nonproprietary data collection, case management, and data archiving tools that conform to international data standards and can be used in many types of research;
- Development of a system of tagging data to allow rapid analysis and data pooling for research data;
- Simulation strategies for comparing complex recruitment strategies; and
- New methods for implementing and analyzing recruitment in large studies and an analytic approach to examine rates, kinetics, and efficiencies to allow selection of optimal recruitment strategies;
- A research portfolio of approximately 300 individual studies, most of which were multicenter, to establish and validate methods to support the Study;
- In conjunction with the U.S. Department of Health and Human Services Office for Human Research Protections, a national network of Institutional Review Boards using a Federated Model that covers all 36 National Children's Study Centers, which saves time and costs for administrative review for human research protections;
- A biobank repository for human biological specimens and environmental samples that is modular and scalable. The repository has collected about 125,000 specimens and has already distributed thousands of specimens for analysis and additional scientific projects;
- A research workflow process in 40 locations that is flexible and cost effective that can be used by many other types of research, as well as the NCS. For example, the Clinical and Translational Science Awards (CTSA) Consortium is adapting the same processes in many of the 28 NCS locations that are also CTSA locations;
- Collaborations with longitudinal birth cohort studies around the globe to harmonize practices and leverage resources; and
- In collaboration with other statistical agencies, new statistical methods for analysis for combining data from multiple types of research.

Question. The President's budget for fiscal year 2013 would add another \$165 million. What do you estimate the cost of the NCS will be in fiscal year 2014, when recruitment is expected to begin?

Answer. Pilot testing conducted through the NCS Vanguard sites showed that a study design based on recruiting participants through healthcare providers was most efficient. Other large Federal studies have also effectively employed this provider-based approach. Also, while the revised approach may use healthcare provider networks as the primary source for recruitment, the NCS could see additional participants through secondary sources (such as title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of all appropriate pop-

ulation groups. The President's budget request for fiscal year 2013, which shows a reduction of approximately 15 percent to \$165 million for the NCS, appropriately reflects these proposed design changes. While future funding needs for the outyears will be determined by early data gathered by the Main Study, we anticipate that the budget for fiscal year 2014 will be the same as for fiscal year 2013.

Question. How long will the recruitment phase take, and do you expect the annual cost will remain fairly constant during that period?

Answer. We expect to issue the Request for Proposals for the Main Study in the fall of 2012, with awards made in 2013 and recruitment beginning in 2014. The recruitment phase is expected to continue for approximately 3 to 3½ years. We anticipate annual costs will remain flat in unadjusted dollars during the recruitment phase.

The NCS is able to reduce overhead costs through greater operational efficiencies and redistribution of tasks and responsibilities. Examples include the use of non-proprietary software to eliminate license fees and proprietary support; use of a federated model for human subject protection to reduce redundancy and speed approvals through elimination of duplicate administrative resources; use of the NCS Program Office as a coordinating center to develop study instruments and protocol documents, to perform data analysis, and to manage field operations and general consolidation of overlapping field operations.

With the reduction in overhead, we anticipate that for fiscal year 2013 we need approximately \$35 million for support services and \$130 million for ongoing Vanguard operations and Main Study initiation. Main Study initiation includes:

- community outreach and advertising;
- memoranda of understanding with cooperating facilities;
- establishment and testing of informatics platforms, including data security and regulatory compliance;
- establishment and testing of biospecimen and environmental sample collection and shipping from study locations;
- training of field personnel;
- regulatory approvals for information collection from participants; and
- establishment of data collection and transmission quality assurance and quality control processes.

Question. Is the annual cost expected to rise or decline after the recruitment phase? If so, by approximately how much (e.g., 25 percent)?

Answer. Once the more labor-intensive recruitment phase has been completed, funding requirements for the NCS over the life of the study are expected to remain stable. While the number of participant visits each year may decrease to once per year, some subgroups in the Study may receive additional questionnaires on specific topics. In addition, as the number of biospecimens and other data collected from Study participants increases, the fiscal needs of the biobank and data warehouse rise, as these data and samples are both stored and made ready for analysis by other scientists.

Question. Do you expect the annual cost will remain fairly constant during the Main Study, once recruitment has been completed?

Answer. Annual unadjusted costs are expected to remain constant in unadjusted dollars following the recruitment phase of the Main Study. The prenatal and infant development phases are of critical importance because of the potentially long-term effects of various environmental exposures; consequently, the NCS plans to "frontload" the Study, conducting more participant visits and sample collections in those years. However, as the frequency and intensity of study visits decreases, the costs associated with biospecimen and environmental sample processing, storage, and analysis and with data processing, storage, analysis, and security will increase.

PAIN RESEARCH

Question. Dr. Collins, I understand that National Institute of Neurological Disorders and Stroke plans to establish a new trans-NIH working group on overlapping chronic pain conditions. Please provide some more details on this effort and what it is intended to accomplish.

In addition, what mechanisms will the NIH employ to:

- expedite scientific understanding of the factors that predispose, trigger, and perpetuate chronic pain;
- advance our knowledge of the diverse underlying mechanisms responsible for chronic pain (including individual differences and sensitivity to pain);
- identify promising effective therapeutic drugs (and other approaches) for pain control; and

—expedite the translation of these findings to those suffering, especially the most at-risk populations such as women?

Answer. In 2011, NIH hosted a number of meetings and workshops focusing on overlapping chronic pain conditions that disproportionately affect women. These workshops included discussions of possible common pathways underlying these conditions as well as the need for improved research diagnostic criteria for overlapping pain conditions. To address these issues further, a new trans-NIH overlapping chronic pain conditions working group was formed in fall 2011. The group is led by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Dental and Craniofacial Research and brings together staff from 13 Institutes and Centers involved in pain research as well as a representative from the patient advocacy community. The working group will help coordinate research efforts across the NIH on overlapping chronic pain conditions and is planning a trans-NIH conference in August 2012 that aims to:

- evaluate and summarize current knowledge on the causes and progression of overlapping pain conditions;
- identify critical research needs, such as improved research diagnostic criteria for this group of conditions; and
- enhance interdisciplinary collaboration and cooperation in this area of research.

NIH utilizes a number of mechanisms to fund research on understanding the factors that predispose, trigger, and perpetuate chronic pain and the underlying mechanisms responsible for individual differences and sensitivity to pain. Sixteen NIH Institutes and offices supported the NIH Blueprint for Neuroscience Grand Challenge on Pain, whose goal was to facilitate highly collaborative, multidisciplinary research to better understand the mechanisms that underlie the transition from acute to chronic pain. Research supported by this initiative aims to understand the important role of neuroplasticity—or changes in the nervous system—in transitioning to chronic pain and the need to reverse these maladaptive changes, to allow recovery. Other projects funded through this initiative are focused on the identification and modulation of genetic changes that predispose individuals to and contribute to the onset of chronic pain. NIH continues to accept competitive revisions that propose a collaborative, 1-year pilot study or new specific aim associated with an active NIH grant as part of this initiative. The Mechanisms, Models, Measurement and Management in Pain Research Initiative supported by 11 NIH Institutes is another example of a trans-NIH solicitation that encourages a wide range of basic, translational, and clinical research on pain including sex differences in the pain experience and genetic contributions to individual variability and response to treatment.

The pain portfolios at a number of NIH Institutes include research focused on risk factors for chronic pain and individual differences in pain perception. For instance, brain imaging studies (fMRI and resting state fMRI) supported by NIH have compared structural and functional brain changes with pain states, supporting the notion that central nervous plasticity is a characteristic of chronic pain. A cutting-edge study used cortical imaging to detect changes in the brain to distinguish which patients transition from acute to chronic back pain and which recover. Extensive use of imaging tools have also shown that differences in patient reported pain sensitivity are correlated to activation of brain regions associated with pain and are linked to sex, race, genetic makeup, and environmental stress levels. Environmental factors such as hormones and stress have been shown to contribute to differences in pain sensitivity and analgesic response, while genetic variants determine individual sensitivity to certain analgesics, ability to sense pain, and risk for chronic pain. Preliminary results from the NIH-supported Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) study have helped identify several genetic markers associated with risk for orofacial pain and related to different patterns of self-reported pain. NIH is also funding the ongoing Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) studies to study pain characteristics that contribute to risk for transition to chronic pelvic pain and a 10-year study on overlapping pain conditions that disproportionately affect women, including episodic migraines.

In addition to funding basic research on underlying mechanisms and causes for chronic pain, NIH supports a number of activities to advance the development of therapies to control and alleviate pain, including multiple activities in partnership with the FDA. Members of the NIH Pain Consortium—a joint undertaking across 25 NIH Institutes, Centers, and offices that facilitates collaborative pain research—currently participate in an advisory committee for the Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTION) Initiative, a public-private partnership program sponsored by FDA to streamline the discovery and development of analgesics. In May 2012, NIH and the Federal Drug Administration plan to hold a state of the science workshop on assessing opioid efficacy and

analgesic treatment in conjunction with the seventh annual NIH Pain Consortium Symposium focusing on advancing pain therapies. More broadly, senior leadership from the NIH and FDA are involved in an NIH–FDA leadership council that is exploring better coordination of NIH and FDA efforts to improve regulatory science and overcome hurdles in the drug development pipeline for common and rare diseases.

The NIH Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) program supports research on developing pain therapies including projects focused on:

- the development of small molecules as anti-inflammatory, analgesic agents;
- neural stimulation to relieve phantom limb pain;
- Internet tools for self-management as an adjunct to chronic pain care;
- improved opioid formulations with fewer side effects; and
- selectively targeting pain nerve fibers for gene delivery.

NIH continues to encourage applications through the SBIR program, Institute-specific translational programs, and other mechanisms including trans-NIH initiatives. For example, the NIH Blueprint for Neuroscience Research currently supports a Grand Challenge for Neurotherapeutics to address the lack of effective treatments for disorders of the nervous system, including chronic pain. Additionally, the newly established National Center for Advancing Translational Sciences (NCATS) at NIH will catalyze the generation of innovative methods and technologies to enhance therapy development for a wide range of human diseases and conditions.

NIH is currently involved in diverse dissemination efforts to inform the public about pain research findings. NIH is a member of the new Interagency Pain Research Coordinating Committee (IPRCC) which was recently created under the Affordable Care Act to enhance pain research efforts and promote collaboration across the government, with the ultimate goals of advancing fundamental understanding of pain and improving pain-related treatment strategies.

The subcommittee has been specifically charged with making recommendations on how to best disseminate information on pain care, and NIH is working together with other member Federal agencies to collect information on current dissemination efforts in order to inform these recommendations.

The NIH Pain Consortium is encouraging medical, dental, nursing, and pharmacy schools to respond to a new funding opportunity to develop Centers of Excellence in Pain Education (CoEPEs). The CoEPEs will act as hubs to develop and disseminate pain management curriculum resources for healthcare professionals and provide leadership for change in pain management education. Additionally, NIH provides online informational material on numerous chronic pain disorders that specifically reference overlapping pain conditions, and funds grants testing methods to teach patients how to access high-quality web-based health information for self-management of pain.

FOOD ALLERGIES

Question. Dr. Fauci, life-threatening food allergy conditions affect millions of America's children. Trials in a small number of patients have demonstrated that oral immunotherapy (OIT) is safe and effective in a significant percentage of patients. Many researchers believe the next step is to determine the most effective dosage and timeframe for treatment through larger and more complex clinical trials. As we both know, however, these trials are expensive. While there are indications of substantial private philanthropic support, Federal money will also be required. One private research group has estimated that the cost of phase II trials for the eight major food allergens (peanut, tree nut, milk, egg, soy, wheat, fish, and shellfish), along with mechanism and longitudinal studies, would total about \$90 million over 6 years.

Answer. The National Institute of Allergy and Infectious Diseases (NIAID) is conducting Phase I and II clinical trials to evaluate OIT or sublingual immunotherapy (SLIT) to treat or prevent food allergy. These clinical trials include studies of various immunologic parameters to understand factors that relate to the development or natural resolution of food allergy and/or response to therapy. Recent and ongoing NIAID-sponsored OIT and SLIT trials include:

- phase II clinical trial that showed that egg OIT is safe and effective in children 5 to 18 years old with egg allergy (in press, *New England Journal of Medicine*);
- phase I/II clinical trial to determine whether peanut extract placed under the tongue (SLIT) is a safe and effective treatment for adolescents and adults with peanut allergy;
- phase II clinical trial of milk OIT combined with anti-immunoglobulin E (omalizumab) for the treatment of children with milk allergy;

- phase II clinical trial to determine if regular consumption of baked foods containing milk will enable children with milk allergy to drink milk and consume milk-containing foods; and
- phase I/II prevention trial in which infants and young children at high risk for peanut allergy regularly consume peanut-containing snacks to determine if this will prevent the development of peanut allergy by age 5–6 years.

Several OIT trials also are in development for children (1–4 years of age) and adults with peanut allergy.

A few additional studies, conducted without NIH sponsorship, have recently been published. Similar in size to the NIH-sponsored studies, these phase I/II clinical trials (typically 20–60 children per study) have focused on milk, egg, and peanut and lead to similar conclusions, i.e., approximately 60–90 percent of those subjects who remain on OIT for 1–2 years can tolerate modest amounts of the food.

Question. Are you in general agreement that the scientific studies already completed on OIT indicate that moving ahead with larger trials on key allergens is appropriate at this time?

Answer. NIAID is enthusiastic about recent results of OIT for milk, egg, and peanut and agree that it will be important to proceed with larger phase II trials for these and other food allergens. While we anticipate many similarities in study design, the most promising approaches will likely differ based on the particular allergen and study populations (e.g., children vs. adults; mild vs. severe disease; treatment vs. prevention design; and single vs. multiple food sensitivities).

Although OIT is currently the most promising approach for treating food allergy, a small number of patients appear not to respond to OIT and others (10–20 percent) are unable to tolerate OIT because of recurrent allergic reactions. Furthermore, patients with a history of severe anaphylaxis, who are most in need of new treatment strategies, have not been enrolled in these early-stage OIT clinical trials due to safety concerns. Further research is necessary to develop and test treatment strategies that will benefit these patients. Novel treatment strategies may also provide improved safety and efficacy for food allergic individuals in general. For example, the addition to OIT of an anti-immunoglobulin E or similar molecule may reduce adverse effects of OIT and allow for larger doses of OIT that might be more effective. Other routes of allergen administration, e.g., via a cutaneous patch, should also be explored.

Question. What is your professional judgment as to the cost and appropriate timing of such a system of trials?

Answer. For OIT that involves administration of a food alone (e.g., milk, egg, and peanut), large phase II studies may be sufficient to change clinical practice (foods are not licensed by the FDA as therapeutics). Nonetheless, many such studies would be comparable in scope, complexity and cost to modest size phase III clinical trials required for drug licensure. In contrast, full phase III licensure studies will be required if OIT is combined with pharmaceuticals or allergen immunotherapy is administered through devices such as a cutaneous patch.

In our professional judgment, a prioritized set of clinical trials would include:

- a series of larger phase II studies to confirm the promising results of the studies on egg, milk, and peanut outlined previously (estimated cohort sizes of 100–300 subjects);
- phase II/III studies of OIT for the same allergens with the addition of pharmaceuticals (e.g., anti-immunoglobulin E) to diminish adverse events in OIT and improve efficacy of OIT;
- phase I–III studies of peanut (and perhaps other food allergens) delivered by cutaneous patch;
- phase I/II pilot studies exploring OIT for the other major food allergens (tree nut, soy, wheat, fish, and shellfish) followed by larger phase II studies (100–300 subjects) to confirm any promising results; and
- various food allergy prevention trials in high-risk infants and young children.

We anticipate that the minimum duration of most phase II–III trials would be 3–4 years and most prevention trials would take 6–7 years.

To ensure that the highest-priority studies are conducted ethically, rigorously, and safely, such studies should be phased in over a period of years. A phased process will allow knowledge gained from the initial studies to inform the design of future studies, improve safety, and enable cost efficiencies.

Factors that contribute to total costs include cohort size, study duration, complexity of treatment regimens and clinical outcomes, the number of protocol-required blinded food challenges, costs of allergen preparation and distribution under Good Manufacturing Practices, costs of additional pharmaceuticals (e.g., biologics, such as monoclonal anti-immunoglobulin E or cutaneous patch delivery devices), and the type and number of immunologic parameters to be studied. Thus, in our professional

judgment, an integrated set of a prioritized set of clinical trials could cost \$150–\$250 million over many years. Additional constraints on implementation of such a highly ambitious set of clinical trials include the limited capacity of academic research centers and the relatively small existing cadre of highly trained and experienced adult and pediatric specialists in food allergy research.

Question. How much money would be required in the first year to initiate a full set of OIT trials?

Answer. NIAID would recommend that a full prioritized set of OIT clinical trials as outlined above not be initiated in a single year. We estimate a first-year total cost of \$20–\$25 million to fund four of the highest priority OIT clinical trials for peanut, egg, and/or milk allergens.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUE

INSTITUTIONAL DEVELOPMENT AWARD PROGRAM

Question. Over the past 13 years, the Congress has supported the National Institutes of Health (NIH) Institutional Development Award (IDeA) program. In IDeA States like Hawaii, our biomedical communities have seen great improvement in our scientists' ability to garner NIH support as well as our capacity to recruit and retain biomedical scientists, physician-scientists, teachers, graduate students, and postdoctoral fellows. With the dissolution of the National Center for Research Resources (NCRR), which administered IDeA, and the proposed budget reduction of IDeA by \$50 million (representing an 18-percent cut), there is concern that NIH is not fully committed to the IDeA program even though the Congress has been supplementing the IDeA budget for the purpose of expanding clinical translation research efforts in IDeA States. What assurances can you provide that NIH supports the IDeA program and will continue to sustain research infrastructure support targeting the chronically underfunded IDeA States?

Answer. Following the dissolution of NCRR, the IDeA program was transferred to the National Institute of General Medical Sciences (NIGMS), a logical home in view of NIGMS' long-standing commitment to research training and capacity building. Nearly all the NCRR staff who managed the IDeA program also moved to NIGMS, enabling the administration of the IDeA grants to proceed seamlessly.

NIGMS is strongly supportive of the IDeA program. NIGMS appreciates its value to States that do not receive high levels of support from NIH's traditional grant mechanisms, as well as its importance in enabling excellent research, training, and career development that benefit the entire Nation. NIGMS intends to essentially maintain the level of support for the Centers of Biomedical Research Excellence (COBRE) and IDeA Networks of Biomedical Research Excellence (INBRE) programs and the new Clinical and Translational Research program.

HEALTH DISPARITIES

Question. Given the continuing disparities in health outcomes and NIH's acknowledgement of the low numbers of underrepresented minority researchers, please describe efforts to address disparities in health outcomes and the representation of minority investigators in NIH support research programs.

Answer. While the overall health of the U.S. population has improved, certain populations continue to have a higher risk of adverse health outcomes. These health disparities are the result of multifactorial biologic and nonbiologic influences. The NIH Health Disparities Strategic Research Plan and Budget, a 5-year plan, provides a blueprint for addressing health disparities and fostering access of racial/ethnic minorities to the clinical benefits of NIH research. The Plan focuses on three major goals each NIH Institute and Center must strive to achieve:

- conduct and support research on the factors underlying health disparities;
- expand and enhance research capacity to create a culturally competent workforce; and
- engage in proactive community outreach, information dissemination, and public health education.

The pace of translation is a recognized barrier to racial/ethnic minorities reaping the benefits of clinical research. NIH is committed to accelerating the pace of research translation by reducing the time it takes for scientific discoveries to reach patients in the form of treatments or health information. Several ongoing research programs and studies contribute to the NIH efforts to translate research findings to racial/ethnic communities and increase their access to the benefits of NIH-funded research, including the following:

Development and Translation of Medical Technologies That Reduce Health Disparities Initiative

National Institute on Minority Health and Health Disparities (NIMHD) and the National Institute of Biomedical Imaging and Bioengineering established a partnership through the Small Business Innovation Research program to support the development and translation of medical technologies aimed at reducing disparities in healthcare access and health outcomes. Potential technologies targeted are telehealth for remote diagnosis and monitoring, sensors for point-of-care diagnosis, devices for in-home monitoring, mobile, portable diagnostic and therapeutic systems, devices which integrate diagnosis and treatment, diagnostics or treatments that do not require special training, devices that can operate in low-resource environments, non-invasive technologies for diagnosis and treatment, and integrated, automated system to assess or monitor a specific condition.

National Institute on Minority Health and Health Disparities Community-Based Participatory Research Initiative

This 11-year initiative is designed to facilitate the translation of scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce health disparities and to disseminate scientific information. These Community-Based Participatory Research (CBPR)-supported intervention studies are expected to enhance clinical practice and improve the health of racial/ethnic populations by actively engaging the community in all phases of research including design, implementation, and dissemination of the research results.

National Institute on Minority Health and Health Disparities Centers of Excellence Program

The Centers of Excellence (COE) program advances scientific knowledge on the biological and nonbiological factors contributing to health disparities and develops interventions to address some of the most prevalent diseases, and health conditions that disproportionately affect racial/ethnic minority populations. Since 2002, NIMHD has supported 91 COE sites in 35 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. Awardees represent all types of institutions including Historically Black Colleges and Universities, Hispanic Serving Institutions, Tribal Colleges and Universities, and Alaska Native and Native Hawaiian Serving Institutions.

Although NIH recognizes a unique and compelling need to promote diversity in the biomedical, clinical, behavioral, and social sciences research workforce; sufficient representation has been to date elusive. Advancing diversity through NIH training support is expected to produce a number of tangible and overlapping benefits including:

- enhancing the overall capacity to address health disparities;
- improving patient satisfaction in ways that enhance participation in clinical research setting; and
- creating and preparing a culturally competent workforce that enhances communication.

Research Supplements To Promote Diversity in Health-Related Research

This NIH-wide program provides supplemental support to existing NIH-funded institutions to encourage the participation of individuals from groups currently under-represented in biomedical, clinical, behavioral, and social sciences throughout the continuum from high school to the faculty level. There is some evidence that individuals who have participated in the NIH administrative supplement program preferentially conduct research in areas related to minority health or health disparities.

National Institute on Minority Health and Health Disparities Extramural Loan Repayment Program for Health Disparities Research

The Loan Repayment Program for Health Disparities Research (LRP-HDR) recruits, trains, and retains highly qualified health professionals through repayment of educational loans in exchange for conducting minority health or health disparities research. More than 60 percent of LRP-HDR scholars are from racial/ethnic minority populations. Since its inception, more than 2,200 awards to individuals representing multiple disciplines including internal medicine, mental health, behavioral science, anthropology, pharmacology, cardiology, epidemiology, health sciences, oncology, psychology, and gastroenterology have been made through this program.

Question. Does the Research Center in Minority Institutions (RCMI) plan to dedicate funding that would further enhance research infrastructure and training opportunities at RCMI institutions that have been dedicated to addressing these concerns? Also, given the importance of science networking within minority serving institutions, are there plans for the RCMI Clinical Translational Research program

to work with the RCMI Translational Research Network to promote more multi-site clinical trials to address health disparities in minority/underserved communities?

Answer. An environment that is conducive to health-related research at academic institutions, including minority institutions, is a priority for the NIH. The NIMHD RCMI program supports the basic underpinning of research to further, biomedical, clinical, behavioral, and social sciences research activities. Enhancement of infrastructure and research capacity includes renovation/alteration of new research facilities, creating shared resources that result in economies of scale for research projects, and developing a diverse scientific workforce. This investment has been instrumental in the engagement of racial/ethnic minority populations in research and in the translation of research advances into culturally competent, measurable, and sustained improvements in health outcomes.

The RCMI Infrastructure for Clinical and Translational Research (RCTR) awards support the development of infrastructure required to conduct clinical and translational science in RCMI institutions. This infrastructure enhancement may include outpatient clinical research resources, biostatistical support, core laboratories, or facilities to support patient-oriented investigations such as community-based research. Multi-site investigations on those diseases that disproportionately impact health disparity populations are an integral component of the RCTR program. As the Data and Technology Coordinating Center for RCMI, the RCMI Translational Research Network will continue working with RCTR to promote scientifically sound, clinical trials involving multiple academic institutions, clinical sites, and community health providers.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

NATIONAL CHILDREN'S STUDY

Question. The National Institutes of Health (NIH) has announced a change in the National Children's Study (NCS) Vanguard contracts from academic centers to a national research firm. How do these changes in contracts affect the scientific integrity of the study?

Answer. The change in Vanguard Study operations, to have primary data collection performed by another contractor, affects 7 of the 40 Vanguard locations for a period of 6 months, from July to December 2012. That contractor, Research Triangle Institute, was selected through a full and open competition in 2010 for the purpose of providing additional data collection capacity for the Vanguard Study. During this 6-month period, the seven locations will participate in a pilot project to optimize the transition process and maintain the scientific quality and integrity of the Study.

Prior to July 2012, new funding opportunities to provide data collection for all of the Vanguard locations will be announced. These new contracts will also be awarded through a full and open competition. All current contractors are eligible to compete for these new contracts. Following award of those contracts, all Vanguard Study centers, including the seven locations in the transition pilot, will transition to the new contractors.

Question. What is NIH's plan for transitioning from a decentralized, academic center based recruitment strategy to a recruitment strategy with a centralized, national research firm?

Answer. The NIH is currently planning recruitment for the NCS Main Study, which is a separate activity from the Vanguard Study. Based on data from the Vanguard Study and consultation with the NCS Federal Advisory Committee and other experts, primary recruitment for the Main Study will be conducted through healthcare providers. We are currently asking for input and gathering additional data on implementation of a healthcare provider approach. New solicitations for recruitment and data collection for the Main Study will be made through a full and open competition. We anticipate that multiple contracts will be awarded. We also intend to award new contracts for supplemental recruitment to target populations that, on the basis of demographics or potential environmental exposures, may be under-represented if one used only a provider based approach.

Question. What is NIH's plan, if any, to collaborate with the current Vanguard centers to maintain those children who have already enrolled in the studies? What are the logistical challenges to this transition?

Answer. Current NCS Vanguard Study contracts expire over the next 17 months; new contracts will be awarded following full and open competitions. The NCS is working with current contractors to ensure the orderly transition of data collection services and of relationships with participants, communities, and other local institutions. As is usual with longitudinal studies that extend across many years, indi-

vidual contractors may continue to change during the course of the study, and it is important for the NCS to have procedures in place to ensure smooth transitions that may occur in the future.

The Vanguard Study will continue to pilot study methods in its current 40 locations, several years in advance of the Main Study, following the children already recruited by the Vanguard Study until they turn 21. In this follow-up phase, it will use a smaller number of contractors than in its earlier recruitment phase, thus following recommendations in the Institute of Medicine report from 2008 and realizing cost savings, while improving scientific quality by achieving greater consistency in data and specimen collection among study sites.

Question. What, if any, role will the current Vanguard sites have within the NCS after the NIH ends their contracts?

Answer. The Vanguard Study will continue in the same sites for the next two decades, although it may not be carried out by the same contractors. All Requests for Proposals for both the Vanguard and Main Studies will have full and open competitions. All current contractors can offer proposals for new contracts and also have other options to participate in the NCS, including partnering with a primary data collector, conducting ancillary studies using NCS infrastructure, and doing their own research analyses using NCS data as they become available.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

NATIONAL INSTITUTES OF HEALTH INSTITUTIONAL DEVELOPMENT AWARD PROGRAM

Question. The National Center for Research Resources (NCRR), an Institute within the National Institutes of Health (NIH), houses a program called the Institutional Development Award (IDeA program). The IDeA program funds research in States that are traditionally underrepresented within the NIH, including Louisiana.

In the fiscal year 2012 U.S. Department of Health and Human Services budget, the Congress increased the funding for the IDeA program by \$46 million. However, for the fiscal year 2013 budget year, the President proposes a \$48 million decrease. It appears that this money is being taken away in order to help fund the new National Center for Advancing Translational Sciences (NCATS).

At a time when NIH budgets are flat, and when the most heavily funded States will continue to be funded as they always have, why would the administration propose reducing the one pot of money that is specifically designed for States that have traditionally been underfunded?

Answer. For fiscal year 2012, the IDeA program was provided with a 21-percent increase in the congressional appropriation, or approximately \$50 million, in funding over fiscal year 2011, while most other NIH programs were held relatively flat. For fiscal year 2013, the budget proposes \$225 million for the IDeA program, about the same as the fiscal year 2011 level, and approximately \$50 million below fiscal year 2012. The IDeA program is valued by NIH and gives many investigators at less research-intensive institutions an opportunity to contribute to biomedical research. Within a constrained budget environment, NIH believes that the IDeA program should not be treated differently than most other programs in the fiscal year 2013 NIH budget which are flat with fiscal year 2011. With regard to NCATS, the fiscal year 2013 budget requests an increase because of the need for innovative solutions to the bottlenecks currently in the development pipeline that hinder the movement of basic research findings into new diagnostics and therapeutics for patients. The request for IDeA is made in the context of the total NIH budget and not as a particular offset to any one program or line item.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES FUNDING LEVELS

Question. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) continues to conduct and support innovative diabetes research that will move the Nation forward in treatment, enhanced detection, and prevention of diabetes.

In the proposed fiscal year 2013 HHS budget, the NIDDK received a slight decrease in funding of \$2 million compared with the fiscal year 2012 funding level. I am concerned that this decrease in funding will affect NIDDK's ability to continue to make progress on promising diabetes research.

Would you please share with us the percentage of grants that NIDDK has been able to fund over the past 2 years and how this cut will affect grants/research going forward?

Answer. In fiscal year 2010 and fiscal year 2011, the success rates for NIDDK-funded Research Project Grants (RPGs) were 26 percent and 21 percent, respectively; the estimate for fiscal year 2012 is 20 percent. In the fiscal year 2013 President's budget request, there is an overall reduction of 1 percent in the average cost of both competing and noncompeting RPGs. NIDDK also expects to have fewer non-competing grants that require funding in fiscal year 2013. As a result, the number of new or competing RPGs would increase by 43, resulting in an estimated success rate of 21 percent in fiscal year 2013. The slight net decrease in funding of \$2.798 million, or -0.1 percent, in the President's budget request, compared with the fiscal year 2012 funding level, is due primarily to a reduction in NIDDK HIV/AIDS research that results from \$30.951 to \$27.635 million or \$3.316 million in AIDS research. The AIDS reduction is a result of the annual AIDS priority level review of all expiring grants in fiscal year 2012 that would be competitively submitted for funding in fiscal year 2013. These projects are no longer considered to be aligned with the fiscal year 2013 priorities for trans-NIH AIDS research. The overall non-AIDS total is increased by \$518,000 resulting from the increased funding in R&D Contracts and National Research Service Award Research Training. The AIDS reduction plus a non-AIDS increase results in a \$2.798 million reduction in the total NIDDK.

GESTATIONAL DIABETES

Question. Currently, gestational diabetes is a disease affecting up to 18 percent of all pregnant women. Long-term health consequences face women and children who have gestational diabetes, such as susceptibility to type 2 diabetes.

Would you please provide a list of the specific research initiatives or projects NIDDK or other Institutes at NIH are currently funding to address this issue?

Answer. The NIDDK and National Institute of Child Health and Human Development are vigorously supporting research and other efforts to address gestational diabetes mellitus (GDM) and its immediate and long-term health consequences for women and their children. While complete data for fiscal year 2012 are not yet available, we are pleased to provide examples of a number of current efforts. The NIDDK, under its "Healthy Pregnancy Program," is supporting three major GDM-related initiatives:

- A multi-center research consortium testing interventions in diverse groups of overweight and obese pregnant women to improve weight and metabolic outcomes in both the women and their offspring. This effort is co-supported by NICHD, National Heart, Lung, and Blood Institute (NHLBI), and the NIH Office of Research on Women's Health.
- The Hyperglycemia and Adverse Pregnancy Outcomes Follow-up Study, which will examine whether elevated blood sugar levels less severe than GDM carry similar long-term health risks for women and their offspring.
- An educational component, led by the National Diabetes Education Program (NDEP), that targets women with a history of GDM, their families, and their healthcare providers to raise awareness of health risks and the steps that women and their children can take to avert health problems. The NDEP is a joint program of the NIDDK and the Centers for Disease Control and Prevention (CDC).

NIDDK and NICHD also support basic and clinical research to better understand GDM, as well as to identify ways to prevent or treat it and its long-term health risks. For example, several studies focus on understanding how maternal diet and metabolism affect fetal development and incur long-term risks for obesity and other health problems. Researchers are also continuing to study women at risk for type 2 diabetes due to GDM history who participated in NIH's landmark Diabetes Prevention Program clinical trial. Researchers are also:

- following a large population of women with a history of GDM to understand how the frequency and duration of their breastfeeding may prevent their later development of type 2 diabetes;
- screening women for GDM in the first months of pregnancy, to understand whether early-emerging and later-emerging forms of GDM differentially affect maternal and child outcomes. Other goals of the research are to refine GDM tests and to determine, at a systems level, whether routine screening for early GDM in obese women improves outcomes in the women and their children;
- searching for abnormalities in fetal development of heart function and other factors that could eventually cause adult heart disease in offspring of pregnant laboratory animals with GDM; and

—analyzing post-partum maternal and infant cord blood samples to determine whether specialized types of human fat and immune cells could be novel biochemical markers to help predict future GDM.

NATIONAL CANCER INSTITUTE FUNDING LEVEL

Question. The funding for NIH, and in turn, National Cancer Institute (NCI), has eroded since fiscal year 2010, not only due to lost purchasing power as a result of biomedical inflation but also due to outright cuts in fiscal year 2011.

How has the eroded funding affected the Institute in terms of the number of new grants funded and harm to existing grants? What decisions have you had to make as a result? If we could restore funding to fiscal year 2010 levels, or even better, increase funding above those levels, what could you do with the new money?

Answer. As a result of the decrease to the NCI budget in fiscal year 2011, we funded 1,106 competing grants, 147 fewer than in 2010. For the 3,769 existing grants that received continuation funding in 2011, the amount was reduced by 3 percent from the fiscal year 2010 level. Principal investigators could have used a number of strategies to accommodate lower funding levels, including reducing staff, deferring the purchase of equipment or supplies, or scaling back their projects in some way.

In fiscal year 2011, NCI applied reductions of 2 to 5 percent in most budgets for our many activities—including the intramural programs, contracts at NCI-Frederick and elsewhere, the NCI-designated cancer centers, and the operating budgets of all NCI components. NCI's leadership made choices to achieve the necessary savings while preserving core elements needed to sustain the pace of discovery. NCI leadership has carefully assessed the overall research portfolio and determined the areas where, in our professional judgment, increased funding could have additional impact over time in reducing cancer incidence and mortality. Any increase in funding would be used in part to increase support for new research grants, especially grants to new investigators to support new ideas. Other critical areas that could receive additional support include cancer genomics and transformation of NCI's clinical trials to increase efficiency and reflect the state of the science. An increase to our appropriation could also allow NCI to fund additional grants through the new Provocative Questions project by augmenting the \$15 million that was dedicated to the project. Additional resources could support more research toward solving some of the enduring paradoxes in cancer research.

NATIONAL CANCER INSTITUTE—DRUG RESISTANCE

Question. We've heard reports of some targeted treatments achieving incredible results, but then cancers stop responding to those drugs. What is the NCI doing to understand and overcome this drug resistance?

Answer. One of the most disappointing features of the development of new targeted therapeutics is how routinely drug resistance emerges and the disease begins to progress. Resistance to treatment with anticancer drugs results from a number of factors—every cancer expresses a different array of drug-resistance genes, and various mechanisms have evolved as protection from toxic agents. As therapy has become more effective, acquired resistance has become common. NCI is aggressively pursuing research to gain an understanding of the mechanisms that lead to drug resistance and is looking for agents that overcome these mechanisms. NCI is supporting studies of combination therapies for patients whose disease has become resistant to therapy, as well as exploring alternative approaches through the Provocative Questions Initiative to determine if controlling rather than killing cancer cells can avoid the development of drug resistance.

One example of the development of resistance following dramatic response is the clinical experience with the targeted drug vemurafenib (Zelboraf), a BRAF inhibitor that has been shown to nearly double the survival of patients with advanced melanoma. Because nearly one-half of all cases of metastatic melanoma—about 4,000 patients per year—have the BRAF mutation, vemurafenib represents a significant breakthrough in treatment. Unfortunately, after an average of 8 months of treatment, many patients become resistant to the drug and their disease begins to progress. However, with NCI support, researchers are making headway in understanding vemurafenib resistance. Recent data from Memorial Sloan Kettering, for example, demonstrated that some resistant BRAF-mutated melanoma cells produce a shortened version of the mutated BRAF protein that remains active even in the presence of vemurafenib. Strategies to overcome the resistance include finding ways to increase potency of the therapy, disrupting the activity of the altered form, or combining therapies. Other leads have come from researchers at the Moffitt Cancer Center, who identified a new approach utilizing a small molecule inhibitor called

XL-888 to target a family of proteins known as Heat Shock Proteins 90 (Hsp90). The Moffitt researchers reported preclinical data that XL-888 overcame six different models of vemurafenib resistance, demonstrating its therapeutic potential. This work was made possible by early NCI research on Hsp90 as an anticancer agent.

Melanoma is just one example of a disease in which drug resistance is driving creative approaches in cancer research. The drug imatinib (Gleevec), for example, is widely recognized for its success in treating chronic myeloid leukemia by targeting a protein known as BCR-ABL. However, some CML patients relapse when new mutations make the BCR-ABL protein resistant to Gleevec, preventing it from binding to its target and allowing the abnormal enzyme to drive white blood cell growth, again despite treatment. It is encouraging to report that NCI-supported research has identified a number of drugs that can target BCR-ABL proteins even after they acquire mutations that confer resistance to Gleevec. Although two of these, approved a few years ago, could not overcome a relatively common resistance mutation, a third generation of drugs has a new way to attack the mutation, freezing the target protein and rendering it inactive. This example illustrates another important point: many different research fields—from genetics to structural biology to pharmacology—were required for these advances in treatment. The need for multidisciplinary teams to address key questions like drug resistance in cancers increasingly defines modern biomedical research.

NATIONAL CHILDREN'S STUDY

Question. NIH wants to cut 15 percent from National Children's Study's (NCS) current \$193 million budget in fiscal year 2013 by shifting away from the sampling plan put forth by the Institute of Medicine in 2008 to an health maintenance organization (HMO)-based sample.

New Orleans was selected as one of the sites for national sampling and this is particularly important because, as Louisiana is near the bottom of every health outcome ranking and near the top in indicators of poverty, this new knowledge could prove invaluable to improving both. The gulf region has a number of health disparity issues and a large number of uninsured mothers who do not participate in an HMO.

How do you plan on maintaining the scientific integrity of the NCS study so that it reflects a national sample, including unique populations such as those in the gulf region?

Answer. The change in the NCS Study design is being considered primarily for scientific reasons but also with awareness of our need to be fiscally responsible. It is based on data generated during the ongoing Vanguard, or pilot phase, of the NCS. As currently envisioned, the NCS Main Study would use a provider-based participant selection and recruitment strategy that the NIH and the Agency for Healthcare Research and Quality have both employed effectively in other studies. This approach uses research-ready healthcare provider networks as the primary source for recruitment. The NCS would gain additional participants through the award of contracts for supplemental recruitment from secondary sources (such as title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of appropriate population groups, specifically those with health disparities. The use of these two coordinated selection and recruitment strategies would improve the quality of the Main Study and allow analyses not feasible with either approach alone.

If adopted, this revised approach would offer several advantages, including:

- greater recruitment efficiency;
- leveraging access to consenting participants' electronic health records, thus improving the amount and consistency of data collected while lowering costs;
- the potential to leverage the existing infrastructure of networks of healthcare providers, again improving the quality of data and lowering costs;
- allowing built-in continuity for participants who move but remain within the provider network (many provider networks have statewide or regional coverage) or join another provider network affiliated with the Main Study.

Current Vanguard Study contracts are due to expire over the next 17 months. New contracts are required to continue into the next phase of the Vanguard Study, and the NCS has issued a pre-solicitation to request preliminary information on the services available to meet the study's evolving needs. (Please see <https://www.fbo.gov/index?s=opportunity&mode=form&id=674a4f3a690d6584870fc84c9cb2b511&tab=core&-cvview=0>.) All new Requests for Proposals for both the NCS Vanguard and Main Studies will have full and open competitions. Whoever is awarded the new contracts, the NCS plans to remain in the Vanguard locations and to following current Vanguard participants until the last enrolled child turns 21 years old.

Question. On a related topic, Tulane University, in New Orleans, was one of the sites selected for national sampling. The New Orleans Study Location represents a strong collaboration among major healthcare providers and universities, including Tulane, LSU, and Ochsner, and employs many full-time and part-time professionals.

Termination of the contract would be a very significant loss both to the universities, the local community and damage the capacity that has been built.

How will this new system account for the loss of expertise and jobs at study sites throughout the Nation?

Answer. To date, the NCS Vanguard Study has accomplished what it set out to do, provide data on recruitment and early retention into the Study. We will continue to follow all children born into the Vanguard Study, until age 21. We have no intention to lose NCS participants from the Vanguard Study; instead, we are developing and field testing a proactive plan that includes personal contacts, special events for participants, linkages to local health resources through other Health and Human Services programs, returning results of Study assessments, and soliciting feedback about the Study experience. In addition, participants that might have been lost under the original Study design because they moved out of a particular geographic area might still be included in a health provider network involved in the Study.

Current NCS Vanguard Study contracts expire over the next 17 months, but none are expected to be prematurely terminated. The NCS is working to standardize the transition process so that if a new contractor replaces a current contractor at an NCS location, the data, the knowledge, the relationships and the continuity can be maintained. We are targeting a minimum 90-day overlap in contracts, to allow for an orderly and systematic transfer.

All new Requests for Proposals for both the Vanguard and Main Studies will have full and open competitions. Academic institutions can offer proposals for new Study contracts for primary data collection, and have other options as well, including partnering with a primary data collector, conducting ancillary studies using NCS infrastructure, or doing their own research analyses using NCS data as they become available. Finally, contractors that complied with NCS specifications for field operations will have established a platform that is flexible and adaptable to multiple uses, so they can leverage that investment for additional projects.

NATIONAL INSTITUTES OF HEALTH INVESTIGATOR-INITIATED RESEARCH

Question. Will the investigator-initiated research be able to grow in the area of translational science, and will basic science be a part of it?

Answer. Within the administration's fiscal year 2013 budget request for NIH of \$30.86 billion, the same overall program level as in fiscal year 2012, we plan to continue to maintain funding emphasis and increase the overall number of Research Project Grants (RPGs). RPGs are NIH's fundamental funding mechanism for investigator-initiated research. The NIH budget request will support an estimated 9,415 new and competing RPGs in fiscal year 2013, an increase of 672 more than fiscal year 2012. The total number of RPGs funded for fiscal year 2013 is expected to be around 35,888, or approximately the same as the 35,944 estimated for fiscal year 2012.

In pursuit of its mission to alleviate the burden of illness, NIH supports a continuum of research, from understanding basic causes and mechanisms of health and disease to translating that understanding into new ways of identifying and intervening upon disease processes, and in turn translating those new interventions into clinical practice. As the leading supporter of basic biomedical research in the world, NIH commits slightly more than one-half its annual budget to better understand the basics of how life works.

Yet, the path from basic research to clinical practice is not always linear; each step in the process may inform any other step. For example, clinical research can inform basic research. This is exemplified by a recent clinical finding made by NIH scientists in the intramural program's Undiagnosed Diseases Program that has led to a dramatic new understanding of basic functioning. These scientists studied a pair of sisters from Kentucky who suffered from joint pain and a mysterious calcification of the arteries in their extremities. Their research uncovered a novel genetic condition that affected a previously unknown enzyme pathway, resulting in blocked arteries. The discovery provides a dramatically new understanding of how large arteries maintain normal functioning, and it has opened the door to many other lines of inquiry across both basic and clinical arenas.

The proposed increase in RPGs provides the framework for NIH to prospectively expand investigator-initiated research across the continuum of biomedical and behavioral science. Each new finding in one arena will inform and lead to new investigations in other areas of basic, translational, and clinical research.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

CONGENITAL HEART DISEASE

Question. Congenital Heart Disease (CHD) is one of the most prevalent birth defects in the United States and a leading cause of birth defect-associated infant mortality. Due to medical advancements more individuals with congenital heart defects are living into adulthood. Please provide an update of research within National Institutes of Health (NIH), particularly the National Heart, Lung, and Blood Institute (NHLBI) related to congenital heart defects across the life-span.

The healthcare reform law included a provision, which I authored, that authorizes the Centers for Disease Control and Prevention (CDC) to expand surveillance and track the epidemiology of CHD across the life-course, with an emphasis on adults. The Consolidated Appropriations Act of 2012 provided the CDC with \$2 million in new funding for enhanced CHD surveillance. Please describe how NIH is working with CDC to enhance CHD surveillance across the life-course. CDC is using a portion of the newly appropriated funds to convene a congenital heart defects experts meeting. Please summarize NIH's role at the expert meeting and in shaping the meeting's research agenda.

Answer. NHLBI continues to make an extensive investment in research related to congenital heart defects across the life-span. The Institute is working in conjunction with the CDC on a number of activities to expand surveillance of CHD and improve our understanding of its epidemiology, including the following:

Newborn Screening for Critical Congenital Heart Diseases.—In September 2011, Secretary Sebelius recommended that screening for Critical Congenital Heart Diseases (CCHD) be added to routine newborn screening and called for research to address evidence gaps that are presently constraining implementation of screening programs. In response, the NHLBI, the National Institute of Child Health and Human Development (NICHD), the CDC, and other Federal partners involved in newborn screening have set up regular calls and meetings to determine how best to proceed. As an example, the CDC and NHLBI have been discussing details of a common nomenclature to be used in screening for cardiovascular malformations and the potential for combining the efforts of the CDC's robust birth defects case-ascertainment and research programs with the NHLBI-funded Pediatric Heart Network and the Pediatric Cardiac Genomics Program to answer research questions about approaches to and effectiveness of screening for CCHD.

Data Set on Sudden Cardiac Death in the Young.—Development of effective screening and prevention strategies for Sudden Cardiac Death in the Young (SCDY) is limited by a lack of prospectively defined epidemiological data, including incidence rates and etiology. NHLBI is planning an innovative program to address this knowledge gap. Its initial phase, in coordination with the CDC and others, would be to develop a surveillance system and registry that broadens and enhances the activities of the National Center for Child Death Review and the Sudden Unexpected Infant Death Registry. This phase would result in the first prospective, population-based U.S. data set on SCDY; it would include data from death certificates, medical records, death-scene investigations, and pathology reports and also include serum samples for DNA extraction. It would be followed by a second phase that would support scientific research using the data set.

Congenital Heart Public Health Consortium.—NHLBI and the CDC were founding Federal advisors to the Congenital Heart Public Health Consortium (CHPHC), a group formed in 2008 to address the public health burden of CHD. The CHPHC has united a variety of organizations, including Federal agencies, patient advocacy groups, and physician associations that have a strong interest in CHD. Its approach includes strong emphasis on enhanced surveillance via monitoring CHD throughout the lifespan, as well as assessment of the needs of patients and families for chronic disease management and age-appropriate preventive care. Representatives from NHLBI and the CDC currently serve as advisors to the Consortium Steering Committee.

NHLBI is working closely with the CDC to organize the upcoming congenital heart defects experts meeting which will occur September 10–11, 2012. Its goal is to determine priorities for public health research on congenital heart disease across the life course in the United States. The planning committee consists of representatives from the CDC and the NHLBI and pediatric cardiologists from academia. The meeting agenda will focus on three main areas of public health concern for congenital heart disease—epidemiology, long-term health outcomes (both medical and nonmedical), and health services research (including access to care, employability,

and economics). Invitations have been sent to a variety of experts, including pediatric cardiologists, adult congenital heart specialists, adult cardiologists with expertise in epidemiology, epidemiologists, cardiac surgeons, health services/outcomes researchers, patient advocates, health economists, and other Federal partners.

ANTIMICROBIAL RESISTANCE

Question. NIH is part of an Interagency Task Force on Antimicrobial Resistance (ITFAR) that was created in 1999. What is the status of the subcommittee's recommendations to address the complex issue of antimicrobial resistance?

Answer. In 2001, the ITFAR published a Public Health Action Plan to Combat Antimicrobial Resistance (the Public Health Action Plan). This plan was updated, with stakeholder input, in 2011 and lays out specific action items in the areas of Surveillance, Prevention and Control, Research, and Product Development to address the complex issue of antimicrobial resistance. The updated plan is posted here: <http://www.cdc.gov/drugresistance/pdf/public-health-action-plan-combat-antimicrobial-resistance.pdf>.

Progress toward the implementation of Action Items under each of the goals in the Public Health Action Plan is reported annually by all participating agencies and documented at this link: <http://www.cdc.gov/drugresistance/annualReports.html>.

At NIH the National Institute of Allergy and Infectious Diseases (NIAID) is the lead institute responsible for research on antimicrobial resistance. NIAID supports basic, translational, and clinical research to understand and combat the problem of antimicrobial resistance. NIH, with support from NIAID, co-chairs the ITFAR and conducts research addressing several of the goals of the Public Health Action Plan, including goals supporting basic, applied, and clinical research on antimicrobial resistance. For example, NIAID is supporting a robust response to Action Items under Goal 7.2: Design and implement studies focused on optimizing the dose and duration of antibacterial agents prescribed for treatment of community-acquired pneumonia, urinary tract infections, skin and soft-tissue infections, and other infectious illnesses. To address this goal, NIAID is supporting clinical trials to inform the rational use of existing antimicrobial drugs to help limit the development of antimicrobial resistance, and is also supporting a clinical study to optimize the use of colistin, an antibiotic approved in the late 1950s that is increasingly being used today to treat multi-drug resistant Gram-negative infections. NIAID-supported clinical trials evaluating the effectiveness of different drug combinations in treating influenza, HIV, and malaria are also ongoing.

In addition, NIAID supports basic research to identify new antimicrobial targets and translational research on strategies to combat antimicrobial-resistant infections. NIAID supports the development of effective diagnostics, drugs, and vaccines to identify, treat, and prevent infectious diseases. As part of this effort, NIAID provides a broad array of preclinical and clinical research resources to researchers in academia and industry designed to facilitate the movement of a product from bench to bedside. By providing these critical services to the research community, NIAID can help to bridge gaps in the product development pipeline and lower the financial risks incurred by industry to develop novel antimicrobials. For example, NIAID supports the preclinical development of new antibacterial agents through directed contracts to companies involved in novel drug design and synthesis. These contracts were solicited through a Broad Agency Announcement entitled "Development of Therapeutics for BioDefense." To foster clinical research on antimicrobial resistance, in January 2012, NIAID released a request for applications to support a new leadership group for an antibacterial resistance clinical trial network similar to the existing HIV/AIDS clinical research networks (<http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-12-019.html>). The antibacterial resistance leadership group would develop and implement a comprehensive clinical research agenda to address the pressing problem of antibacterial resistance.

The research described above represents only a small portion of NIAID's significant investment in research addressing the problem of antimicrobial resistance. For more information, please visit the ITFAR annual report linked above as well as the NIAID Web page at: <http://www.niaid.nih.gov/topics/antimicrobialresistance/Pages/default.aspx>.

DIABETES PREVENTION PROGRAM

Question. Diabetes Prevention Program (DPP) was a clinical research study investigating the impact of lifestyle and drug interventions on diabetes prevention. Two new NIH initiatives have taken advantage of DPP's findings and are building on the discoveries. Please summarize the two new programs and explain how they are different from DPP.

Answer. NIH's landmark DPP clinical trial proved that an intensive lifestyle intervention reduced rates of diabetes incidence by 58 percent among an at-risk population. The lifestyle intervention was effective in all ethnic groups, and was particularly effective in those older than age 60 at the beginning of the trial, among whom it reduced diabetes incidence by 71 percent. The trial also found that the safe, well-tolerated, inexpensive, generic diabetes drug metformin reduced diabetes incidence by 31 percent, and was most effective in younger participants, and women with a history of gestational diabetes, who otherwise develop type 2 diabetes at particularly high rates.

NIH has built on these major findings in several ways. First, most of the DPP participants elected to enroll in a follow-on study, the DPP Outcomes Study (DPPOS). Phase 1 of this study showed that both interventions are durable, and continue to provide significant diabetes prevention benefit for at least a decade. Moreover, participants in the lifestyle arm of the study had dramatically better quality of life and a reduced need for medications to control blood pressure and cholesterol. Both lifestyle and metformin were also found to be highly cost effective, and metformin was actually found to be cost saving. Phase 2 of DPPOS will assess the long-term impact of the interventions on diabetes complications. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is also currently working with National Cancer Institute (NCI) to determine the feasibility of detecting potential effects of the interventions on later development of cancer.

To develop ways to make diabetes prevention more practical and affordable, the NIH-funded research to translate the DPP lifestyle intervention into widespread practice. Some particularly promising projects have focused on research to reduce costs, while maintaining efficacy, by delivering the intervention in a group-based form. Strong preliminary results from one such ongoing study led to creation of the "National" DPP (NDPP) by the Centers for Disease Control and Prevention, which is working to train and credential a cadre of group lifestyle intervention providers for diabetes prevention. Many of the providers trained so far work at YMCAs, which now provide access to these services to people with prediabetes at more than 50 locations (<http://www.ymca.net/diabetes-prevention/participating-ys.html>). Additional work to help realize the potential of the DPP and other diabetes studies is being conducted through the Diabetes Translational Research Centers program.

Detailed DPP genetic analyses have shown that the lifestyle intervention helps prevent diabetes even among those at greatest genetic risk. Interestingly, a gene was identified that substantially reduces the efficacy of metformin in about 1 in 3 people. NIH is supporting a June 7 conference on metformin pharmacogenetics to explore this and related issues.

Question. Although the long-term outlook for children with type 1 diabetes has improved, the rates of diagnoses continue to rise. Please provide an update on research efforts within NIH related to type 1 diabetes and how additional innovations in research could prevent children from developing this disease.

Answer. NIH-supported research has shown that people with type 1 diabetes are living longer and healthier lives than ever before. However, research has also shown that rates of type 1 diabetes are rising, especially in children under 4 years of age. One approach to curb the rising rates of type 1 diabetes is to identify a disease prevention strategy. Toward this goal, the NIDDK has undertaken a bold, long-term initiative—called The Environmental Determinants of Diabetes in the Young (TEDDY) study—to identify the environmental triggers that intersect with genetic risk and lead to the development of type 1 diabetes. More than 8,600 newborns are enrolled in the study—after screening more than 420,000 newborns—and researchers are collecting biological samples, as well as information about the children's diet, illnesses, vaccinations, and allergies, until the children are 15 years of age. Knowledge gained from the TEDDY study can revolutionize our ability to prevent type 1 diabetes. For example, the discovery of a viral cause could lead to development of a vaccine to prevent the disease. Identification of a dietary factor as a cause could lead to changes in feeding practices.

NIH-supported researchers are also conducting clinical trials testing promising prevention therapies in people at high genetic risk of developing type 1 diabetes. For example, the NIDDK's Type 1 Diabetes TrialNet is conducting two clinical trials testing agents to prevent the disease in relatives of people with type 1 diabetes. The NICHD's Trial to Reduce IDDM (insulin-dependent diabetes mellitus) in the Genetically At-Risk, or TRIGR, is testing whether hydrolyzed infant formula compared to cow's milk-based formula decreases the risk of developing type 1 diabetes in at-risk children.

NATIONAL CHILDREN'S STUDY

Question. The National Children's Study (NCS) will examine environmental influences on the health and development of a cohort of U.S. children from birth until age 21. Field work for the study ended in March 2012, which provided data about recruitment processes and costs associated with the study. How are these data being used to inform the cost-effectiveness of the main study?

Answer. Data generated during the ongoing Vanguard, or pilot, phase of the NCS showed that a study design based on recruiting through healthcare providers was more efficient than recruitment through door-to-door contact or direct outreach to the public. Other large Federal studies have also effectively employed provider-based approaches.

More specifically, the NCS uses several methods to analyze costs and cost effectiveness. We maintain our own internal data base of contract invoices and analyze the invoice data for costs and level of effort based on activity. In addition, operational data elements that record the activities, logistics and costs of all aspects of the Vanguard Study have been embedded into the protocol data collection. These operational data elements are the primary outcome measures for the Vanguard Study goals of testing feasibility, acceptability, and cost-of-study operations. These data are captured in a central data repository and analyzed every 2 weeks to guide operations and assess overall data quality. In a third approach, two contractors, one a consulting firm and the other an academic institution, have been engaged to project operational resources and potential costs based on data from the field.

Question. A recent restructuring of the field operations will centralize some data collection to a single subcontractor. Please explain the rationale and cost-effectiveness of this restructuring.

Answer. The change in Vanguard Study operations, to have primary data collection performed by another contractor, affects 7 of the 40 Vanguard locations for a period of 6 months, from July to December 2012. That contractor, Research Triangle Institute, was selected through a full and open competition in 2010 for the purpose of providing additional data collection capacity for the Vanguard Study. During this 6-month period, the seven locations will participate in a pilot project to optimize the transition process and maintain the scientific quality and integrity of the Study.

Prior to July 2012, new funding opportunities to provide data collection for all of the Vanguard locations will be announced. These new contracts will also be awarded through a full and open competition. All current contractors are eligible to compete for these new contracts. Following award of those contracts, all Vanguard Study centers, including the seven locations in the transition pilot, will transition to the new contractors.

Question. The NIH/NICHHD has suggested an alternative sampling strategy that uses health plans or health providers to identify and recruit pregnant women. How can the proposed strategy ensure the sample represents all U.S. children, particularly uninsured, minority, immigrants, and low-income children?

Answer. As currently envisioned, the NCS Main Study would use a provider-based participant selection and recruitment strategy that the NIH and the Agency for Healthcare Research and Quality have both employed effectively in other studies. This approach uses research ready healthcare provider networks as the primary source for recruitment. The NCS would gain additional participants through the award of contracts for supplemental recruitment from secondary sources (such as title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of appropriate population groups, specifically those with health disparities. The use of these two coordinated selection and recruitment strategies would improve the quality of the Main Study and allow analyses not feasible with either approach alone.

 QUESTIONS SUBMITTED BY SENATOR JACK REED

NATIONAL CHILDREN'S STUDY

Question. You mentioned during the hearing that the proposed re-design of the National Children's Study (NCS) will be as effective and more efficient in enrolling study participants. However, you didn't mention the scientific basis for this re-design. Did you consult the national panel of experts—the Institute of Medicine (IOM), and the National Children's Study Federal Advisory Committee that informed the original design of the study with this new re-design? If these individuals and entities have already been consulted, do you plan to make those comments available to the public? If they have not already been consulted, do you intend to consult these groups and make those comments public?

Answer. The change in NCS design is being considered primarily for scientific reasons but also with awareness of our need to be fiscally responsible. It is based on data generated during the ongoing Vanguard, or pilot phase, of the NCS. The Vanguard data showed that the proposed study design would not enroll sufficient numbers of families within a scientifically acceptable timeframe or within a fiscally sound budget. Pilot testing conducted through the Vanguard sites showed that a study design based primarily on recruiting participants through healthcare providers was most efficient and could offer scientific advantages that would more than offset its scientific compromises. This provider-based approach also has been employed effectively in other large Federal studies. The President's fiscal year 2013 budget request, which shows a reduction of approximately 15 percent, to \$165 million annually, for the NCS, appropriately reflects these proposed design changes.

As currently envisioned, the NCS Main Study would use a provider-based participant selection and recruitment strategy that the NIH and the Agency for Healthcare Research and Quality have both employed effectively in other studies. This approach uses research ready healthcare provider networks as the primary source for recruitment. The NCS would gain additional participants through the award of contracts for supplemental recruitment from secondary sources (such as title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of appropriate population groups, specifically those with health disparities. The use of these two coordinated selection and recruitment strategies would improve the quality of the Main Study and allow analyses not feasible with either approach alone.

If adopted, this revised approach would offer several advantages, including:

- greater recruitment efficiency;
- leveraging access to consenting participants' electronic health records, thus improving the amount and consistency of data collected while lowering costs;
- the potential to leverage the existing infrastructure of networks of healthcare providers, again improving the quality of data and lowering costs; and
- allowing built-in continuity for participants who move but remain within the provider network (many provider networks have statewide or regional coverage) or join another provider network affiliated with the Main Study.

NCS continues to refer to the IOM report that was written by a panel of experts convened to review the original study design. Many of the changes recommended in the report have already been addressed, including the need for an ongoing Vanguard Study to test the study protocol and scientific methodology. The report also noted that the large number of field contractors was a weakness of the Study design, and the NCS is moving to correct this weakness.

The NCS Study Advisory Committee meets at least four times a year; the April 24, 2012 meeting was the 32d meeting of the subcommittee. These meetings are open to the public, and a public comment period is provided. Presentations to the Advisory Committee also are posted on the NCS Web site. As they have become available, data from the Vanguard Study have been presented at each of the subcommittee's meetings. The topic of a provider-based approach to Study recruitment was discussed twice in the last year with the Advisory Committee, first in April 2011 and then again in July 2011, before being the focus of the entire April 24, 2012 meeting. The NCS Study Director holds weekly national conference calls for Vanguard Study contractors to update them on recent developments and to receive their input. The investigators also provide expertise and comments through a monthly Executive Steering Committee meeting, through 2-day, face-to-face meetings every 6 months, through circulation of all study instruments and protocol changes to all investigators for comment, and through a mailbox account dedicated to contractors.

Question. I am also concerned that the re-design will jeopardize 70 high-quality jobs in Rhode Island, including 20 full-time positions that would have otherwise been created for the Main Study. How will this proposal impact the work of researchers and practitioners already participating in the study and the potential for job growth in my State? Does NIH plan to abandon its commitment to the 105 counties that have been selected to participate in the study?

Answer. To date, the NCS Vanguard Study has accomplished what it set out to do, provide data on recruitment and early retention into the Study. We will continue to follow all children born into the Vanguard Study, until age 21. We have no intention to lose NCS participants from the Vanguard Study; instead, we are developing and field testing a proactive plan that includes personal contacts, special events for participants, linkages to local health resources through other Health and Human Service programs, returning results of Study assessments, and soliciting feedback about the Study experience. In addition, participants that might have been lost under the original Study design because they moved out of a particular geographic area might still be included in a health provider network involved in the Study.

Current NCS Vanguard Study contracts expire over the next 17 months. All Requests for Proposals for both the Vanguard and Main Studies will have full and open competitions. Academic institutions can offer proposals for new Study contracts for primary data collection, and have other options as well, including partnering with a primary data collector, conducting ancillary studies using NCS infrastructure, or doing their own research analyses using NCS data as they become available. Finally, contractors that complied with NCS specifications for field operations will have established a platform that is flexible and adaptable to multiple uses, so they can leverage that investment for additional projects.

As indicated above, the change in study design is based on data generated during the ongoing Vanguard pilot phase of the NCS, which showed that the previously proposed study design would not enroll sufficient numbers of families within a scientifically acceptable timeframe or within a fiscally sound budget. Pilot testing conducted through the Vanguard sites showed that a study design based primarily on recruiting participants through healthcare providers was most efficient and could offer scientific advantages that would more than offset its scientific compromises.

PEDIATRIC CANCER RESEARCH

Question. Dr. Varmus, last year you and Dr. Collins provided me with a detailed explanation of NIH efforts to address pediatric cancers, including late-term effects. However, I am still concerned that a mere 4 percent—just \$200 million—of NCI funding is allocated to cancer research specifically for this population. I am concerned that this funding level remains stagnant because the peer-review process doesn't recognize the importance of pediatric cancer research in terms of years of life lost and poor quality of life for many survivors. How could a Pediatric Cancer Study Section improve the funding devoted to pediatric cancer research?

Answer. Over the past year, the National Cancer Institute (NCI) has worked with members of the Congressional Childhood Cancer Caucus to discuss this very question, and to explore how pediatric cancer research proposals fare in comparison to other proposals under the current peer-review process, with a goal of determining whether or not pediatric cancer grant applications are competitive in the peer-review process. NCI performed this analysis, which showed that pediatric cancer grant applications actually have success rates (number of grants awarded/number of grants received) that are equal to—and in some cases higher than—grant applications focusing on adult cancers. NCI further focused on R01 (individual investigator initiated) grant applications to exclude large program grants (such as cancer center support grants, for example) that have little competition. And again the data showed that pediatric cancer-focused R01 grant applications are quite competitive in the peer-review process.

The NIH Center for Scientific Review (CSR), which oversees the NIH peer-review process, considers a number of criteria when it establishes study sections. These criteria were developed by an external blue ribbon panel set up to systematically assess and reorganize CSR's review groups. For example, these guiding principles indicate that applications pertaining to a given disease/organ system are best reviewed in the context of the biological question being addressed. They provide that study section boundaries should not be too broad or too narrow, and that sufficient overlap should exist between other study sections inside and outside their integrated review groups (IRGs—clusters of study sections based on scientific discipline).

Therefore, the NIH has no standing study sections that review applications relevant to specific diseases, groups of diseases, or organ sites; rather, study sections are formed around scientific disciplines, e.g., epidemiology, genomics, therapeutics development, populations, behavior, etc., and are populated by productive investigators with expertise in those areas.

Within the category of pediatric cancer research, applications under consideration for funding pose an extremely diverse set of biological questions, as evidenced by the array of standing study sections that are called upon to review grant applications relevant to pediatric cancer. Because pediatric cancers are so heterogeneous, it makes sense scientifically to distribute review of these applications among multiple study sections.

Data analyzed from fiscal year 2008 through fiscal year 2010 indicate that the NCI supports pediatric cancer research applications via numerous mechanisms, and that support of pediatric cancer research grants has increased during that time period. As previously noted, success rates were in line with—and in many cases exceeded—those for other cancer types. This evidence suggests that pediatric cancer applications are very competitive within NIH's scientific review process.

Additionally, although disease-specific funding estimates can be useful indicators of some focused work, they do not reflect the full level of NCI's investment (approximately \$1.9 billion) into research exploring cancer biology and cancer causation—broad areas of inquiry applicable to all types of cancers, including pediatric cancers. It is important to consider NCI's full cancer research portfolio, and to also recognize that investments in one area of cancer research can, and often do, contribute to advances in others. For example, identifying the clinical value of crizotinib in the treatment of adults affected by lung cancer with abnormalities of the Alk gene has led to the current clinical testing children with neuroblastoma whose tumors have Alk abnormalities.

QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

PANCREATIC CANCER RESEARCH

Question. Dr. Varmus, during the hearing you testified that research for pancreatic cancer is being prioritized by National Cancer Institute (NCI) and that the Institute currently has flexibility to fund grant applications that fall below what used to be called the “pay line” in cases where therapeutic progress in relation to a disease has been low. Are there examples you can describe of grants in relations to pancreatic cancer where the Institute exercised this flexibility?

Answer. Pancreatic cancer is a high priority for the NCI, and we are supporting a wide range of research projects to rapidly develop the tools needed to diagnose pancreatic tumors as early as possible, to characterize tumors genetically, and to find new ways to treat this disease. NCI has been paying special attention to grants that might not be funded because they fell below what used to be considered a “payline,” a percentile score derived from the results of peer review. Beginning in fiscal year 2011, NCI scientific program leaders have been performing additional evaluations of grant applications to ensure a balanced grant portfolio and to recognize the value of research proposals that are highly original or address important scientific priorities, such as research on pancreatic cancer, even though they might not have received percentile scores that fall within a pre-determined payline. Of the applications that were focused exclusively on pancreatic cancer and were funded in fiscal year 2011, more than one-third were selected as a result of this programmatic review, rather than on the basis of receiving exceptionally high scores.

Examples of pancreatic cancer projects approved by this process include:

- a case-control study aimed at characterizing a select group of biomarker candidates in pancreatic juice that may enable earlier detection;
- a study to develop a multifunctional nanoparticle platform with both imaging and drug delivery capabilities;
- a study of corcetin (a carotenoid molecule isolated from saffron) that has been shown to have anticancer effects as a potential therapy for pancreatic cancer; and
- a study focused on identifying vulnerable areas of pancreatic tumors and overcoming the tough “stromal barrier” of pancreatic tumors that limits the delivery and diffusion of drugs.

LONG-TERM GOALS

Question. In the past, this subcommittee has urged NCI to develop a long-range plan for research in the area of pancreatic cancer research. Research advocates have been disappointed with the plan and view it more as a summary of research that's already underway. Would it be possible for NCI to lay out more of a long-term research strategy—something that sets out concrete goals and objectives for the future that moves beyond current practice?

Answer. Pancreatic cancer is distinct from other cancers due to its complex biology, late manifestation of symptoms, and the lack of early screening tools. In addition, there are a large number of genetic mutations involved, which complicates the development of effective targeted therapies to disable the growth of cancer cells and arrest progression of the disease. These factors explain the poor outcomes for most pancreatic cancer patients. However, there is great opportunity to change these outcomes. Recent NCI-supported research has demonstrated that there is a long time period—more than 11 years—between the first cancer-related mutation in a pancreatic cell and the development of a mature pancreatic tumor. This means that with the right tools for detection and targeted treatments, pancreatic cancer could be diagnosed while it is surgically curable.

Both NCI's research portfolio and the fiscal year 2011 strategic plan for pancreatic cancer reflect several specific goals, including:

- in-depth gene sequencing of pancreatic tumors to develop tools for detection and treatment;
- identification of genetic factors, environmental exposures, and gene-environment interactions that contribute to the development of this cancer;
- identification and development of biomarkers to allow early detection;
- improvement in our ability to detect tumors when they are much smaller than those currently able to be detected with our imaging capabilities; and
- development of effective targeted therapies.

To accomplish these goals, NCI is supporting a breadth of research across its portfolio that applies to the scientific underpinnings of all of these goals, including in-depth sequencing of pancreatic tumors through The Cancer Genome Atlas. But it is also important to note that advances in oncology that have great benefit for a particular type of cancer do not necessarily flow from research specifically on that cancer type. For example, investment in a rare disease, retinoblastoma, was critical for the discovery of tumor suppressor genes, a class of genes that is altered in essentially every cancer. Similarly, work on an animal model of neuroblastoma led to the discovery of an oncogene, HER2, which is targeted by antibodies now widely used in the treatment of breast cancer. Thus, while it is crucial for the NCI to give full attention to the clinical consequences of every cancer type, we must also be responsive to opportunities and ideas that seem likely to offer the best chances of making discoveries that bring us closer to understanding all cancers, as well as individual cancer types.

QUESTIONS SUBMITTED BY SENATOR BARBARA A. MIKULSKI

CANCER GENOME ATLAS

Question. Dr. Varmus, please provide an update on how The Cancer Genome Atlas (TCGA) is proceeding and how it is contributing to reaching the goal of precision medicine that was described in the 2011 Institute of Medicine report, “Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease.”

Answer. TCGA, a joint effort of the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI), is the largest and most comprehensive analysis of the molecular basis of cancer ever undertaken. Through the application of genome analysis technologies, including large-scale genome sequencing, TCGA is beginning to provide a comprehensive foundation of the abnormalities associated with the tumor types under study, the degree to which tumors within each type are similar and distinct, and the degree of overlap between tumor types. This foundation has the potential of improving our ability to diagnose, treat, and prevent cancer, providing an important element in reaching the goal of precision medicine.

TCGA began as a pilot project in 2006, studying cancers of the lung, brain (glioblastoma) and ovary, and it has been expanded over time to include additional tumor types. Currently in the third year of its post-pilot phase, TCGA has begun the comprehensive analysis of 16 additional cancers including breast, colorectal, kidney, lung, endometrial, and pancreatic cancers, among others. Of these projects, one-quarter are published or in manuscript form; one-quarter are in late-stage analysis; and the remaining one-half are still being collected and studied, with TCGA on track to conclude this phase in 2014. TCGA has also initiated a small project on rare tumors, with plans to complete initial discovery by the end of this year.

TCGA’s efforts to advance the understanding of the molecular basis of cancer are already providing the biological insights considered critical by the 2011 report, “Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease,” to reaching the goal of precision medicine. The report, produced by the National Research Council of the National Academy of Sciences, and sponsored by the National Institutes of Health, identifies a “knowledge network of disease” as necessary to enable a new taxonomy of disease that integrates molecular and clinical data, as well as health outcomes. TCGA’s findings, as well as other work supported by the NCI’s Center for Cancer Genomics, are poised to contribute directly to this network. The NCI is taking a leadership role in advancing precision medicine in cancer, and in April 2012 hosted a workshop that brought together NCI scientists and colleagues from across the cancer community to consider ways in which NCI can support the acceleration of precision medicine to cancer research and treatment.

ANGIOGENIC LEVELS

Question. Dr. Collins, what work is NIH conducting to help establish baseline angiogenic levels in healthy individuals and those with disease? How will this work impact NIH's ability to measure the effects of diet on blood vessel development?

Answer. NCI funds angiogenesis-related research that includes examination of cancer-related angiogenesis and exploration of therapies targeting this process, as well as research on diet, angiogenesis, and cancer prevention. Research is also underway to investigate the effect of moderate intensity exercise on blood vessels. Angiogenesis, and specifically research measuring the effects of diet on blood vessel development, is an area of research the NCI continues to support. Two examples of ongoing NCI research related to angiogenesis include:

- An examination of the underlying mechanisms for the association between increased physical exercise and decreased risk of several types of cancer and the effects of exercise on angiogenesis-related biomarkers in serum.
- A diagnostic imaging study examining baseline tissue angiogenic markers and the outcomes of chemotherapy delivered directly to liver tumors via a catheter (transarterial chemo embolization therapy).

STRATEGIC SCIENTIFIC PLAN

Question. Dr. Collins, NIH has published a Request for Information seeking comments on the Strategic Scientific Plan for the proposed new Substance Use and Addiction Disorders Institute. Does NIH intend to provide access to these comments to the scientific community and the general public? Will NIH make all of the responses available to the public as they are received?

Answer. The Request for Information seeking input into the Scientific Strategic Plan is open through May 11, 2012. NIH will provide access to all of the responses after the comment period closes. NIH will also provide a summary of the comments after completing an analysis of the responses.

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

NATIONAL CHILDREN'S STUDY

Question. Dr. Collins, I am hearing serious concerns from the research community regarding proposed changes to the National Children's Study (NCS). The study was originally designed around a representative door-to-door sampling of the U.S. population and now the sampling strategy has been significantly changed to be based on provider locations instead.

How much input did you receive from the scientific community and in particular the principal investigators participating in the study and your advisory committee, on the changes being made to the sampling strategy?

Answer. The change in the NCS Study design is being considered primarily for scientific reasons but also with awareness of our need to be fiscally responsible. It is based on data generated during the ongoing Vanguard, or pilot phase, of the NCS. The Vanguard data showed that the proposed study design would not enroll sufficient numbers of families within a scientifically acceptable timeframe or within a fiscally sound budget. Pilot testing conducted through the Vanguard sites showed that a study design based primarily on recruiting participants through healthcare providers was most efficient and could offer scientific advantages that would more than offset its scientific compromises. This provider-based approach also has been employed effectively in other large Federal studies. The President's fiscal year 2013 budget request, which shows a reduction of approximately 15 percent, to \$165 million annually, for the NCS, appropriately reflects these proposed design changes.

As currently envisioned, the NCS Main Study would use a provider-based participant selection and recruitment strategy that the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality have both employed effectively in other studies. This approach uses research ready healthcare provider networks as the primary source for recruitment. The NCS would gain additional participants through the award of contracts for supplemental recruitment from secondary sources (such as title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of appropriate population groups, specifically those with health disparities. The use of these two coordinated selection and recruitment strategies would improve the quality of the Main Study and allow analyses not feasible with either approach alone.

- If adopted, this revised approach would offer several advantages, including:
- greater recruitment efficiency;

- leveraging access to consenting participants' electronic health records, thus improving the amount and consistency of data collected while lowering costs;
- the potential to leverage the existing infrastructure of networks of healthcare providers, again improving the quality of data and lowering costs; and
- allowing built-in continuity for participants who move but remain within the provider network (many provider networks have statewide or regional coverage) or join another provider network affiliated with the Main Study.

NCS continues to refer to the Institute of Medicine (IOM) report that was written by a panel of experts convened to review the original study design. Many of the changes recommended in the report have already been addressed, including the need for an ongoing Vanguard Study to test the study protocol and scientific methodology. The report also noted that the large number of field contractors was a weakness of the Study design, and the NCS is moving to correct this weakness.

The National Children's Study Advisory Committee meets at least four times a year; the April 24, 2012 meeting was the 32d meeting of the committee. These meetings are open to the public, and a public comment period is provided. Presentations to the Advisory Committee also are posted on the NCS Web site. As they have become available, data from the Vanguard Study have been presented at each of the committee's meetings. The topic of a provider based approach to Study recruitment was discussed twice in the last year with the Advisory Committee, first in April 2011 and then again in July 2011, before being the focus of the entire April 24, 2012 meeting. The NCS Study Director holds weekly national conference calls for Vanguard Study contractors to update them on recent developments and to receive their input. The investigators also provide expertise and comments through a monthly Executive Steering Committee meeting, through 2-day face-to-face meetings every 6 months, through circulation of all study instruments and protocol changes to all investigators for comment, and through a mailbox account dedicated to contractors.

Question. How will the academic community be involved going forward?

Answer. Current NCS Vanguard Study contracts expire over the next 17 months. All Requests for Proposals for both the Vanguard and Main Studies will have full and open competitions. Academic institutions can offer proposals for new Study contracts for primary data collection, and have other options as well, including partnering with a primary data collector, conducting ancillary studies using NCS infrastructure, or doing their own research analyses using NCS data as they become available.

In addition, the NCS holds workshops and conferences several times a year and holds open Advisory Committee meetings on a quarterly basis to which the academic community is welcome. NCS also meets with professional societies and other organizations on an ongoing basis and NCS personnel plan and attend academic meetings throughout the year.

Question. In 2010, the committee was informed by NIH that the approximate cost of the entire NCS program would double—from \$3.1 to \$6 billion. Now, you are cutting the request by 15 percent. The budget justification provides no details on how you arrived at the request amount for fiscal year 2013. Can you lay out, specifically, how the \$165 million request was reached?

Answer. NCS is able to reduce overhead costs through greater operational efficiencies and redistribution of tasks and responsibilities. Examples include the use of nonproprietary software to eliminate license fees and proprietary support; use of a federated model for human subject protection to reduce redundancy and speed approvals through elimination of duplicate administrative resources; use of the NCS program office as a coordinating center to develop study instruments and protocol documents, to perform data analysis, and to manage field operations and general consolidation of overlapping field operations.

With the reduction in overhead, we anticipate that for fiscal year 2013 we need about \$35 million for support services and about \$130 million for ongoing Vanguard operations and Main Study initiation.

Question. Why are there no longer any study hypotheses which address the congressional concerns for the NCS put forth in the Children's Health Act of 2000?

Answer. As directed by the Children's Health Act of 2000, the NCS is a longitudinal birth cohort study with the overall goal of examining the role that environmental influences (including physical, chemical, biological, and psychosocial) have on children's health and development. Hypotheses about what factors affect children's health and development will inform the questions asked and the data collected for the Study, but the NCS will not be hypothesis-driven. Children's environments are likely to change substantially over the next two decades, and our goal is to create the richest possible data, biospecimen, and environmental specimen resource to answer important questions about health and development as they arise.

Question. It is my understanding that the new proposal will move the sampling scope from a door-to-door model to a health maintenance organization-based model. By design, this would exclude involvement of the uninsured and likely the involvement of rural and minority populations. These populations are a critical component to achieving scientifically valid findings. How will you address this issue?

Answer. As currently envisioned, the NCS Main Study would use a provider-based participant selection and recruitment strategy that the NIH and the Agency for Healthcare Research and Quality (AHRQ) have both employed effectively in other studies. This approach uses research ready healthcare provider networks as the primary source for recruitment. The NCS would gain additional participants through the award of contracts for supplemental recruitment from secondary sources (such as title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of appropriate population groups, specifically those with health disparities. The use of these two coordinated selection and recruitment strategies would improve the quality of the Main Study and allow analyses not feasible with either approach alone.

Question. The Vanguard Centers have created nearly a decade's worth of research infrastructure including costly "build outs" of field office space composed of laboratories for processing biological and environmental specimens, and call centers. These facilities were built to detailed specifications provided by the NCS program office. Other NCS research infrastructure include the hiring, certifying and training of staff, development of a Federated Institutional Review Board, and establishment of a Federal Information Security Management Act compliant environment. In addition, the Vanguard Centers have spent years developing cooperative agreements and memoranda of understanding with countless delivery hospitals to ensure that NCS participant biological and medical data can be obtained at the time of birth. Given the newly proposed design of the NCS, it appears as though this infrastructure could go to waste without utilizing the resources of the existing Vanguard Centers. What assurances can you provide that these Vanguard Centers will be eligible to compete for continued participation in the NCS and be afforded a reasonable, full, and fair opportunity to do so?

Answer. The Vanguard Study will continue to pilot study methods in its current 40 locations, several years in advance of the Main Study, following the children already recruited by the Vanguard Study until they turn 21. In this follow-up phase, it will use a smaller number of contractors than in its earlier recruitment phase, thus following recommendations in the IOM report from 2008 and realizing cost savings, while improving scientific quality by achieving greater consistency in data and specimen collection among study sites.

Current NCS Vanguard Study contracts expire over the next 17 months; new contracts will be awarded following full and open competitions. The NCS is working with current contractors to ensure the orderly transition of data collection services and of relationships with participants, communities, and other local institutions. As is usual with longitudinal studies that extend across many years, individual contractors may continue to change during the course of the study, and it is important for the NCS to have procedures in place to ensure smooth transitions that may occur in the future.

All Requests for Proposals for both the Vanguard and Main Studies will have full and open competitions. Academic institutions can offer proposals for new Study contracts for primary data collection, and have other options as well, including partnering with a primary data collector, conducting ancillary studies using NCS infrastructure, or doing their own research analyses using NCS data as they become available. Finally, contractors that complied with NCS specifications for field operations will have established a platform that is flexible and adaptable to multiple uses, so they can leverage that investment for additional projects.

DRUG RESCUE AND REPURPOSING

Question. Dr. Collins, at the NIH hearing last year, we discussed drug rescue and repurposing—that is, leveraging existing compounds to develop new, novel treatments for patients. In January, NIH released a concept for a program called the Drug Rescue Program to fund research to identify new therapeutic uses of proprietary investigational drugs and biologics. I am pleased to see NIH moving forward on this issue since it is an ideal opportunity for academia to team with industry to bring treatments to patients faster. However, repurposing compounds brings up a number of challenges, including concerns regarding intellectual property rights and liability. In particular, will pharmaceutical companies be interested in repurposing drugs they currently make money on if a new patient population could open them up to new lawsuits? How will you address these concerns?

Answer. In early May, National Center for Advancing Translational Sciences (NCATS) expects to establish a pilot collaborative drug rescue program, Discovering New Therapeutic Uses for Existing Molecules, to match researchers with a selection of industry-developed molecular compounds in an attempt to identify a therapeutic use. These compounds are currently not approved for any use and are not being pursued by the pharmaceutical company. The program will incorporate innovative template agreements designed to streamline the legal and administrative process for participation by multiple organizations. These templates will reduce time, cost, and effort, as well as enable greater participation than traditional partnerships. The templates also provide a roadmap for handling intellectual property used in or developed through the program. Participating industry partners will retain the ownership of their compounds, while academic research partners will own any intellectual property they discover through the research project with the right to publish the results of their work.

This pilot program will focus on drug rescuing only. It does not include drug repurposing, which is an attempt to find a new use for a drug that is already approved for another therapeutic use. NCATS is considering how best to structure initiatives which enable drug repurposing, with the understanding that repurposed drugs would undergo the same Federal Drug Administration (FDA) requirements and clinical development investments as newly developed compounds and will need to meet FDA patient safety and efficacy requirements.

HEALTH ECONOMICS

Question. Dr. Collins, the President's budget requests \$13 million from the Common Fund for health economics research. Diverting biomedical research funds to pay for health economics research is not only a significant departure from traditional NIH research funding but also duplicative of AHRQ health economics research and the Center for Disease Control and Prevention research on the economics of prevention. For example, one of the programs four major initiatives in the budget request is for a program entitled: "The Science of Structure, Organization, and Practice Design in the Efficient Delivery of Healthcare." This initiative appears directly duplicative of AHRQ's existing program, the Patient-Centered Health Research/Effective Health Care, that seeks to conduct research around the same areas on healthcare delivery and efficiency. Since AHRQ's mission seems more appropriately suited toward researching the economics and efficiency of healthcare delivery, why should we be taking money away from valuable investments in biomedical research, when much of this work appears to be in progress within other Health and Human Services Operating Divisions?

Answer. We are working with AHRQ and other agencies to collaborate on this critical issue to ensure that NIH research does not conflict with their efforts and missions. NIH's mission is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability." We initiated this Common Fund program in Health Economics as a way to measure the success of the translation of the benefits of our research into enhanced health of the U.S. population.

Much of the NIH research enterprise generates optimism that a new era of personalized medicine (meaning both prevention and treatment) will lead to improved outcomes while keeping cost growth under control. For this promise to be realized, we will need to understand the reasons organizations and individuals adopt new approaches.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

CLINICAL AND TRANSLATIONAL SCIENCE AWARDS

Question. The largest single Federal grant at Vanderbilt University is a clinical and translational science award (CTSA) for approximately \$50 million. Vanderbilt is also the national coordinating center for all of the CTSA's. How do you see the interactions between the CTSA's and the rest of the National Center for Advancing Translational Science (NCATS) developing, and what is being done to support a high level of interaction?

Because of the shortage of products in the drug pipeline, do you see NCATS as more focused on drug development, or will the CTSA's also continue to be able to build on the programs of training, career development for young investigators, research informatics, community engagement, and clinical research infrastructure? All of these are still important for biomedical research.

Answer. With the creation of NCATS on December 23, 2011, the administration of the CTSA program moved into a new home. Within NCATS, the program will continue to support the highest quality translational research. Now as part of a new division, the Division of Clinical Innovation (DCI), the CTSA program is benefiting from adjacency to the new Division of Preclinical Innovation (DPI). DPI includes programs that focus on re-engineering the early phases of translation (including assay development, high-throughput screening, lead optimization, and predictive toxicology) as well as the Therapeutics for Rare and Neglected Diseases program. A fully integrated program will be put in place so that the DPI and the DCI are truly a single effort guided by a shared mission.

One of the great successes of the CTSA program has been its development of training programs for clinical researchers and allied professionals in the many aspects of translational science. As the CTSA program incorporates the mission of NCATS, this emphasis on training will be sustained and expanded to build in specific areas of need, such as informatics and pharmacology. We anticipate that the CTSA will have an important role in facilitating first-in-human trials for new therapies, promoting innovation in research methods, and re-engineering the processes for clinical research. We expect that they will continue to provide a home for community outreach and education at institutions across the country. The CTSA program will continue to support the entire spectrum of translational research, evolving to meet the most pressing scientific needs and opportunities. NCATS is not a drug development center; its broader mission is to enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of diseases and conditions.

PERSONALIZED MEDICINE

Question. The physicians and researchers at Vanderbilt are investing a great deal in the science of personalized medicine. Can you tell us what the term “personalized medicine” means to you, and what role you see for National Institutes of Health (NIH)?

Answer. Personalized medicine, or more precisely “genomic medicine,” is the medical application of genomics for the purposes of disease prevention, diagnosis, and treatment. It is sometimes referred to as “precision medicine” or “individualized medicine.” Through genomic medicine, we will anticipate and often pre-empt the onset of disease, diagnose disease more quickly and accurately, and tailor the choice of medications according to an individual’s genomic information.

This vision for improved healthcare tools and options was a key driving force behind the Human Genome Project (HGP; <http://www.genome.gov/10001772>)—a major international project led by the NIH. Scientists recognized that, in order to realize genomic medicine, we would first need much more detailed knowledge of the human genome. Through the HGP, scientists were able to determine the full molecular sequence of the human genome and its genes.

NIH, led by the National Human Genome Research Institute (NHGRI), is now building on the success of the HGP. In 2011, NHGRI published a new strategic vision describing the research path necessary for genomic medicine to become reality (<http://www.genome.gov/sp2011/>). The plan emphasizes that a deeper understanding of the basic biology of the genome, such as identifying all its functional elements and how genomes vary from person to person is needed. It also highlights the need to investigate how genome variation influences health and disease and the work to be accomplished to explore the clinical applications of genomics. NIH is now leading this research through cutting-edge programs and research initiatives.

For instance, NHGRI and the National Cancer Institute collaboratively lead “The Cancer Genome Atlas” to better understand the molecular basis of cancer. NHGRI also is funding research to detect the genetic underpinnings of thousands of rare diseases for which there is no known cause, as well as undertaking a major project to investigate the genetic causes of Alzheimer’s disease. While it will be many years before genomics is fully incorporated into patient care, NHGRI-funded researchers are investigating the clinical use of genomics in patients at risk for many diseases, including those with mysterious conditions that have long eluded diagnosis. Institutes and Centers (ICs) across NIH are conducting genomic research to elucidate the genomic causes of disease and how the genome influences the effectiveness of treatment.

Though sometimes envisioned as a phenomenon of the future, genomic medicine is already having an impact on how patients are treated. This is especially true in the field of pharmacogenomics, where drug selection and administration increasingly is assisted by prior genetic testing. The Food and Drug Administration now lists approximately 100 approved drugs with pharmacogenomic information on their

labels. These include abacavir, now the standard of care for HIV-infected patients, as well as drugs for the treatment of cancers, clopidogrel for treating cardiovascular disease, and warfarin for preventing blood clotting.

Genomics is also being used to help patients who do not respond to conventional treatment. An example of this was described by NIH Director Francis Collins, M.D., Ph.D. during his testimony before the subcommittee during the NIH hearing on March 28. Dr Collins told the story of twins Alexis and Noah Beery, who suffered from a rare and devastating movement disorder called dystonia. The causative mutation was identified through sequencing of their genomes, after which their treatment was changed and their health improved remarkably.

Genomics promises to advance healthcare over the next several decades. NIH will continue to lead the way toward genomic medicine through funding and conducting the pioneering science that will be necessary to realize the full potential of genomic medicine.

DIABETES

Question. Diabetes continues to be a costly and growing epidemic for Tennessee and the United States. Dr. Collins and Dr. Rodgers, can you tell us how NIH, and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in particular, are addressing this epidemic?

Answer. NIH and NIDDK are working to develop and test prevention and treatment strategies for type 1 and type 2 diabetes through a robust research program that supports basic, clinical, and translational research, as well as research training. Future research will be guided by a strategic plan for diabetes research that was recently released by the NIDDK (<http://www2.niddk.nih.gov/AboutNIDDK/ReportsAndStrategicPlanning/DiabetesPlan/PlanPosting.htm>). Landmark clinical research supported by the NIH has included the Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study, which established the value of tight blood glucose control in reducing complications in type 1 and type 2 diabetes respectively; and the Diabetes Prevention Program, which proved that type 2 diabetes can be prevented or delayed through delivery of an intensive lifestyle intervention, or, to a lesser degree, with the generic drug metformin. Knowledge from NIH diabetes research is communicated to patients, health professionals, and the public through the National Diabetes Information Clearinghouse and the National Diabetes Education Program.

In 2011, NIDDK completed the first major trial of type 2 diabetes management in children and adolescents, a newly emerging problem, and demonstrated that intensive glucose control in people with type 1 diabetes can reduce rates of chronic kidney disease and end-stage renal disease by 50 percent 22 years later. NIDDK supported planning grants for a comparative effectiveness clinical trial testing different medications, in combination with metformin, for type 2 diabetes treatment, and for a clinical trial testing vitamin D in prevention of type 2 diabetes based on a promising pilot study. Other clinical trials include Action for Health in Diabetes (Look AHEAD), to determine the value of a lifestyle intervention for improving diabetes outcomes, and investigation of bariatric surgery as treatment for diabetes, complemented by studies in animal models.

New initiatives are fostering research toward preserving function of insulin-producing beta cells early in the course of type 2 diabetes, and a new consortium was launched to study approaches to prevent gestational diabetes. The Beta Cell Biology Consortium identified a potential new strategy to induce beta cell regeneration to replace lost beta cells and reverse aging-associated decline in beta cell growth. NIDDK is also working to understand and ameliorate disparities in diabetes with research to identify gene regions conferring type 2 diabetes risk in multiple ethnic groups, translational research to bring scientific discoveries to all who can benefit, and a clinical trial of type 2 diabetes management including minority youth and adolescents.

MINORITY HEALTH AND HEALTH DISPARITIES

Question. Dr. Collins, the healthcare reform law clarified the role of the National Institute on Minority Health and Health Disparities (NIMHD) at NIH as it pertains to coordinating health disparities research. How are you and the IC Directors going to work together to make the newly elevated NIMHD the coordinating body at NIH on health disparities?

Answer. The law clearly identifies the NIMHD as the coordinating body for minority health and health disparities at NIH. The NIH Institutes and Centers will continue to administer their programs on minority health and health disparities and work with the NIMHD as required in its coordinating role.

Question. Where does the NIH stand in terms of funding that is allotted to minority health and health disparities? In the last strategic plan, there was \$2.5 billion being spent on minority health and health disparities at various ICs. What is that amount now, and how are you going to work with the new health reform law so that the NIMHD is the coordinating entity at NIH for these issues?

Answer. The overall NIH fiscal year 2011 funding for health disparities was \$2.7 billion. NIMHD recently hired a Deputy Director for strategic scientific planning and program coordination, who will lead the NIMHD coordination of minority health and health disparities working with the Institutes and Centers.

Question. Considering last year's NIH study, which showed possible bias against African Americans with the awarding of NIH R01 grants, will you work with Meharry Medical College and the Association of Minority Health Professions Schools to ensure their annual health profession pipeline symposium, exposing hundreds of students to the health professions, receives adequate funding?

Answer. A working group of the National Advisory Council (ACD) has been working on this vexing problem and is scheduled to report its recommendations at the June 14 meeting of ACD. The president of Meharry Medical College, Dr. Wayne Riley, is a member of this working group. As part of this deliberative process, outreach efforts have included many of the institutions represented by the Association of Minority Health Professions Schools (AMHPS). Meharry Medical College and the AMHPS have successfully competed in the past for NIH funding to support the annual health professions symposium, and are encouraged to continue applying for NIH funding. Several of the NIH Institutes and Centers have contributed funds to support the symposium.

Question. The NIH has issued two strategic plans and budgets to reduce and eliminate health disparities since the Congress enacted the legislation requiring it. What is the status of the next strategic plan?

Answer. The NIH Health Disparities Strategic Plan and Budget fiscal year 2009–2013 has been approved and is available on the NIMHD Web site at http://www.nimhd.nih.gov/about_ncmhd/index2.asp.

Question. Can you provide detailed funding information for minority health and health disparities activities at the NIH broken out programmatically by Institute and Center?

Answer. The NIH Health Disparities Strategic Plan and Budget fiscal year 2009–2013 provides information on programs/activities by Institutes and Centers with associated budgets for each goal by IC and is available on the NIMHD Web site at http://www.nimhd.nih.gov/about_ncmhd/index2.asp.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

INTERSECTION OF NATIONAL CANCER INSTITUTE AND NATIONAL CENTER FOR
ADVANCING TRANSLATIONAL SCIENCE

Question. We have heard Dr. Collins and others discuss the value to National Institutes of Health (NIH) of the newly created National Center for Advancing Translational Science, or (NCATS). NCATS is being positioned to become a resource that will support the translational research work across all of NIH's Institutes and Centers.

Could you clarify how the National Cancer Institute (NCI) will work with NCATS to optimize the investments that will be made in NCATS and the knowledge that will be developed in this new center?

Answer. Translational research supported by NCI transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce cancer incidence, morbidity, and mortality—it is a critical piece of the NCI's research portfolio and encompasses numerous programs and funding mechanisms.

For example, researchers working in NCI's Specialized Programs of Research Excellence (SPOREs) and investigator initiated Program Project (P01) grants at NCI-supported research institutions across the country, conduct promising translational research. The NCI Drug Discovery and Development Program, run through the Frederick National Laboratory for Cancer Research, has successfully guided drug candidates through the final steps of development to first-in-human studies. The Cancer Genome Atlas (TCGA) and Therapeutically Applicable Research to Generate Effective Treatment (TARGET) programs are generating data on the genomic foundations of cancer, and the Cancer Target Discovery and Development (CTDD) Network is accelerating the transition of molecular data from initiatives like TARGET and TCGA to new treatments through gene validation studies as well as high-throughput screening of small molecules.

NCATS will complement these efforts, particularly by providing resources and infrastructure to assist the basic research community in moving their discoveries to the next phase. NCATS will work to improve the methodology of translational research, and will also collaborate with and utilize NCI programs in the process. There will be points where NCI and NCATS intersect to share knowledge and technology. For example, Clinical and Translational Science Awards (CTSA) are an initiative funded principally by NCATS. Most academic institutions that have an NCI-designated Cancer Center also have a CTSA and many collaborative projects have emerged from these synergies.

VALUE OF CANCER CENTERS

Question. I have had the opportunity to visit a cancer center in my home State—The University of Kansas Cancer Center. I have seen basic research at work in impressive labs. In particular, at the University of Kansas (KU) I have seen how this research is being translated into the development of early phase drugs—in one case through a ground-breaking collaboration between the University of Kansas Cancer Center, NIH, and the Leukemia Lymphoma Society. I believe that collaborations such as this that bring public and private resources and expertise together are important if we are to maximize the return on the investments of our Federal dollars. And last but definitely not least, I have seen patients coming to KU with the ability to participate in clinical trials, with the hope and real potential that the delivery of cutting-edge research into their care may change the course of their disease for the better.

What are the programs at NCI that make this cycle of innovation and translation possible?

Specifically, do you see a specific role for the Cancer Centers program in making sure that this cycle of translation of basic research findings into clinic application continues to take place?

Answer. NCI engages in multiple collaborations along the research continuum, including funding a variety of innovative biotechnology companies via its Small Business Innovation Research program.

The NCI's 66 Designated Cancer Centers, which are distributed in all regions of the United States, play a crucial role in the Nation's cancer research effort and are the primary source of new discoveries about cancer prevention, diagnosis, and treatment. The Cancer Centers deliver state-of-the-art care to patients and their families, inform healthcare professionals and the general public, and often work through partnerships with other healthcare organizations to reach underserved populations. Clinical application—providing prevention, diagnosis, and therapies for patients—is the ultimate goal for all cancer research, and NCI-designated Cancer Centers have a proud history of leadership in clinical trials, many of which have led to changes in the standard of care for cancer patients. Along with the many other NCI-funded research and academic institutions, and NCI's intramural program, they are a major source of new discoveries into cancer's causes, prevention, diagnosis, and treatment.

The NCI-Designated Cancer Centers are required to facilitate the rapid transfer of clinical observations to laboratory experiments, and promising lab-based discoveries to innovative applications in the prevention, detection, diagnosis, treatment, and survivorship of cancer. The Cancer Centers are required to work together and with the NCI to facilitate the translation of fundamental discoveries into tangible patient benefit. For example, researchers at the University of California San Francisco Cancer Center have shown that a molecular test measuring the activity of 14 genes in cancerous lung tissue can improve the accuracy of prognosis and guide treatment options for patients with the most common form of lung cancer. Other recent developments include identification of the first major genetic mutation associated with inherited prostate cancer by researchers from the Johns Hopkins Cancer Center, with implications for the development of genetic tests to identify the mutation and screening practices for men with a family history of prostate cancer. And at the Koch Institute for Integrative Cancer Research at MIT, cancer researchers and engineers are working together to develop more effective drug delivery systems such as nanoparticle “smart bombs” that deliver high concentrations of drugs directly to the cancer cells, a technology currently being studied in a phase I clinical trial.

UPDATE ON NATIONAL CANCER INSTITUTE INITIATIVES

Question. When I read stories about the development of cutting-edge treatments, particularly those that use the body's own immune system to fight cancer and other diseases, I know that we are doing something right to save lives and lower

healthcare costs. Can you explain some of the most promising cancer research opportunities and discoveries that the NCI is currently pursuing?

Answer. NCI supports a diverse research portfolio aimed at increasing our understanding of the genomic foundations of cancer, improving screening technologies, advancing effective treatments including immunotherapies, and developing new approaches for overcoming drug resistance.

Genomic Foundations of Cancer.—Using genomics to match drugs to the patients most likely to benefit from them, and conversely sparing patients courses of treatment from which they will not benefit, promises to be among the new modalities for successfully managing cancer. Understanding the genomic underpinnings of cancer allows for the development of molecularly targeted agents that may be effective against several cancer types, and can often be used in combination with other therapies. NCI's Center for Cancer Genomics, with a mission of developing and applying genome science to better treat cancer patients, coordinates this research area across the NCI.

Screening Technologies.—Tools that can accurately detect and diagnose tumors have potential to markedly improve outcomes for cancer patients since these tools often detect cancer early, before it has spread throughout the body and when treatment is more likely to be curative. Last year, NCI released results from the National Lung Screening Trial indicating that screening with low-dose-computed tomography results in 20 percent fewer lung-cancer deaths among current and former heavy smokers compared with screening with chest xray. This development marks the first time that a screening test has been found to reduce mortality from lung cancer, the most common cause of cancer deaths in the United States and the world. Other initiatives and projects, including a large portfolio of grants, are pursuing biomarkers and imaging techniques with potential to aid in early detection and diagnosis of several types of cancers.

Immunotherapies.—The pace of research advances to stimulate the body's immune system to fight cancer has quickened in recent years, with clinical trials of different therapies showing positive results for several different cancer types. In 2010, data from a large clinical trial established a monoclonal antibody called ipilimumab as the first immunotherapeutic agent to show an increase in survival for patients with advanced melanoma. The drug stimulates the immune system to attack melanoma cells by binding to and inhibiting a molecule called CTLA-4 that is found on the surface of immune cells.

In March 2011, the Food and Drug Administration (FDA) approved the antibody (marketed as Yervoy) to treat late-stage melanoma. NCI-supported research has validated CTLA-4 as a target and has paved the way for studies of the drug for prostate, lung, and renal cancers. Other potentially promising immunotherapy approaches include "adoptive cell transfer," in which T-cells are taken from a patient's tumor, stimulated and reproduced, then put back into the body; and the targeting of "tumor initiating cells" (thought to be the chief cause of cancer recurrences) as well as normal cells that cooperate with cancer cells to help them survive and spread.

Drug Resistance.—One of the most disappointing features of the development of new targeted therapeutics is how routinely drug resistance emerges and the disease begins to progress. Resistance to treatment with anticancer drugs results from a number of factors—every cancer expresses a different array of drug-resistance genes, and various mechanisms have evolved as protection from toxic agents. As therapy has become more effective, acquired resistance has become common. NCI is aggressively pursuing research to gain an understanding of the mechanisms that lead to drug resistance and is looking for agents that overcome these mechanisms. NCI is supporting studies of combination therapies for patients whose disease has become resistant to therapy, as well as exploring alternative approaches through the Provocative Questions Initiative to determine if controlling rather than killing cancer cells can avoid the development of drug resistance.

Question. Also, since NIH's work has been managed over the past few years with flat and decreased funding when you account for inflation, what innovative strategies have you found, or do you plan, that will allow NIH to continue making research progress in this challenging budgetary environment?

Answer. NCI is employing a number of innovative strategies to ensure efficient stewardship of the Nation's investment in cancer research, particularly in the face of stagnant budgets. As mentioned at the recent subcommittee hearing, the Provocative Questions (PQ) project is one creative approach that contributes to this goal. The project is assembling a list of important but nonobvious questions that will stimulate the NCI's research communities to use laboratory, clinical, and population

sciences in especially effective and imaginative ways. While this initiative does not replace the NCI's longtime and essential emphasis on funding investigator-initiated research, it represents a useful new approach to making the greatest impact with our research dollars. Reductions in funding tend to prompt all parts of the research community to become more conservative, often converging on similar subjects, narrowing research portfolios. By pooling the imaginations of the research community to address understudied areas, an initiative such as PQ provides a venue for innovative approaches even in times of fiscal constraint.

Another area where NCI is making strategic changes is its Clinical Trials Cooperative Groups program. Clinical trials are a critical step in moving potential therapies into clinical practice, and the Cooperative Groups are an essential part of this process. The groups are now being reorganized, consolidating nine adult groups into four, with the Children's Oncology Group remaining a separate group. The consolidation is an effort to streamline the development and execution of trials, while continuing to select and prioritize trials through stringent peer review, and to fund the most promising and innovative studies. This process will reduce redundancy and improve the effectiveness and efficiency of trials; and will also result in simplified and better harmonized operations centers, data management centers, and tumor banks. The streamlined framework will also foster a more collaborative approach to selecting the most important trials to perform.

NCI is also changing the way it conducts early phase clinical research. Over the last several years, NCI has developed the ability to do "proof of mechanism" studies, which allow the research community to understand early on whether a drug hits its target. This work defines patient populations that are most likely to benefit from targeted therapies as early in the process as possible. Continued progress in this area will lead to clinical research models that are not only more efficient, but more effective in identifying the appropriate treatment approach for specific patient populations. These are just a few examples that demonstrate NCI's strategic approaches to continue to make progress in a challenging budgetary environment.

Question. The Cancer Genome Atlas (TCGA) is one of NIH's most prominent examples of research growing out of the HGP and is the basis for much of the work taking place today that explores the genomic foundations of cancer. Researchers are working to increase our understanding of the genetic basis of various forms of cancer and how to best capitalize on these genomic breakthroughs. Can you provide an update on how TCGA is proceeding and how this project is contributing to advancements in precision medicine?

Answer. TCGA, a joint effort of the NCI and the National Human Genome Research Institute (NHGRI), is the largest and most comprehensive analysis of the molecular basis of cancer ever undertaken. Through the application of genome analysis technologies, including large-scale genome sequencing, TCGA is beginning to provide a comprehensive foundation of the abnormalities associated with the tumor types under study, the degree to which tumors within each type are similar and distinct, and the degree of overlap between tumor types. This foundation has the potential of improving our ability to diagnose, treat, and prevent cancer, providing an important element in reaching the goal of precision medicine.

TCGA began as a pilot project in 2006, studying cancers of the lung, brain (glioblastoma) and ovary, and it has been expanded over time to include additional tumor types. Currently in the third year of its post pilot phase, TCGA has begun the comprehensive analysis of 16 additional cancers including breast, colorectal, kidney, lung, endometrial and pancreatic cancers, among others. Of these projects, one quarter are published or in manuscript form; one quarter are in late-stage analysis; and the remaining one-half are still being collected and studied, with TCGA on track to conclude this phase in 2014. TCGA has also initiated a small project on rare tumors, with plans to complete initial discovery by the end of this year.

TCGA's efforts to advance the understanding of the molecular basis of cancer are already providing biological insights considered critical to reaching the goal of precision medicine. The work supported by NCI's Center for Cancer Genomics, including not only TCGA but also CTDD and Therapeutically Applicable Research to Generate Effective Treatments (TARGET), will contribute to the advancement of precision medicine.

Question. Last year, the Journal of Oncology published an article entitled "Tumor Angiogenesis as a Target for Dietary Cancer Prevention" examining the suppression of tumor growth by controlling blood vessel growth through diet. I understand that promoting healthy blood vessel growth may have applications in not only fighting cancer but also Alzheimer's disease, arthritis, and cardiovascular disease. I also understand that evaluating baseline angiogenic levels in healthy individuals and those with disease are critical to measuring the effects of diet on blood vessel development. What work is NIH conducting to help establish baseline angiogenic levels?

Answer. NCI funds angiogenesis-related research that includes examination of cancer-related angiogenesis and exploration of therapies targeting this process, as well as research on diet, angiogenesis, and cancer prevention. Research is also underway to investigate the effect of moderate intensity exercise on blood vessels. Angiogenesis, and specifically research measuring the effects of diet on blood vessel development, is an area of research the NCI continues to support. NCI's Division of Cancer Prevention is considering hosting a workshop to bring together experts in angiogenesis and nutrition to explore current science regarding angiogenesis modification, diet, and cancer. Two examples of ongoing NCI research related to angiogenesis include:

- an examination of the underlying mechanisms for the association between increased physical exercise and decreased risk of several types of cancer and the effects of exercise on angiogenesis-related biomarkers in serum; and
- a diagnostic imaging study examining baseline tissue angiogenic markers and the outcomes of chemotherapy delivered directly to liver tumors via a catheter (transarterial chemo embolization therapy).

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you all very much.

[Whereupon, at 11:54 a.m., Wednesday, March 28, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2013**

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

[CLERK'S NOTE.—The subcommittee was unable to hold hearings on some departmental and all nondepartmental witnesses. The statements and letters of those submitting written testimony are as follows:]

DEPARTMENTAL WITNESSES

RAILROAD RETIREMENT BOARD

PREPARED STATEMENT OF MICHAEL S. SCHWARTZ, CHAIRMAN OF THE BOARD

Mr. Chairman and members of the subcommittee: We are pleased to present the following information to support the Railroad Retirement Board's (RRB) fiscal year 2013 budget request of \$112,415,000 to operate the agency.

The RRB administers comprehensive retirement/survivor and unemployment/sickness insurance benefit programs for railroad workers and their families under the Railroad Retirement and Railroad Unemployment Insurance Acts. The RRB also has administrative responsibilities under the Social Security Act for certain benefit payments and Medicare coverage for railroad workers. In recent years, the RRB has also administered extended unemployment benefits under the American Recovery and Reinvestment Act of 2009 (Public Law 111-5) and the Worker, Homeownership, and Business Assistance Act of 2009 (Public Law 111-92), as amended. The recently enacted Middle Class Tax Relief and Job Creation Act of 2012, (Public Law 112-96) provides extended unemployment benefits for periods of eligibility beginning through calendar year 2012.

During fiscal year 2011, the RRB paid \$11 billion, net of recoveries and offsetting collections, in retirement and survivor benefits to about 578,000 beneficiaries. We also paid \$90.9 million in net unemployment and sickness insurance benefits under the Railroad Unemployment Insurance Act and \$7.8 million under Public Law 111-92, as amended, for special extended unemployment benefits to a total of about 28,000 claimants. In addition, the RRB paid benefits on behalf of the Social Security Administration amounting to \$1.4 billion to about 115,000 beneficiaries.

PROPOSED FUNDING FOR AGENCY ADMINISTRATION

The President's proposed budget would provide \$112,415,000 for agency operations, which would enable us to maintain a staffing level of 885 full-time equivalent staff years (FTEs) in 2013. The proposed budget would also provide \$3,562,000 for conversion of our obsolete integrated financial management system to a shared service provider. Furthermore, \$1,176,000 would be invested into more information technology (IT) to continue stretching the value of our baseline funding that has remained substantially below required amounts for the past 3 years. The IT investments include \$621,000 for IT tools and infrastructure replacement, \$275,000 for network operations and emergency services, and \$280,000 for E-Government initiatives and conversion of employee official personnel files to an electronic format.

AGENCY OPERATIONS

Although funding for agency operations has been held at nearly the same level for the past 3 years, the RRB is achieving its mission. During fiscal year 2011, the agency provided benefit services within the timeframes promised in the RRB Customer Service Plan 99.2 percent of the time, and maintained benefit payment accuracy rates exceeding 99 percent. Customer satisfaction with RRB services has also been high. In January 2012, the RRB achieved a score of 81 in a survey of claimants receiving unemployment and sickness insurance benefits. This was 14 points higher than the Federal Government average.

These results have been possible due to the efforts of the RRB's experienced and dedicated workforce, supported by advanced information technology. To ensure that the RRB can continue to provide this level of service in future years, the agency will need sufficient funding to recruit and train qualified staff to replace 40 percent of our retirement eligible workforce, sustain our technological infrastructure, continue with modernization of systems, and uphold optimal results of processing operations against a constrained baseline. As rising costs of doing business erode the agency's buying power each year, it becomes more of a challenge today to fiscally plan for the outyears to protect current services without undermining the impact of modernization activities, which are essential to maintaining service levels in the future.

FINANCIAL MANAGEMENT INTEGRATED SYSTEM

The RRB's fiscal year 2013 budget request includes \$3,562,000 for a major project to migrate from our obsolete legacy financial management system to the cloud or a shared service provider. While the system continues to meet our financial processing and reporting requirements, conversion to a shared service provider hosted solution follows applicable laws and current Office of Management and Budget guidance while removing the risk associated with dependence on a system that has reached the end of its lifecycle in 2003.

Advantages of a conversion include compliance with the Financial Management Lines of Business processes established by the Financial Systems Integration Office, improved end-user reporting capabilities that replace manual processes, a user-friendly interface supporting faster transaction processing, and the transfer of daily system operations to an outside service provider. The transfer of system operations relieves the RRB of activities such as supporting the financial management system application upgrades, configurations, maintenance, and modifications.

OTHER REQUESTED FUNDING

The President's proposed budget includes \$45 million to fund the continuing phase-of vested dual benefits, plus a 2-percent contingency reserve of \$900,000 which "shall be available proportional to the amount by which the product of recipients and the average benefit received exceeds the amount available for payment of vested dual benefits." In addition, the President's proposed budget includes \$150,000 for interest related to uncashed railroad retirement checks.

FINANCIAL STATUS OF THE TRUST FUNDS

Railroad Retirement Accounts.—The RRB continues to coordinate its financial activities with the National Railroad Retirement Investment Trust (Trust), which was established by the Railroad Retirement and Survivors' Improvement Act of 2001 (RRSIA) to manage and invest railroad retirement assets. Pursuant to the RRSIA, the RRB has transferred a total of \$21.276 billion to the Trust. All of these transfers were made in fiscal years 2002 through 2004. The Trust has invested the transferred funds, and the results of these investments are reported to the RRB and posted periodically on the RRB's Web site. The net asset value of Trust-managed assets on September 30, 2011, was approximately \$22.1 billion, a decrease of \$1.6 billion from the previous year. As of March 2012, the Trust had transferred approximately \$12.5 billion to the Railroad Retirement Board for payment of railroad retirement benefits.

In June 2011, we released the annual report on the railroad retirement system required by section 22 of the Railroad Retirement Act of 1974, and section 502 of the Railroad Retirement Solvency Act of 1983. The report addressed the 25-year period 2011–2035, and included projections of the status of the retirement trust funds under three employment assumptions. These assumptions indicated that barring a sudden, unanticipated, large decrease in railroad employment or substantial investment losses, the railroad retirement system would experience no cash flow problems for the next 23 years. Even under the most pessimistic assumption, the cash flow

problems would not occur until the year 2034. The report did not recommend any change in the rate of tax imposed by current law on employers and employees.

Railroad Unemployment Insurance Account.—The RRB's latest annual report on the financial status of the railroad unemployment insurance system was issued in June 2011. The report indicated that even as maximum daily benefit rates rise 38 percent (from \$66 to \$91) from 2010 to 2021, experience-based contribution rates are expected to keep the unemployment insurance system solvent. Due to short-term cash-flow problems, \$46.5 million was borrowed from the Railroad Retirement Account during fiscal year 2010. The loans were fully repaid by the end of fiscal year 2011.

Unemployment levels are the single most significant factor affecting the financial status of the railroad unemployment insurance system. However, the system's experience-rating provisions, which adjust contribution rates for changing benefit levels, and its surcharge trigger for maintaining a minimum balance, help to ensure financial stability in the event of adverse economic conditions. No financing changes were recommended at this time by the report.

Thank you for your consideration of our budget request. We will be happy to provide further information in response to any questions you may have.

OFFICE OF INSPECTOR GENERAL

PREPARED STATEMENT OF MARTIN J. DICKMAN, INSPECTOR GENERAL

Mr. Chairman and members of the subcommittee: My name is Martin J. Dickman, and I am the Inspector General for the Railroad Retirement Board. I would like to thank you, Mr. Chairman, and the members of the subcommittee for your continued support of the Office of Inspector General.

BUDGET REQUEST

The President's proposed budget for fiscal year 2013 would provide \$8,820,000 to the Office of Inspector General (OIG) to ensure the continuation of the OIG's independent oversight of the Railroad Retirement Board (RRB). During fiscal year 2013, the OIG will focus on areas affecting program performance; the efficiency and effectiveness of agency operations; and areas of potential fraud, waste and abuse.

OPERATIONAL COMPONENTS

The OIG has three operational components: the immediate Office of the Inspector General, the Office of Audit (OA), and the Office of Investigations (OI). The OIG conducts operations from several locations: the RRB's headquarters in Chicago, Illinois; an investigative field office in Philadelphia, Pennsylvania; and five domicile investigative offices located in Virginia, Texas, California, Florida, and New York. These domicile offices provide more effective and efficient coordination with other Inspector General offices and traditional law enforcement agencies, with which the OIG works joint investigations.

OFFICE OF AUDIT

The mission of the Office of Audit is to promote economy, efficiency, and effectiveness in the administration of RRB programs and detect and prevent fraud and abuse in such programs. To accomplish its mission, OA conducts financial, performance, and compliance audits and evaluations of RRB programs. In addition, OA develops the OIG's response to audit-related requirements and requests for information.

During fiscal year 2013, OA will focus on areas affecting program performance; the efficiency and effectiveness of agency operations; and areas of potential fraud, waste, and abuse. OA will continue its emphasis on long-term systemic problems and solutions, and will address major issues that affect the RRB's service to rail beneficiaries and their families. OA has identified four broad areas of potential audit coverage: Financial Accountability; Railroad Retirement Act & Railroad Unemployment Insurance Act Benefit Program Operations; Railroad Medicare Program Operations; and Security, Privacy, and Information Management. OA must also accomplish the following mandated activities with its own staff: Audit of the RRB's financial statements pursuant to the requirements of the Accountability of Tax Dollars Act of 2002 and evaluation of information security pursuant to the Federal Information Security Management Act (FISMA).

During fiscal year 2013, OA will complete the audit of the RRB's fiscal year 2012 financial statements and begin its audit of the agency's fiscal year 2013 financial

statements. OA contracts with a consulting actuary for technical assistance in auditing the RRB’s “Statement of Social Insurance”, which became basic financial information effective in fiscal year 2006. In addition to performing the annual evaluation of information security, OA also conducts audits of individual computer application systems which are required to support the annual FISMA evaluation. Our work in this area is targeted toward the identification and elimination of security deficiencies and system vulnerabilities, including controls over sensitive personally identifiable information.

OA undertakes additional projects with the objective of allocating available audit resources to areas in which they will have the greatest value. In making that determination, OA considers staff availability, current trends in management, congressional and Presidential concerns.

OFFICE OF INVESTIGATIONS

The Office of Investigations (OI) focuses its efforts on identifying, investigating, and presenting cases for prosecution, throughout the United States, concerning fraud in RRB benefit programs. OI conducts investigations relating to the fraudulent receipt of RRB disability, unemployment, sickness, and retirement/survivor benefits. OI investigates railroad employers and unions when there is an indication that they have submitted false reports to the RRB. OI also conducts investigations involving fraudulent claims submitted to the Railroad Medicare Program. These investigative efforts can result in criminal convictions, administrative sanctions, civil penalties, and the recovery of program benefit funds.

OI INVESTIGATIVE RESULTS FOR FISCAL YEAR 2011

Civil judgments	21
Indictments/Informations	60
Convictions	62
Recoveries/Receivables	¹ \$106,717,426

¹This total includes the results of joint investigations with other agencies.

OI anticipates an ongoing caseload of about 480 investigations in fiscal year 2013. During fiscal year 2011, OI opened 369 new cases and closed 234. At present, OI has cases open in 48 States, the District of Columbia, and Canada with estimated fraud losses of nearly \$42 million. Disability fraud cases represent the largest portion of OI’s total caseload. These cases involve more complicated schemes and often result in the recovery of substantial amounts for the RRB’s trust funds. They also require considerable resources such as travel by special agents to conduct surveillance, numerous witness interviews, and more sophisticated investigative techniques. Additionally, these fraud investigations are extremely document-intensive and require forensic financial analysis. Of particular significance is an ongoing investigation related to alleged disability fraud in New York. Eleven individuals have been indicted, and OI agents will likely have to spend a substantial amount of time traveling for trial preparation in fiscal year 2013.

During fiscal year 2013, OI will continue to coordinate its efforts with agency program managers to address vulnerabilities in benefit programs that allow fraudulent activity to occur and will recommend changes to ensure program integrity. OI plans to continue proactive projects to identify fraud matters that are not detected through the agency’s program policing mechanisms.

CONCLUSION

In fiscal year 2013, the OIG will continue to focus its resources on the review and improvement of RRB operations and will conduct activities to ensure the integrity of the agency’s trust funds. This office will continue to work with agency officials to ensure the agency is providing quality service to railroad workers and their families. The OIG will also aggressively pursue all individuals who engage in activities to fraudulently receive RRB funds. The OIG will continue to keep the subcommittee and other Members of Congress informed of any agency operational problems or deficiencies. The OIG sincerely appreciates its cooperative relationship with the agency and the ongoing assistance extended to its staff during the performance of their audits and investigations. Thank you for your consideration.

CORPORATION FOR PUBLIC BROADCASTING

PREPARED STATEMENT OF PATRICIA HARRISON, PRESIDENT AND CEO

Mr. Chairman and members of the subcommittee, thank you for allowing me to submit this testimony on behalf of our country's public media service—public television and public radio, on-air, online, and in your community.

American public media serves our citizens with quality and trusted content that educates, informs and inspires. This trusted noncommercial service is available for free to all Americans of all backgrounds, race and ethnicities, and to underserved and unserved audiences in rural and urban communities throughout the country.

We are a system comprising approximately 1,300 locally owned and operated public radio and television stations connected to communities across the country. Together, these stations ensure that 99 percent of the American people have access to quality educational and informational services that may not otherwise be available to them. Public media stations work for, and are accountable to, the people in the communities they serve. That connection is important as stations acquire national programming and produce local content and services based on the needs of their respective communities.

By design of the Public Broadcasting Act, the Federal investment in this service, administered by the Corporation for Public Broadcasting (CPB), is the foundation on which the public broadcasting system operates. More than 95 percent of the Federal investment goes to support public media's service to the American people. Approximately 70 percent of CPB funding goes directly to local stations, and approximately 19 percent of CPB funding is directed to the production or acquisition of programming, making CPB the largest single funder of content—for children's programming like "Sesame Street" and "The Electric Company"; for public affairs programming like "PBS NewsHour", "Morning Edition" and "Frontline"; and for programming like "Nature", "Nova", "American Experience", "Native American News", "StoryCorps", and the films of Ken Burns.

CPB also supports the creation of programming for radio, television, and digital media. The statute ensures diversity in this programming by requiring CPB to fund independent and minority producers. CPB fulfills these obligations by funding the Independent Television Service, the five Minority Consortia in television (which represent African-American, Latino, Asian American, Native American, and Pacific Islander producers) and numerous minority stations in radio.

Stations use CPB funding for local operations and to produce and acquire programming, which allows them to raise additional operational funds from corporations, foundations, State and local governments and from individual contributions, which are the largest source of non-CPB funding for public media. On average, every Federal \$1 invested in CPB is leveraged by stations to raise \$6 locally. This successful public-private partnership is uniquely entrepreneurial and uniquely American. Though models vary, funding for other countries' public broadcasting systems comes almost exclusively from their governments, from licensing fees or from dedicated taxes. At \$1.39 per American, the cost of our country's service is proportionally small compared to other developed nations.

And for this investment Americans have a safe place to educate their children with unmatched noncommercial educational programming that is proven to prepare children to learn. For this investment, Americans have access to quality news and public affairs programming and information that is trusted and treats the audience as citizens, not consumers. For this investment, Americans can access lifelong educational programming about science, nature, and history that is otherwise not supported in the commercial marketplace. And for this investment, Americans have a valuable public service that reflects our country, contributes to our civil society, and is accountable to the citizens we serve.

CORPORATION FOR PUBLIC BROADCASTING

CPB's mission is to strengthen and advance public media's service to the American people. We are a nonprofit private corporation, and we serve as the steward of the taxpayer's investment in this service. Although our funding is distributed through a statutory formula, under which we can only use 5 percent for administrative expenses, we work every day to ensure that the taxpayers' money is wisely invested in stations and programs that contribute to our country and serve our citizens. Over the past few years, we have instituted policies and procedures to make us even more accountable and transparent to the taxpayers who fund us. In this respect, CPB acts as a guardian of the mission and purposes for which public broadcasting was established.

For the past 3 years, CPB has strategically focused our investments on the “Three D’s”—Digital, Diversity, and Dialogue. This refers to our support for innovation on digital platforms, extending public media’s reach and service over multiple platforms; content that is for, by and about diverse people; and services that foster dialogue and a deeper engagement between the American people and the public service media organizations that serve them.

One example of a CPB investment that embodies each of the Three D’s is our education investment. In the words of our statute, “[I]t is in the public interest to encourage . . . the use of [public] media for instructional, educational, and cultural purposes.” For more than 40 years, public broadcasting stations have made a robust and vital contribution to education, with proven results in improving reading and math skills for the Nation’s youngest children, particularly those furthest behind. We have built on our success in early education and launched a new national initiative to help communities tackle the high school dropout crisis called, “American Graduate: Let’s Make It Happen.”

Every year, approximately 1 million kids drop out of high school, a tragedy for these kids and a travesty for our country. The dropout epidemic is costing our Nation more than \$100 billion annually in lost wages and taxes, plus increased social costs due to crime and healthcare. American Graduate is a significant public media effort to help improve our Nation’s high school graduation rates and, through this initiative, public media, both nationally and locally, is bringing our collective resources to bear to address the dropout epidemic.

Sixty-eight public media stations in key dropout epicenters across 30 States, Puerto Rico, and the District of Columbia are working directly with students, parents, teachers, mentors, volunteers and business leaders to lower the dropout rate in their communities by communicating the need and highlighting solutions. Stations are using broadcast, web and mobile platforms to create content that helps to tell this story in a compelling way. Some of the activities include: producing public service announcements to improve understanding about dropout statistics and their implications, hosting teacher town hall meetings and community forums on strategies to decrease dropout rates in their communities, and local news and public affairs reporting to deepen the understanding of the scope of the problem and the unique community challenges and solutions.

This is a united effort across the country and across public media. In addition to local action by stations in their communities, there has been significant work done by national producers to increase understanding of the crisis, including work by “PBS NewsHour”, “Tavis Smiley”, “StoryCorps”, NPR, “Roadtrip Nation”, “Ideas in Action” with Jim Glassman, and others.

Through strategic investments, CPB has also fueled innovation in the system. In New York and Florida, stations are coming together to consolidate engineering and master control operations, which allows them to save money, operate more efficiently, and spend more time and resources on content and services for their communities. Stations throughout the country are looking to replicate this model, which could save stations millions over several years.

CPB has invested in seven regional local journalism centers, which are clusters of public television and radio stations who have come together to increase the quality and capacity of their local reporting on critically important topics to their communities and regions. Whether it is border issues in the Southwest, agribusiness issues in the Heartland, economic revitalization in upstate New York or education issues in the South, these station collaborations are creating and sharing original content that is vital to the communities they serve.

The focus on diversity is deeply embedded in CPB’s culture and increased service to diverse audiences is a consideration in virtually every investment CPB makes. In 2009, we created the Diversity and Innovation fund, which is dedicated to supporting the creation of content of interest and service to diverse communities. The D&I fund supports documentaries such as the award-winning “Freedom Riders” and “Slavery By Another Name”, expanded news and public affairs programming for diverse communities, translation services for news and election programming, a new radio service in Los Angeles and the full-time multicast World Channel, designed to attract a diverse audience.

CORPORATION FOR PUBLIC BROADCASTING’S REQUEST FOR APPROPRIATIONS

Public media stations continue to evolve, both operationally and in the ways they serve their communities. Stations are committed to reaching viewers and listeners on whatever platform they use—from smart phones to tablets to radios to television sets. While stations can and will continue to adapt and operate in the digital age, they cannot provide service on evolving platforms without sufficient support. As the

Federal Communications Commission's National Broadband Plan noted, "Today, public media is at a crossroads . . . [it] must continue expanding beyond its original broadcast-based mission to form the core of a broader new public media network that better serves the new multi-platform information needs of America. To achieve these important expansions, public media will require additional funding."

Corporation for Public Broadcasting Base Appropriation (Fiscal Year 2015).—CPB requests a \$445 million advance appropriation for fiscal year 2015, to be spent in accordance with the Public Broadcasting Act's funding formula. The 2-year advance appropriation for public broadcasting, in place since 1976, is the most important part of the "firewall" that the Congress constructed between Federal funding and the programs that appear on public television and radio. President Gerald Ford, who initially proposed a 5-year advance appropriation for CPB, said it best when he said that advance funding "is a constructive approach to the sensitive relationship between Federal funding and freedom of expression. It would eliminate the scrutiny of programming that could be associated with the normal budgetary and appropriations processes of the Government."

Our fiscal year 2015 request, which is the same level as the administration's request for CPB, balances the fiscal reality facing our Nation with the stark fact that stations are struggling to provide service to their communities in the face of shrinking non-Federal revenues—a \$380 million, or 16 percent, drop between fiscal year 2008 and 2010 alone. Even with these challenges, public broadcasting contributes to American society in many ways that are worthy of greater Federal investment. In fiscal year 2015, CPB will continue to support a range of programming and initiatives through which stations provide a valuable and trusted service to millions of Americans.

Ready To Learn (Fiscal Year 2013).—CPB requests that the U.S. Department of Education's Ready To Learn (RTL) program be funded at \$27.3 million, the same level as fiscal year 2012. Mr. Chairman, education is at the heart of public media. RTL is a partnership between the Department, CPB, PBS and local public television stations that leverages the power of digital television technology, the Internet, gaming platforms and other media to help millions of young children learn the reading and math skills they need to succeed in school. The partnership's work over the past few years has demonstrably increased reading scores particularly among low-income children and has erased the performance gap between children from low-income households and their more affluent peers. An appropriation of \$27.3 million in fiscal year 2013 will enable RTL to develop tools to improve children's performance in math as well as reading and bring on-the-ground, station-convened early learning activities to more communities.

Mr. Chairman, all told, the Federal contribution to public media through CPB amounts to \$1.39 per American per year and the returns for taxpayers are exponential. Whether in-depth news and public affairs programming on the local, State, national and international level; unmatched, commercial-free children's programming; formal and informal educational instruction for all ages; or inspiring arts and cultural content; we in America's public media system are working every day to serve our citizens.

In last year's final appropriations legislation, CPB was instructed to report to the Congress about alternative sources of funding for public media. We are actively looking at that question and will report back to the subcommittee prior to our deadline on June 20.

Mr. Chairman and members of the subcommittee, thank you again for allowing CPB to submit this testimony. On behalf of the public broadcasting community, including the stations in your States and those they serve, we sincerely appreciate your support.

NONDEPARTMENTAL WITNESSES

PREPARED STATEMENT OF THE ALZHEIMER'S ASSOCIATION

The Alzheimer's Association appreciates the opportunity to comment on the fiscal year 2013 appropriations for Alzheimer's disease research, education, outreach, and support at the Department of Health and Human Services.

Founded in 1980, the Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease and other dementias through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. As the largest, private non-profit funder of Alzheimer's research, the Association is committed to accelerating progress of new treatments, preventions and ultimately, a cure. Through our partnerships and funded projects, we have been part of every major research advancement over the past 30 years. Today, the Association works on a global level to enhance care and support for all those affected by Alzheimer's and reaches millions of people affected by Alzheimer's, and their caregivers, through our national office and more than 70 local chapters and service areas.

Alzheimer's Impact on the American People and Economy

In addition to the human suffering caused by the disease, Alzheimer's is creating an enormous strain on the healthcare system, families and the Federal budget. Alzheimer's is a progressive brain disorder that damages and eventually destroys brain cells, leading to loss of memory, thinking and other brain functions. Ultimately, Alzheimer's is fatal. Currently, Alzheimer's is the sixth leading cause of death in the United States and the only 1 of the top 10 without a means to prevent, cure, or slow its progression. Today, there are 5.4 million Americans living with Alzheimer's—5.2 million aged 65 and over, and 200,000 under the age of 65.¹ Of Americans aged 65 and over, 1 in 8 has Alzheimer's, and nearly one-half of people aged 85 and older have the disease. While deaths from other major diseases, including heart disease, stroke and HIV continue to experience significant declines, those from Alzheimer's have increased 66 percent between 2000 and 2008.

Although Alzheimer's is not normal aging, age is the biggest risk factor, which means the graying of America equates to the bankrupting of America. With the first of the baby boomer generation now turning 65, the U.S. population aged 65 and over is expected to double, meaning there will be more and more Americans living with Alzheimer's—as many as 16 million by 2050, when there will be nearly 1 million new cases each year. Caring for people with Alzheimer's will cost all payers—Medicare, Medicaid, individuals, private insurance, and HMOs—\$20 trillion over the next 40 years. In 2012, America will spend an estimated \$200 billion in direct costs caring for those with Alzheimer's, including \$140 billion in costs to Medicare and Medicaid. Average per person Medicare costs for those with Alzheimer's and other dementias are 3 times higher than those without these conditions. Medicaid spending is 19 times higher. Moreover, Alzheimer's makes treating other diseases more expensive, as most individuals with Alzheimer's have one or more co-morbidity that complicate the management of the condition(s) and increase costs. For example, a senior with diabetes and Alzheimer's costs Medicare 81 percent more than a senior who only has diabetes. Nearly 30 percent of people with Alzheimer's or another dementia who have Medicare also have Medicaid coverage, compared with 11 percent of individuals without dementia or Alzheimer's. Alzheimer's disease is also extremely prevalent among dual-eligibles in nursing homes, where 64 percent of residents live with the disease. Unless something is done, the costs of Alzheimer's in

¹ Alzheimer's Association, 2012 Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia, Volume 8, Issue 2.

2050 are estimated to total \$1.1 trillion (in today's dollars).² Costs to Medicare and Medicaid will increase nearly 500 percent and there will be a 400 percent increase in out-of-pocket costs.

With Alzheimer's, it is not just those with the disease who suffer—it is also their caregivers and families. In 2011, 15.2 million family members and friends provided unpaid care valued at more than \$210 billion. Caring for a person with Alzheimer's takes longer, lasts longer, is more personal and intrusive, and takes a heavy toll on the health of the caregivers themselves. More than 60 percent of Alzheimer's and dementia caregivers rate the emotional stress of caregiving as high or very high; with one-third reporting symptoms of depression. Caregiving may also have a negative impact on health, employment, income, and family finances. Due to the physical and emotional toll of caregiving on their own health, Alzheimer's and dementia caregivers had \$8.7 billion in additional healthcare costs in 2011.

Changing the Trajectory of Alzheimer's

Until recently, there was no strategy on how to address this looming crisis. In 2010, thanks to bipartisan support in the Congress, the National Alzheimer's Project Act (NAPA) (Public Law 111–375) passed unanimously, requiring the creation of an annually updated strategic National Alzheimer's Plan (Plan) to help those with the disease and their families today and to change the trajectory of the disease for the future. The Plan is required to include an evaluation of all federally funded efforts in Alzheimer's research, care, and services—along with their outcomes. In addition, the Plan must outline priority actions to reduce the financial impact of Alzheimer's on Federal programs and on families; improve health outcomes for all Americans living with Alzheimer's; and improve the prevention, diagnosis, treatment, care, institutional-, home-, and community-based Alzheimer's programs for individuals with Alzheimer's and their caregivers. NAPA will allow the Congress to assess whether the Nation is meeting the challenges of this disease for families, communities and the economy. Through its annual review process, NAPA will, for the first time, enable the Congress and the American people to answer this simple question: Did we make satisfactory progress this past year in the fight against Alzheimer's?

As mandated by NAPA, the Secretary of Health and Human Services, in collaboration with the Advisory Council on Alzheimer's Research, Care, and Services, is developing the first-ever Plan to be transmitted to the Congress later this Spring. The Advisory Council, made of both Federal members and expert non-Federal members, is an integral part of the planning process as it advises the Secretary in developing and evaluating the annual Plan, makes recommendations to the Secretary and the Congress, and assists in coordinating the work of Federal agencies involved in Alzheimer's research, care, and services. In advance of the first Plan, the President's fiscal year 2013 budget request included \$80 million for Alzheimer's research and \$20 million for education, outreach, and support. These funds are a critically needed downpayment for needed research and services for Alzheimer's patients and their families.

A disease-modifying or preventative therapy would not only save millions of lives but would save billions of dollars in healthcare costs. Specifically, if a treatment became available in 2015 that delayed onset of Alzheimer's for 5 years (a treatment similar to anti-cholesterol drugs), savings would be seen almost immediately, with Medicare and Medicaid spending reduced by \$42 billion in 2020. Today, despite the remarkable advances in Alzheimer's research, there are growing concerns that we still lack effective treatments that will slow, stop, or cure the disease and that the pace of progress in understanding the disease and developing breakthrough discoveries is much too slow to make any impact on the growing crisis before us. Currently, for every \$28,000 Medicare and Medicaid spends caring for individuals with Alzheimer's, the National Institutes of Health (NIH) spends only \$100 on Alzheimer's research. Scientists fundamentally believe that we have the ideas, the technology and the will to develop new Alzheimer's interventions, but that progress depends on a prioritized scientific agenda and on the resources necessary to carry out the scientific strategy for both discovery and translation for therapeutic development. The Alzheimer's Association urges the Congress to support the President's budget request of \$80 million for Alzheimer's research at the National Institutes of Health in fiscal year 2013, and the priority research recommendations included in the National Alzheimer's Plan required under Public Law 111–375.

For too many individuals with Alzheimer's and their families, the system has failed them, and today we are unnecessarily losing the battle against this dev-

² Alzheimer's Association, *Changing the Trajectory of Alzheimer's Disease: A National Imperative*, 2010.

astating disease. Despite the fact that an early and documented formal diagnosis allows individuals to participate in their own care planning, manage other chronic conditions, participate in clinical trials, and ultimately alleviate the burden on themselves and their loved ones, as many as one-half of the 5.4 million Americans with Alzheimer's have never received a formal diagnosis. Unless we invest in an effective dementia-capable system that finds new solutions to providing high-quality care, provides community support services and programs, and addresses Alzheimer's health disparities, Alzheimer's will break the healthcare system. For example, people with Alzheimer's and other dementias have more than 3 times as many hospital stays as other older people. Furthermore, 1 out of 7 individuals with Alzheimer's or another dementia lives alone and up to one-half do not have an identifiable caregiver. These individuals are more likely to need emergency medical services because of self-neglect or injury, and are found to be placed into nursing homes earlier, on average, than others with dementia. It has been estimated that delaying long-term care by 1 month for each person in the United States age 65 or older could save \$60 billion a year. Ultimately, supporting individuals with Alzheimer's disease and their families and caregivers requires giving them the tools they need to plan for the future and ensuring the best quality of life for individuals and families impacted by the disease. The Alzheimer's Association urges the Congress to support the President's budget request of \$20 million for Alzheimer's education, outreach, and support at the Administration on Aging (AoA) in fiscal year 2013, and the priorities included in the National Alzheimer's Plan required under Public Law 111-375.

Additional Alzheimer's Programs:

National Alzheimer's Call Center.—The National Alzheimer's Call Center, funded by the AoA, provides 24/7, year-round telephone support, crisis counseling, care consultation, and information and referral services in 140 languages for persons with Alzheimer's, their family members and informal caregivers. Trained professional staff and master's-level mental health professionals are available at all times. In the 12 month period ending July 31, 2011, the Call Center handled more than 300,000 calls through its national and local partners, and its online message board received more than 13 million page views and more than 100,000 individual postings. The Alzheimer's Association urges the Congress to support \$1.3 million for the National Alzheimer's Call Center.

Healthy Brain Initiative.—The Centers for Disease Control and Prevention's (CDC) Healthy Brain Initiative (HBI) program works to educate the public, the public health community and health professionals about Alzheimer's as a public health issue. Although there are currently no treatments to delay or stop the deterioration of brain cells caused by Alzheimer's, evidence suggests that preventing or controlling cardiovascular risk factors may benefit brain health. In light of the dramatic aging of the population, scientific advancements in risk behaviors, and the growing awareness of the significant health, social and economic burdens associated with cognitive decline, the Federal commitment to a public health response to this challenge is imperative. The Alzheimer's Association urges the Congress to support \$2.2 million for the Healthy Brain Initiative.

Alzheimer's Disease Supportive Services Program.—The Alzheimer's Disease Supportive Services Program (ADSSP) at the AoA supports family caregivers who provide countless hours of unpaid care, thereby enabling their family members with Alzheimer's and dementia to continue living in the community. The program develops coordinated, responsive, and innovative community-based support service systems for individuals and families affected by Alzheimer's. The Alzheimer's Association urges the Congress to support \$11.441 million for the Alzheimer's Disease Supportive Services Program.

Conclusion

The Association appreciates the steadfast support of the subcommittee and its priority setting activities. We look forward to continuing to work with the Congress in order to address the Alzheimer's crisis. We ask the Congress to address Alzheimer's with the same bipartisan collaboration demonstrated in the passage of the National Alzheimer's Project Act (Public Law 111-375) and with a commitment equal to the scale of the crisis.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN CANCER INSTITUTES

The Association of American Cancer Institutes (AACI), representing 95 of the Nation's premier academic and free-standing cancer centers, appreciates the opportunity to submit this statement for consideration by the United States Senate Sub-

committee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations.

AACI appreciates the long-standing commitment of the President, the Congress, and the subcommittee to ensuring quality care for cancer patients, as well as for providing researchers with the resources that they need to develop better cancer treatments and, ultimately, to cure this disease.

President Obama's fiscal year 2013 budget calls for maintaining the fiscal year 2012 funding levels for the National Institutes of Health (NIH) and the National Cancer Institute (NCI) (\$30.9 billion and \$5 billion, respectively). AACI joins with our colleagues in the biomedical research community in recommending that the subcommittee recognize NIH as a critical national priority by providing at least \$32 billion in funding in the fiscal year 2013 Labor-HHS-Education appropriations bill, including an equivalent percentage increase in funding for NCI. This funding level represents the minimum investment necessary to avoid further loss of promising research.

AACI cancer centers are at the front line in the national effort to eradicate cancer. The cancer centers that AACI represents house more than 20,000 scientific, clinical, and public health investigators who work collaboratively to translate promising research findings into new approaches to prevent and treat cancer. But making progress against cancer is complex. It is more a marathon than a sprint, and it takes time for the scientific discovery process to yield fruit. However, the pace of discovery and translation of novel basic research to new therapies could be faster if researchers could count on a significant and predictable investment in Federal cancer funding.

AACI and its members are keenly aware of the country's fiscal obstacles. The vast majority of our cancer centers exist within universities that already face drastic budget reductions. Furthermore, because of the reduced funding pool for meritorious grant applications, many of our senior and most promising young investigators are now without NCI funding and require significant bridge funding from private sources. In recent years, however, it has become more challenging to raise philanthropic and other external funds. As a result, we continue to be highly dependent on Federal cancer center grants.

The Obama administration has estimated that if the NIH budget stays flat in fiscal year 2013, as it has proposed, the agency would be able to fund 9,415 new grants. However, even with flat funding relatively few people who apply for grants from NIH can expect to receive them. Over the past 9 years NIH has lost about 20 percent of its purchasing power for medical research due to inflation, and only about 1 in 7 grant applications are approved for funding, the lowest rate in NIH history. NIH's ability to sustain current research capacity and encourage promising new areas of science has been significantly compromised by stagnant funding.

This situation will be even more acute if an 8-percent budget cut being considered as part of the Budget Control Act of 2011, takes effect in January. The cut is even deeper than it appears because the agency's fiscal year starts October 1, 3 months into the fiscal year. As a result, NIH would be able to fund 2,300 fewer grants in fiscal year 2013, according to NIH Director Francis Collins.

Impact Beyond the Lab

The negative effects of diminished biomedical research funding reach beyond the lab and into local communities, as chronicled this past winter by a number of AACI cancer center directors who were featured in newspaper editorials that highlighted the impact of NIH and NCI funding on people and local economies in their individual States.

For example, the leaders of the UC San Diego Moores Cancer Center and the San Diego-based Sanford Burnham Medical Research Institute noted that NIH funding brought \$1.3 billion to their local economy in 2010. In San Antonio, the director of the Cancer Therapy & Research Center at the University of Texas Health Science Center noted that his institution received more than \$30 million in cancer-related grants and clinical trials.

AACI Past President Michael A. Caligiuri, MD, director of the Ohio State University Comprehensive Cancer Center and chief executive officer of the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, put it succinctly in an editorial in his hometown paper, *The Columbus Dispatch*: "The work we do at Ohio State affects the entire continuum of cancer care. And cancer research done at Ohio State and other organizations supports high-quality jobs in Ohio communities and allows our residents to benefit from the advances happening right here."

An AACI-commissioned economic analysis of proposals for NIH's fiscal year 2011 budget estimated that a "conservative" 0.8-percent cut in the NIH's annual budget would result in about 4,000 jobs lost nationally. Looking specifically at NCI's budg-

et, the Nation's research institutions, which house AACI's member cancer centers, received an estimated \$3.71 billion from NCI to conduct cancer research in fiscal year 2010; more than two-thirds of NCI's total budget. At the time that AACI's analysis was published, an "aggressive" budget reduction of 5.3 percent was under consideration and would have led to more than 4,200 jobs lost nationwide and an economic loss of more than \$564 million.

Other recent studies have also concluded that Federal support for medical research is a major determinant in the economic health of communities across the country. In one such report, United for Medical Research, a coalition of leading research institutions, patient and health advocates and private industry, estimated that NIH funding generated the greatest number of jobs in California (63,196), Massachusetts (34,598), New York (33,193), Texas (25,878), and Maryland (24,557) and also supported more than 10,000 jobs each in Pennsylvania, North Carolina, Washington, Illinois, Ohio, Florida, Michigan, and Georgia. Fifty-three AACI cancer centers are located in those 13 States.

Cancer centers are already challenged to provide infrastructure resources necessary to support funded researchers, and cuts in Federal cancer center grants will limit our members' ability to provide well-functioning shared resources to investigators who depend on them to complete their research. For most academic cancer centers, the majority of NCI grant funds are used to sustain shared resources that are essential to basic, translational, clinical and population cancer research, or to provide matching dollars which allow departments to recruit new cancer researchers to a university and support them until they receive their first grants.

Independent investigator research is a particularly valuable resource, especially in genomics and molecular epidemiology. Such research depends on state-of-the-art shared resources like tissue processing and banking, DNA sequencing, microRNA platforms, proteomics, biostatistics and biomedical informatics. This infrastructure is expensive, and it is not clear where cancer centers would acquire alternative funding if NCI grants for these efforts were reduced.

Cancer Research: Improving America's Health

The broad portfolio of research supported by NIH and NCI is essential for improving our basic understanding of diseases, and it has paid off handsomely in terms of improving Americans' health.

Death rates from all cancers combined for men, women, and children in the United States continued to decline between 2004 and 2008, the latest year for which we have complete analysis. Age-adjusted mortality rates for 11 of the 18 most common cancers among men and for 14 of the 16 most common cancers in women have declined. The overall rate of new cancer diagnoses among both men and women also declined over similar periods, although for women the decline leveled off from 2006–2008 (National Cancer Institute, 2012 Annual Report to the Nation on the Status of Cancer). A broader data set shows that cancer death rates have dropped 11.4 percent among women and 19.2 percent among men over the past 15 years, due in large part to better detection and more effective treatments.

Despite that success, cancer remains the second leading cause of death in the United States, exceeded only by heart disease. In 2007, more than 562,000 people died of cancer, and more than 1.45 million people had a diagnosis of cancer (Centers for Disease Control and Prevention, United States Cancer Statistics: 1999–2007 Cancer Incidence and Mortality Data).

The network of cancer centers represented by AACI continues the fight against cancer by conducting the highest-quality cancer research in the world and provides exceptional patient care. In 2010, \$3.9 billion from NCI was awarded extramurally to research institutions, including the AACI's member cancer centers. This represents 77 percent of NCI's total budget (U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute 2010 Fact Book). Because these centers are networked nationally, opportunities for collaborations are many—assuring wise and nonduplicative investment of scarce Federal dollars.

Conclusion

The National Institutes of Health estimates overall costs of cancer in 2010 at \$263.8 billion: \$102.8 billion for direct medical costs (total of all health expenditures); \$20.9 billion for indirect morbidity costs (cost of lost productivity due to illness); and \$140.1 billion for indirect mortality costs (cost of lost productivity due to premature death) (American Cancer Society, 2010 Facts & Figures).

In the face of that economic burden, the Nation's financial support of NIH and NCI has paid dividends by wiping out diseases that killed our grandparents. Those investments have led us to the brink of new discoveries in deadly and debilitating illnesses, cancer perhaps foremost among them. The AACI cancer center network is

unsurpassed in its pursuit of excellence, and places the highest priority on delivering superior cancer care to all Americans, including novel treatments and clinical trials. It is through the power of collaborative innovation that we will continue to move toward a future without cancer, and Federal research funding is essential to achieving our goals.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

As the national voice for baccalaureate and graduate nursing education, the American Association of Colleges of Nursing (AACN) represents 700 schools of nursing that educate more than 360,000 students and employ more than 16,000 full-time faculty members. Collectively, these institutions produce approximately one-half of our Nation's Registered Nurses (RNs) and all nurse faculty and researchers. AACN requests that nursing education, research, and practice are strongly supported in fiscal year 2013 through a continued investment in the Nursing Workforce Development programs (authorized under Title VIII of the Public Health Service Act [42 U.S.C. 296 et seq.]), the National Institute of Nursing Research (NINR), and the Nurse-Managed Health Clinics (NMHCs) (Title III of the Public Health Service Act), so that our Nation's nurses will be prepared to care for the growing number of patients requiring a complex range of healthcare services.

JOB GROWTH IN THE NURSING WORKFORCE

The demand for nurses is greater than previously anticipated. In February of this year, the Bureau of Labor Statistics (BLS) released their publication *Employment Projections for 2010–2020*, which projects significant growth in the nursing workforce from 2.74 million in 2010 to 3.45 million in 2020. This upsurge in demand translates to 712,000 nurses, or an increase of 26 percent. The BLS further projects the need for 495,500 additional nurses to replace those soon to retire, bringing the total number of job openings for nurses due to growth and replacements to 1.2 million by 2020.

The aging of the nursing workforce and America's patients underscores this alarming projection. According to the 2008 National Sample Survey of Registered Nurses, of the 2.6 million RNs currently practicing in America, more than 1 million are age 50 or older, and of these more than 275,000 nurses are over the age of 60. As this large segment of the workforce begins to retire, the Nation will soon face a significant deficit in the number of experienced nurses available to provide services. Concurrent with the aging of the nursing workforce is the aging of America's baby boomer population. It is estimated that more than 80 million baby boomers reached age 65 in 2011. As this population transitions into the Nation's oldest generation, these citizens will continue to require more primary care services related to chronic illness treatment, medication management, and patient education. A significant investment must be made in the education of new nurses to provide the Nation with the nursing services it requires.

TITLE VIII NURSING WORKFORCE DEVELOPMENT PROGRAMS

For nearly five decades, the Nursing Workforce Development programs, authorized under title VIII of the Public Health Service Act, have helped build the supply and distribution of qualified nurses to meet our Nation's healthcare needs. Between fiscal year 2005 and 2010 alone, the title VIII programs supported more than 400,000 nurses and nursing students as well as numerous academic nursing institutions and healthcare facilities. The title VIII programs bolster nursing education at all levels, from entry-level preparation through graduate study, and provide support for institutions that educate nurses for practice in rural and medically underserved communities. Today, the title VIII programs are essential to ensure the demand for nursing care is met by supporting future practicing nurses and the faculty who educate them.

Given the projected demand for RNs, nursing schools are looking to admit more students into their programs. However, faculty vacancies have repeatedly been cited as a fundamental obstacle to maximizing nursing school enrollment. Data from AACN's 2011–2012 enrollment and graduations survey show that nursing schools were forced to turn away 75,587 qualified applications from entry-level baccalaureate and graduate nursing programs in 2011 due primarily to faculty vacancies. To counter this disparity, the title VIII Nurse Faculty Loan Program aids in increasing nursing school enrollment capacity by supporting students pursuing graduate education, provided they serve as faculty for 4 years after graduation. In fiscal year 2010, the title VIII Nurse Faculty Loan Program supported 271 faculty members

who graduated and went on to teach in our Nation's nursing schools. Yet this only fills a small portion of the nearly 1,800 vacant faculty positions reported by AACN member schools in academic year 2011–2012.

The title VIII programs also increase the number of practicing nurses entering the pipeline and the placement of these nurses into medically underserved areas. AACN's title VIII Student Recipient Survey, which gathers information annually about title VIII funding and outcomes related to nursing education and career trajectories, provides evidence to the effectiveness of these programs in recruiting more students to the nursing profession and more importantly, practice in rural and underserved areas. The 2011–2012 survey, which included responses from more than 1,600 students, revealed that 52 percent of respondents reported that title VIII funding affected their decision to enter nursing school, and that practicing in a rural or underserved community was in the top five career plans after graduation. In fiscal year 2011, the title VIII Nursing Education Loan Repayment Program committed to supporting 1,304 nurses working in these facilities. In addition, the Advanced Education Nursing Traineeship Program graduated 7,744 nursing students during the 2010–2011 academic cycle, of which 7,548 (97 percent) went on to practice in medically underserved areas. Moreover, personal testimony of several survey respondents revealed that many title VIII recipients intend to practice in the community in which they were educated, a direct State investment.

Additionally, 68 percent of respondents stated that title VIII funding allowed them to attend school full-time, as these loan and scholarship programs alleviated the financial burden that obligates many students to complete their education on a part-time basis. The title VIII programs decrease the length of time needed to obtain their education, thus helping to ensure that students enter the workforce without delay. These efforts directly align with recommendations in the Institute of Medicine's landmark report "Future of Nursing: Leading Change, Advancing Health" which state, "Nurses should achieve higher levels of education and training through an improved education system that promotes seamless academic progression." Financial support from title VIII programs ensure that more nurses are efficiently integrated into the workforce.

AACN respectfully requests \$251 million for the Nursing Workforce Development programs authorized under title VIII of the Public Health Service Act in fiscal year 2013.

NATIONAL INSTITUTE OF NURSING RESEARCH: ADVANCING NURSING SCIENCE

The healthcare community is increasingly concerned with investigating methods to improve the delivery of high-quality care in a financially sustainable manner. As one of the 27 Institutes and Centers at the National Institutes of Health (NIH), the NINR is dedicated to promoting this endeavor through research initiatives aimed at reducing disease prevalence and improving health outcomes. While other health-related research is aimed at curing disease, nurse-researchers at NINR focus on the prevention of illnesses that threaten to exacerbate an already overburdened healthcare system. More specifically, NINR funded research investigates methodologies that improve chronic illness management, communicable disease prevention, pain management, and caregiver support.

Studies conducted at NINR address health and wellness across the entire lifespan. Reducing rates of infant prematurity, controlling rates of high-blood pressure among adults, and evaluating transitional care models to improve outcomes of the elderly represent the vast array of population-specific NINR research initiatives. Additionally, NINR seeks to improve understanding of the processes underlying palliative care efforts to develop patient-centered care delivery models.

NINR allocates a generous 6 percent of its overall budget to the education and training of nurse researchers, many of whom dually serve as nurse faculty within our Nation's nursing schools. As researchers, these nurses work to strengthen the foundation of evidence-based nursing practice. As educators, they help to fulfill the need for nurse faculty and teach current, evidence-based practice that is consistent with changing healthcare needs.

For NINR to adequately continue and further its mission, the institute must continue to receive adequate funding. Cuts in funding have impeded the institute from supporting larger comprehensive studies needed to advance nursing science and improve the quality of patient care.

AACN respectfully requests \$150 million for the NINR in fiscal year 2013. This level of funding is on par with the Ad Hoc Group for Medical Research's \$32 billion request for the total NIH budget in fiscal year 2013.

NURSE-MANAGED HEALTH CLINICS: EXPANDING ACCESS TO CARE

Managed by Advanced Practice Registered Nurses and staffed by an interdisciplinary team, NMHCs provide necessary primary care services to medically underserved communities. Often times, nurse-managed health clinics and nurse practitioners are the sole providers for primary care for these areas. NMHCs serve as critical access points to keep patients out of the emergency room, thus saving the healthcare system millions of dollars annually.

NMHCs provide care to vulnerable populations in a host of regions of the country, including rural communities, Native American reservations, senior citizen centers, elementary schools, and urban housing developments. These communities are the most susceptible to developing chronic illnesses that create heavy financial burden on patients and the healthcare system. NMHCs aim to reduce disease and create healthier communities through improved patient education and health practices. NMHCs provide primary care, health promotion, and disease prevention to individuals with limited access to care, regardless of their ability to pay. These vulnerable individuals who are often plagued with highest rates of detrimental chronic disease rely on the services provided at these clinics, which help to target early screening and risk reduction. These services include physical exams, cardiovascular checks, diabetes and osteoporosis screenings, smoking cessation programs, immunizations, and other additional services.

Often associated with a school, college, university, department of nursing, federally qualified health center, or independent nonprofit healthcare agency, NMHCs also serve as clinical education training sites for students of nursing, medicine, physical therapy, social work, and ancillary healthcare services. According to AACN, the lack of clinical training sites is often cited as a top reason for turning away qualified applications in nursing programs.

AACN respectfully requests \$20 million for the Nurse-Managed Health Clinics in fiscal year 2013.

CONCLUSION

AACN recognizes that the subcommittee and the Congress face difficult decisions regarding appropriations for fiscal year 2013. AACN respectfully requests the Congress to continue a robust investment in the health of our Nation by providing \$251 million for the title VIII Nursing Workforce Development programs, \$150 million for the National Institute of Nursing Research, and \$20 million for Nurse-Managed Health Clinics in fiscal year 2013. These programs directly advance the nursing profession in the areas of education, research, and practice, to meet our Nation's calling for a more highly skilled nursing workforce. A strong investment in our Nation's nurses is a strong investment in the future of America's health.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF
OSTEOPATHIC MEDICINE

On behalf of the American Association of Colleges of Osteopathic Medicine (AACOM), I am pleased to submit this testimony in support of increased funding in fiscal year 2013 for programs at the Health Resources Services Administration (HRSA), the National Institutes of Health (NIH), and the Agency for Healthcare Research and Quality (AHRQ). AACOM represents the administrations, faculty, and students of the Nation's 26 colleges of osteopathic medicine at 34 locations in 25 States. Today, more than 20,000 students are enrolled in osteopathic medical schools. Nearly 1 in 5 U.S. medical students is training to be an osteopathic physician.

Title VII

The health professions education programs, authorized under title VII of the Public Health Service Act and administered through HRSA, support the training and education of health practitioners to enhance the supply, diversity, and distribution of the healthcare workforce, acting as an essential part of the healthcare safety net and filling the gaps in the supply of health professionals not met by traditional market forces. Title VII and title VIII nurse education programs are the only Federal programs designed to train clinicians in interdisciplinary settings to meet the needs of special and underserved populations, as well as increase minority representation in the healthcare workforce.

According to HRSA, an additional 33,000 health practitioners are needed to alleviate existing health professional shortages. Combined with faculty shortages across health professions disciplines, racial and ethnic disparities in healthcare, a growing,

aging population and the anticipated demand for access to care, these needs strain an already fragile healthcare system.

While AACOM appreciates the investments that have been made in these programs, we recommend increasing funding to \$247.5 million for Title VII. We strongly support investment in the following programs in order to address the primary care workforce shortage: Primary Care Training and Enhancement (PCTE) Program at \$58 million, the Health Careers Opportunity Program (HCOP) at \$14.9 million, the Centers of Excellence (COE) at \$22.9 million, the Geriatric Education Centers (GECs) at \$30.6 million and the Area Health Education Centers (AHECs) at \$33.142 million. Strengthening the workforce has been recognized as a national priority, and the investment in these programs recommended by AACOM will help meet the demand for a well-trained, diverse workforce facing this country.

Teaching Health Centers Graduate Medical Education Program

The Teaching Health Center Graduate Medical Education (THCGME) Program is the first of its kind to shift GME training to community-based care settings that emphasize primary care and prevention. It is uniquely positioned to provide much needed primary care training in underserved populations. However, because the program is the first of its kind, most community-based settings do not have existing infrastructure to provide this training. AACOM strongly supports the President's budget request of \$10 million to fund the THCGME Development Grants. This funding would allow potential THCGME training sites to develop the infrastructure needed to administer residency training programs.

National Health Service Corps

Approximately 50 million Americans live in communities with a shortage of health professionals, lacking adequate access to primary care. Through scholarships and loan repayment, the National Health Service Corps (NHSC) supports the recruitment and retention of primary care clinicians to practice in underserved communities. At the close of fiscal year 2010, the NHSC provided a network of 7,500 primary healthcare professionals in 10,000 sites in underserved communities. However, this still fell approximately 20,000 practitioners short of fulfilling the need for primary care, dental and mental health practitioners in Health Professions Shortage Areas (HPSAs). Growth in HRSA's Community Health Center Program must be complemented with increases in the recruitment and retention of primary care clinicians to ensure adequate staffing, which the NHSC provides. AACOM strongly supports fully funding all aspects of the NHSC from both discretionary and mandatory funding sources and recommends that the full \$300 million in mandatory funding be allocated and should be supplemented by discretionary dollars in fiscal year 2013.

Workforce Commission

As the United States struggles to address with healthcare provider shortages in certain specialties and in rural and underserved areas, the country lacks a defined policy to address these critical issues. The National Health Care Workforce Commission was designed to develop and evaluate training activities to meet demand for healthcare workers. Without funding, the Commission cannot identify barriers that may create and exacerbate workforce shortages and improve coordination on the Federal, State and local levels. Having this type of coordinating body in place is becoming more critical as more Americans have insurance coverage and the population ages, requiring access to care. For these reasons, AACOM recommends that \$3 million be appropriated to fund the Commission.

National Institutes of Health

Research funded by the NIH leads to important medical discoveries regarding the causes, treatments, and cures for common and rare diseases as well as disease prevention. These efforts improve our Nation's health and save lives. To maintain a robust research agenda, further investment will be needed. AACOM recommends \$32 billion in fiscal year 2013 for the NIH.

In today's increasingly demanding and evolving medical curriculum, there is a critical need for more research geared toward evidence-based osteopathic medicine. AACOM believes that it is vitally important to maintain and increase funding for biomedical and clinical research in a variety of areas related to osteopathic principles and practice, including osteopathic manipulative medicine and comparative effectiveness. In this regard, AACOM encourages support for the NIH's National Center for Complementary and Alternative Medicine to continue fulfilling this essential research role.

Agency for Healthcare Research and Quality

AHRQ supports research to improve healthcare quality, reduce costs, advance patient safety, decrease medical errors, and broaden access to essential services. AHRQ plays an important role in producing the evidence base needed to improve our Nation's health and healthcare. The incremental increases for AHRQ's Patient Centered Health Research Program in recent years, as well as the funding provided to AHRQ in the ARRA, will help AHRQ generate more of this research and expand the infrastructure needed to increase capacity to produce this evidence. More investment is needed, however, to fulfill AHRQ's mission and broader research agenda, especially research in patient safety and prevention and care management research. AACOM recommends \$400 million in fiscal year 2013 for AHRQ's base, discretionary budget. This investment will preserve AHRQ's current programs while helping to restore its critical healthcare safety, quality, and efficiency initiatives.

AACOM is grateful for the opportunity to submit its views and looks forward to continuing to work with the Subcommittee on these important matters.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY

The American Association of Colleges of Pharmacy (AACP) is pleased to submit this statement for the record regarding fiscal year 2013 funding. The 126 accredited pharmacy schools are engaged in a wide range of programs supported by funding administered through the agencies of the Department of Health and Human Services (HHS) and the Department of Education. Recognizing the difficult task of balancing needs and expectations with fiscal responsibility, AACP respectfully offers the following recommendations for consideration as you undertake your deliberations.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

AACP supports the Friends of HRSA recommendation of \$7 billion for Health Resources and Services Administration (HRSA) in fiscal year 2013. Faculty at schools of pharmacy are integral to the success of many HRSA programs conducting research rural health delivery to reduce healthcare costs through the integration of pharmacist-provided patient care services. Schools of pharmacy are supported by HRSA to operate 9 of the 42 Poison Control Centers and, this year, Dr. Scott Schaefer of the University of Oklahoma received a \$100,000 poison center incentive grant for a deaf and hard of hearing poison prevention outreach project.

AACP supports the Bureau of Health Professions and the National Center for Health Workforce Analysis. Through the Pharmacy Workforce Center, AACP joins HRSA-funded efforts to compile national health workforce statistics to better inform future health professions workforce needs in the United States.

AACP supports the Health Professions and Nursing Education Coalition (HPNEC) recommendation of \$280 million for title VII and VIII programs in fiscal year 2013. AACP member institutions are active participants in BHP programs. Schools of pharmacy engage in title VII programs, including Geriatric Education Centers and Area Health Education Centers (AHEC). These community-based, interprofessional programs are essential for providing the educational models to improve quality through team-based, patient-centered care and serve as valuable experiential education sites for student pharmacists and other health professions students. Nine North Carolina AHECs are supported by 500 preceptor pharmacists and 22 academic pharmacists from the State's schools of pharmacy. The Northeast Pennsylvania (NEPA) AHEC partners with the NEPA Interprofessional Education Coalition to train student pharmacists from Wilkes University to develop interprofessional communication skills and recognize the importance of patient-centered care.

For the AHEC program AACP recommends a funding level of at least \$75 million in fiscal year 2013. Pharmacy schools are eligible to participate in the Centers of Excellence program and the Scholarships for Disadvantaged Students program, to increase the number of underserved individuals attending health professions schools and minority workforce representation.

Agency for Healthcare Research and Quality

AACP supports the Friends of AHRQ recommendation of \$400 million for AHRQ programs in fiscal year 2013. Pharmacy faculty are strong partners with the Agency for Healthcare Research and Quality (AHRQ). Academic pharmacists Drs. Glen T. Schumock, University of Illinois at Chicago, and Sean Hennessy, University of Pennsylvania, are 2 of 11 principal investigators involved in the Developing Evidence to Inform Decisions about Effectiveness center to support research on patient-

centered outcomes of healthcare with a focus on comparing clinical effectiveness, safety and usefulness of medical treatments. Drs. Gary R. Matzke, Virginia Commonwealth University, and Leigh Ann Ross, University of Mississippi School of Pharmacy, were appointed to the AHRQ Effective Health Care Program Pharmacy Workgroup. The Minnesota Pharmacy Practice-Based Research Network has been accepted for the AHRQ Primary Care Registry, existing as a living laboratory with a focus on the collection of information using a network of pharmacies to address the medication use process related to health and wellness.

Centers for Disease Control and Prevention

AACP supports the CDC Coalition recommendation of \$7.7 billion for Centers for Disease Control and Prevention (CDC) core programs in fiscal year 2013 and the Friends of NCHS recommendation of \$162 million for the National Center for Health Statistics. Information from the NCHS is essential for faculty engaged in health services research and for the professional education of the pharmacist. The educational outcomes established through the Center for the Advancement of Pharmaceutical Education include those related to public health. The opportunity for pharmacists to identify potential public health threats through regular interaction with patients provides public health agencies with on-the-ground epidemiologists providing risk identification measures when patients seek medications associated with preventing and treating travel-related illnesses. Pharmacy faculty are engaged in CDC-supported research and activities including delivery of immunizations, integration of pharmacogenetics in the pharmacy curriculum, inclusion of pharmacists in emergency preparedness, and the Million Hearts campaign. Faculty pharmacists at the University of Mississippi received a \$300,000 grant from CDC for a project evaluating pharmacy cardiovascular risk reduction and \$49,000 to study active surveillance attitudes and perceptions in prostate cancer. Pharmacy schools actively participate in disaster relief response efforts in their community. Student pharmacists and faculty from University of Missouri Kansas City School of Pharmacy organized efforts to assist Joplin and southern Missouri just hours after the disaster and were among the first to respond to the area.

National Institutes of Health

AACP supports the Adhoc Group for Medical Research recommendation of \$32 billion for National Institutes of Health (NIH) funding in fiscal year 2013. Pharmacy faculty are supported in their research by nearly every institute at the NIH. The NIH-supported research at AACP member institutions spans the full spectrum from the creation of new knowledge through the translation of that new knowledge to providers and patients. In 2011, pharmacy faculty researchers received more than \$263 million in grant support from the NIH and retain a strong commitment to increasing the number of biomedical researchers. At Purdue University, Karen S. Hudmon received \$264,927 in funding from NIH National Cancer Institute for a pharmacy-based tobacco cessation program. University of Tennessee Health Sciences Center School of Pharmacy's Junling Wang received \$886,742 from the NIH National Institute on Aging to study medication therapy management and its effect on racial and ethnic disparities. Christopher J. Destache, Creighton University, received \$410,913 to study on once-monthly antiretroviral nanoparticles for HIV-1 treatment. James C. Cloyd, University of Michigan, received up to \$7,500,000 for neurophysiologically based response pharmacotherapy for epilepsy. And, Jennifer Marie Cochoba, University of California San Francisco, received \$165,952 from the NIH for a study on the effect of Pharmacist counseling on antiretroviral adherence, 5K23MH087218-02.

Centers for Medicare and Medicaid Services

AACP recommends a funding level of \$526.2 billion for Centers for Medicare and Medicaid Services (CMS) programs in fiscal year 2013. The impact of the ongoing efforts from CMS and the Innovation Center continue depends on the integration of pharmacist into healthcare teams. Marie A. Smith of the University of Connecticut received \$133,453 from CMS to study transitions of care from hospital to home care and the role of medication reconciliation and medication therapy management and Almut G. Winterstein, University of Florida, received \$255,000 from CMS for the development of new medication measures that address the detection and prevention of adverse medication-related patient safety events for future quality improvement and reporting programs. Miriam Mobley-Smith, Dean of the Chicago State University School of Pharmacy, was appointed to the CMS Advisory Panel on Outreach and Education (APOE) in 2011. Pharmacy faculty work to integrate pharmacists as members of the health team through studies in health information technology, electronic health records, transitions of care, and medication management.

U.S. DEPARTMENT OF EDUCATION

The Department of Education supports the education of healthcare professionals by assuring access to education through student financial aid programs, educational research allows faculty to determine improvements in educational approaches; and the oversight of higher education through the approval of accrediting agencies. AACP supports the Student Aid Alliance's recommendations to maintain the \$5,550 maximum Pell grant. Admission to the pharmacy professional degree program requires at least 2 years of undergraduate preparation. Student financial assistance programs are essential to assuring students have access to undergraduate, professional and graduate degree programs. AACP recommends a funding level of at least \$80 million for the Fund for the Improvement of Post Secondary Education (FIPSE) as this is the only Federal program that supports the development and evaluation of higher education programs that can lead to improvements in higher education quality.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH

The AACR, representing 34,000 laboratory, translational, and clinical researchers; other healthcare professionals; and cancer survivors and patient advocates, is pleased to offer the following testimony. As the world's oldest and largest scientific organization focused on every aspect of high-quality, innovative cancer research, our mission is to prevent and cure cancer through research, education, communication, and collaboration.

To improve the health of all Americans, sustain the momentum generated through past investments in biomedical research and restore lost purchasing power due to stagnant budgets, the AACR recommends a funding level increase to \$33 billion for the NIH in fiscal year 2013 and a commensurate increase for the National Cancer Institute (NCI). This level of support will enable the future scientific advances needed to seize today's scientific momentum, save countless lives, and spur innovation and economic prosperity for our country and all of our citizens.

The vigorous pursuit of new breakthroughs in cancer research and biomedical science supported through the NIH, as well as the NCI, saves lives and promises to improve the entire spectrum of patient care, from prevention, early detection, and diagnosis, to treatment and long-term survivorship. As detailed in the AACR Cancer Progress Report 2011, there has been an amazing acceleration in the rate of advances against the 200 diseases we call cancer, reaching back 40 years to the signing of the National Cancer Act. We are in a time of unprecedented scientific opportunity, driven in large part by the vast new knowledge generated through the mapping of the human genome and growing knowledge of the biology of cancer. This wealth of information is being translated into new treatments and preventive strategies for a number of cancers.

Some of the extraordinary advances made against cancer include:

- From 1990 to 2007, death rates from all cancers combined dropped by 22 percent for men and 14 percent for women, resulting in nearly 900,000 fewer deaths during that time.
- Today, more than 68 percent of adults live 5 years or more after diagnosis, up from 50 percent in 1975.
- Today, 80 percent of children live 5 years or more after diagnosis, up from 52 percent in 1975.
- There are about 12 million cancer survivors living in the United States; 15 percent of them were diagnosed 20 or more years ago.
- Breast cancer death rates fell by about 28 percent from 1990 to 2006.
- Death rates from cervical cancer have dropped by nearly 31 percent from 1990 to 2006.
- Prostate cancer death rates have fallen by 39 percent from 1990 to 2006.
- Colorectal cancer death rates have fallen by 28 percent in women, and 33 percent in men.
- Death rates from stomach cancer have fallen by 34 percent in women, and 43 percent in men.

The research community's ability to sustain this scientific momentum, however, is increasingly jeopardized—particularly given the Nation's current fiscal constraints. Funding for NIH has remained essentially flat for the past decade, and due to the rate of biomedical inflation, the agency has lost approximately \$5.5 billion in purchasing power since 2003. Even without adjusting for inflation, enacted spending bills in recent years have imposed outright cuts, and looming sequestration mandated by the Budget Control Act threatens further reductions in 2013.

Cancer Remains a Significant Public Health Challenge

Despite the significant progress we have achieved, cancer remains the leading cause of death for Americans under age 85, and the second-leading cause of death overall. In 2012, more than 1.6 million new cancer cases will be diagnosed and more than one-half million American lives will be lost to this devastating disease. And due to its enormous complexity, progress against certain cancers—such as pancreatic, brain and lung cancers—has been extremely difficult.

Furthermore, funding challenges come at a time when we are facing a “cancer tsunami” as the baby boomer generation reaches age 65 and beyond. More than three-quarters of all cancers are diagnosed in individuals aged 55 and older, and the number of new cancer cases is estimated to approach 2 million per year by 2025. This will dramatically exacerbate the current problems with our healthcare system, and will undoubtedly hit hardest those who can least afford it—the elderly, medically underserved, and minority populations. We have reached a critical inflection point in our ability to conquer cancer, and we can only continue to make significant advances if we renew our commitment to allocate the required resources to do so.

The investments that our Nation makes in cancer research and biomedical science, particularly those supported by public funds through the NCI and NIH will play a vital role in addressing the rising cancer incidence, while at the same time curbing the overall annual costs of cancer—which exceeded \$263 billion in 2010.

Targeted Therapies as the Future of Cancer Treatment

One of the most promising new approaches in modern cancer treatment is our ability to treat patients based on the specific characteristics of a patient and his or her disease—often referred to as personalized or precision medicine. Cancer research is leading the way toward the realization of personalized medicine, in no small part thanks to Federal investment in deciphering the underlying biology, such as the Human Genome Project and, more recently, The Cancer Genome Atlas, an NCI project that is identifying important genetic changes involved in cancer.

Building on the tremendous progress in our understanding of the molecular mechanisms of cancer, numerous novel agents have been developed in recent years and many more are in development. New and innovative clinical trials are now being conducted that use molecular tests to identify which patients should be treated with which drugs. The NCI is investing in efforts that will facilitate the translation of this wealth of basic knowledge into new treatments, including validating cancer biomarkers for prognosis, metastasis, treatment response, and progression; accelerating the identification and validation of potential cancer molecular targets; minimizing the toxicities of cancer therapy; and integrating the clinical trial infrastructure for speed and efficiency.

In fact, in 2011, two newly approved drugs—one for melanoma and one for lung cancer—were breakthroughs in personalized medicine. Each drug was approved with a diagnostic test that identifies patients for whom the drug is most likely benefit.

Fighting Cancer in Challenging Fiscal Times

It is imperative that efforts to improve our Nation’s fiscal stability be grounded in the goal of securing the prosperity and well-being of the American people. And it is not by chance that the United States remains a leader in cancer research innovation and the development of lifesaving treatments. Our preeminence is a direct result of the steadfast determination of the American public and the Congress to reduce the burden of this devastating disease by supporting and investing in research through the NIH and NCI.

Further, maintaining American global competitiveness is predicated on its commitment to Federal support for biomedical research and development (R&D). The United States led the world’s economies in the 20th century because it led the world in innovation. Today, we recognize that the competition is more intense; the challenge is tougher; and therefore, continuing to innovate is more important than ever before. A sustained investment in research and development is essential to creating new jobs for the 21st century. According to Science and Engineering Indicators 2012, between 1999 and 2009, the United States share of global R&D dropped from 38 percent to 31 percent, whereas it grew from 24 percent to 35 percent in the “Asia-10” (China, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan and Thailand). While the United States remains a leader in supporting science and technology, that position could soon be overtaken as Asian countries, particularly China, continue to increase their national investments in R&D. Biomedical research not only keeps America competitive globally, it also has a strong positive impact on State and local economies. NIH dollars are creating and saving high-wage, high-tech jobs at a critical time for the U.S. economy. A recent

report published by a consortium of science and research medical organizations estimated that NIH directly and indirectly supported nearly 488,000 public and private sector jobs, and generated \$68 billion in new economic activity in 2010 alone.

The National Institutes of Health Needs Stable, Predictable Increases in Funding

One out of every three women and one out of every two men in America will develop cancer over their lifetime. More than a half million people will succumb to this disease in 2012—accounting for nearly 1 of every 4 deaths in America. This is the challenge we face today. Only a sustained investment in research will allow us to continue to build on the advances made during the past few decades to curb the number of lives lost to cancer.

The AACR recognizes that the Congress is being called upon to make difficult decisions among many competing priorities. However, one of the most important investments our country can make is in the NIH. Our ability to exploit new and exciting findings for the benefit of cancer patients is contingent on a strong, bipartisan commitment from the Congress to provide the necessary funding for the NIH and NCI. Millions of current and future cancer patients and their loved ones are relying on your support to change the face of cancer.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR DENTAL RESEARCH

Introduction

Mr. Chairman and members of the subcommittee, I am Rena D'Souza, Chair of the Department of Biomedical Sciences at the Texas A&M Health Science Center at Baylor College of Dentistry. My testimony is on behalf of the American Association for Dental Research (AADR).

I thank the subcommittee for this opportunity to testify about the exciting advances in oral health science and for your past support of research at the National Institutes of Health (NIH). This support has made it possible for research funded by the National Institute of Dental and Craniofacial Research (NIDCR) to improve oral health. The investments we make today will create an exciting tomorrow for the treatment and prevention of oral health diseases and disorders. In this testimony, I will highlight how the advances described above have benefited taxpayers and some of the challenges that lie ahead that need to be addressed to prevent lapsing further behind other nations throughout the world both scientifically and economically.

What is the American Association for Dental Research?

The American Association for Dental Research is a nonprofit organization with more than 4,000 members in the United States. Its mission is to: (1) advance research and gain a better understanding of the importance of oral health; (2) support and represent the oral health research community; and (3) educate the public about research findings. The AADR is the largest Division of the International Association for Dental Research.

Why is Oral Health Important?

Oral health is an essential component of health throughout life. Poor oral health and untreated oral diseases and conditions can affect the most significant human needs including the ability to eat and drink, swallow, maintain proper nutrition, smile and communicate. For over half a century, there has been a dramatic improvement in oral health. However, it is still a major concern. Tooth decay and gum disease represent most of the problem but complete tooth loss, oral cancer, and facial anomalies are also factors. Tooth decay is the most common oral health problem in the United States. More than 40 percent of poor adults 20 years and older have at least one untreated decayed tooth. Tooth decay affects more than 90 percent of adults over age 40. Moreover, as the nation ages, oral health issues related to gum disease and the impact of medical treatments and medicines will increase.

Oral Health Research and Development

Oral and Pharyngeal Cancer.—Most oral diseases and disorders arise from the interplay of complex biological, behavioral, environmental and genetic factors. Scientists now have the tools to understand health and disease from a powerful systems perspective. Such deep insights will enhance our ability to predict and more effectively manage many oral, dental diseases and craniofacial abnormalities such as orofacial clefting and ectodermal dysplasias. However, understanding and addressing complex oral diseases will require melding these advances with state-of-the-science clinical, epidemiological and bioinformatics approaches to more precisely identify diseases at their earliest inception, direct individualized therapies, and pre-

dict disease outcomes. One area that offers considerable opportunity is oral and pharyngeal cancer, which kills about 7,600 Americans each year. These deaths are particularly tragic because detection and treatment of early stage oral cancer usually results in much higher survival rates than if the disease is diagnosed and treated at late stages. Despite annual U.S. spending of approximately \$3.2 billion on head and neck cancer treatment, relative survival rates have not improved during the past 16 years and remain among the lowest of all major cancers. Oral cancer survival among African-American men has actually decreased. Approaches under development include devices to aid in earlier detection such as rapid gene-expression measurement tools that assess suspicious lesions removed for biopsy and integration of screening, diagnosis, and treatment. For example, toward achieving this goal, NIDCR-supported researchers recently devised a customized optical device that allows clinicians to visualize in a completely new way areas in the oral cavity that may be developing oral cancer.

Genome-Wide Association Studies.—The emerging science of genome-wide association studies (GWAS) and other rapidly evolving genome-wide technologies is producing exciting findings in oral, dental and craniofacial health. A recent family based genome-wide linkage study indicated possible developmental links between cleft lip and/or palate, caries and a range of dental malformations and identified several candidate genes for caries risk, pointing unexpectedly to genetic loci for salivary flow and diet preference. The NIDCR's continued support of genomic approaches may yield important new insights into the causes and progression of other complex conditions such as temporomandibular muscle and joint disorders associated with chronic orofacial pain, oral cancer, periodontal diseases and Sjogren's syndrome.

Saliva-based Diagnostic Tests.—Saliva-based diagnostic tests offer significant potential for improving both oral and general health. Thus further development and validation of these approaches will enable improved preemptive care by detecting molecular markers predictive of disease before symptoms arise, or by providing diagnosis of the earliest signs of disease. Recently, a consortium of NIDCR-supported research groups compiled the first comprehensive list of proteins secreted by the major salivary glands, leading to a compendium of salivary proteins that will form the basis for future efforts in salivary diagnostics and therapeutics.

Biomedical Research Workforce.—The investment decisions that the Congress makes this year will have a profound impact on the future of America's physical, dental, and economic health. Federal investments in basic research play a major role in scientific discovery, leading to economic growth and fostering global competitiveness. NIDCR is committed to ensuring that the biomedical research workforce is prepared to address unique dental and craniofacial research questions. The task of getting students interested in biomedical research needs to be combined with mentoring opportunities to bolster retention.

National Center for Advancing Translational Sciences.—NIH has established a new center, called the National Center for Advancing Translational Sciences (NCATS). Currently, many costly, time-consuming bottlenecks exist in the translational pipeline. Working in partnership with the public and private sectors, the Center will develop innovative ways to reduce, remove or bypass these bottlenecks. This will speed the delivery of new drugs, diagnostics and medical devices to patients, including the results of oral health research.

National Institutes of Health Public Access Policy.—The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. The scientific community relies on publishers to manage the post-grant peer review process to evaluate the merit and authenticity of the conclusions of the research. However, post-grant peer review is not funded by the agencies at all. No Federal funding goes into the publication process. In essence, privately funded articles, which are not subject to an open or public access policy, will have to subsidize the decreased readership resulting from the public access policy. In order for a journal to maintain readership, a ratio of privately funded research versus federally funded research will have to be maintained. With an expanded open access policy, it is feared that a number of small nonprofit scholarly journals will experience decreased subscriptions that will create an operating loss for the journal.

Challenges to Research

For many years, the United States has been a world leader in research and development. In order for the United States to thrive in today's innovation-oriented economy, we need to maintain a world class commitment to science and research. Future advances in healthcare depend on today's investments in basic research on the fun-

damental causes and mechanisms of disease, new technologies to accelerate discoveries, innovations in clinical research, and a robust pipeline of creative and skillful biomedical researchers. To continue reaping the benefits of a bold research funding platform, the Congress must make science a national priority. With continued support, NIH investigators will help to revolutionize patient care, reduce the growth of healthcare costs, and generate significant national economic growth.

Fiscal Year 2013 Budget Request

As you can see, Mr. Chairman, there are many research opportunities with an immediate impact on patient care that need to be pursued. A steady and substantial funding stream for NIH overall, and NIDCR in particular, is absolutely necessary in order to continue improving the oral health of Americans. We support the recommendation of the Ad Hoc Group for Medical Research that the Subcommittee recognize NIH as a critical national priority by providing at least \$32 billion in funding in the fiscal year 2013 Labor, Health and Human Services, Education appropriations bill. Of this amount, NIDCR should receive a fiscal year 2013 appropriation of \$450 million. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

Thank you for this opportunity to testify. We at AADR look forward to having the opportunity to work with the Congress and NIH to help build a strong and successful research enterprise.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF FAMILY PHYSICIANS

The American Academy of Family Physicians, representing 100,300 family physicians and medical students nationwide, urges the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education to invest in our Nation's primary care physician workforce in the fiscal year 2013 appropriations bill to promote the efficient, effective delivery of healthcare.

We recommend that the Committee provide the Health Resources and Services Administration and the Agency for Healthcare Research and Quality:

- At least \$71 million for Health Professions Primary Care Training and Enhancement, authorized under title VII, section 747 of the Public Health Service Act (PHSA);
- \$10 million for Teaching Health Centers development grants (PHSA Title VII, § 749A);
- \$4 million for Rural Physician Training Grants (PHSA Title VII, § 749B);
- \$122.2 million for the Office of Rural Health Policy (PHSA §§ 301, 330A, and 338J, and §§ 711 and 1820(j), title XVIII of the Social Security Act);
- At least \$300 million for the National Health Service Corps (PHSA § 338A, B, and I);
- \$120 million for the Primary Care Extension program (PHSA § 399V-1) in fiscal year 2013; and
- \$3 million for the National Health Care Workforce Commission (ACA § 5101).

HEALTH RESOURCES AND SERVICES ADMINISTRATION

The AAFP urges the subcommittee to provide at least \$7 billion for Health Resources and Services Administration (HRSA) in the fiscal year 2013 appropriations bill. Fundamental to HRSA's mission of improving access is supporting efforts to train and place the necessary primary care physician workforce. There is ample evidence that primary care physicians serve as a strong foundation for a more efficient and effective healthcare system. Federal investment not only would help to guide health system change to achieve optimal, cost-efficient health for everyone, but also would support primary care medicine training in what the January 2012 Bureau of Labor Statistics Projections recognized as "the most rapidly growing sector in terms of employment through 2020."

Title VII Health Professions Training Programs.—As the only medical specialty society devoted entirely to primary care, the AAFP is gravely concerned that a failure to provide adequate funding for the title VII, section 747, Primary Care Training and Enhancement (PCTE) program, will destabilize education and training support for family physicians. Between 1998 and 2008, in spite of persistent primary care physician shortages, family medicine lost 46 training programs and 390 residency positions, and general internal medicine lost nearly 900 positions.¹ A study

¹ Phillips RL and Turner, BJ. The Next Phase of Title VII Funding for Training Primary Care Physicians for America's Health Care Needs. *Ann Fam Med.* 2012;10(2):163–168.

published in the *Annals of Family Medicine* on the impact of title VII training programs found that physicians who work with the underserved at Community Health Centers and National Health Service Corps sites are more likely to have trained in title VII-funded programs.² Title VII primary care training grants are vital to departments of family medicine, general internal medicine, and general pediatrics; they strengthen curricula; and they offer incentives for training in underserved areas. In the coming years, medical services utilization is likely to rise, given the increasing and aging population, as well as the insured status of more people. These demographic trends will worsen family physician shortages. The AAFP urges the subcommittee to increase the level of Federal funding for primary care training to at least \$71 million in fiscal year 2013 to support the continuing work of grantees and allow for a new grant cycle.

Teaching Health Centers.—The AAFP has long called for reforms to graduate medical education programs in order to encourage the training of primary care residents in nonhospital settings, where most primary care is delivered. An excellent first step is the innovative Teaching Health Centers program, authorized under Title VII, § 749A, to increase primary care physician training capacity now administered by HRSA.

Federal financing of graduate medical education has led to training that occurs mainly in hospital inpatient settings, even though most patient care is delivered outside of hospitals in ambulatory settings. The Teaching Health Centers program provides resources to qualified community-based ambulatory care settings that operate a primary care residency. We believe that this program requires an investment of \$10 million in fiscal year 2013 for planning grants.

Rural Health Needs.—HRSA's Office of Rural Health Policy focuses on key rural health policy issues and administers targeted rural grant programs. As members of the medical specialty most likely to enter rural practice, family physicians recognize the need to dedicate resources to rural health needs.

A recent study found that medical school rural programs have had a significant impact on rural family physician supply and called for wider adoption of that model to substantially increase access to care in rural areas, compared with greater reliance on international medical graduates or unfocused expansion of traditional medical schools.³ HRSA's Rural Physician Training Grant Program will help medical schools recruit students most likely to practice medicine in rural communities. This program will help provide rural-focused experience and increase the number of medical school graduates who practice in underserved rural communities. The AAFP recommends that the Committee provide \$4 million for the Rural Physician Training Grant Program in fiscal year 2013.

Primary Care in Underserved Areas.—The National Health Service Corps (NHSC) recruits and places medical professionals in Health Professional Shortage Areas to meet the need for healthcare in rural and medically underserved areas. The NHSC provides scholarships or loan repayment as incentives for physicians to enter primary care and provide healthcare to Americans in Health Professional Shortage Areas. By addressing medical school debt burdens, the NHSC also helps to ensure wider access to medical education opportunities. The AAFP recommends that the Committee provide at least \$300 million for the National Health Service Corps for fiscal year 2013.

The AAFP has worked closely with HRSA to promote data-driven community health center expansion. The mapping tool developed and managed by the Robert Graham Center for Policy Studies in Family Practice and Primary Care identifies areas in greatest need of federally Qualified Health Centers. Since the launch of the tool on July 1, 2010, the UDS Mapper has registered more than 4,500 users; it can be found at <http://www.udsmapper.org/about.cfm>.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The AAFP supports the work of AHRQ's Center for Primary Care, Prevention, and Clinical Partnerships (CP³), which serves as the home for the AHRQ's Practice-Based Research Network of primary care ambulatory practices. This network studies community-based practice.

Furthermore, we recognize AHRQ as an important resource for primary care workforce data. The AAFP asks that the Committee provide at least \$400 million for AHRQ in fiscal year 2013.

²Rittenhouse DR, et al. Impact of Title VII training programs on community health center staffing and National Health Service Corps participation. *Ann Fam Med*. 2008;6(5):397–405.

³Rabinowitz, HK, et al. Medical School Rural Programs: A Comparison With International Medical Graduates in Addressing State-Level Rural Family Physician and Primary Care Supply. *Academic Medicine*, Vol. 87, No. 4/April 2012.

Primary Care Extension Program.—The AAFP supports AHRQ’s Primary Care Extension Program to provide information to primary care physicians about evidence-based therapies and techniques so that they can incorporate them into their practice. As AHRQ develops more scientific evidence on best practices and effective clinical innovations, the Primary Care Extension Program will disseminate the information learned to primary care practices across the Nation in much the same way as the Federal Cooperative Extension Service provides small farms with the most current agricultural information and guidance. The AAFP recommends that the subcommittee provide \$120 million for the AHRQ Primary Care Extension program in fiscal year 2013.

NATIONAL HEALTH CARE WORKFORCE COMMISSION

Appointed on September 30, 2010, the 15-member National Health Care Workforce Commission was intended to serve as a national resource with a broad array of expertise. The Commission was directed to analyze current workforce distribution and needs; evaluate healthcare education and training; identify barriers to improved coordination at the Federal, State, and local levels and recommend ways to address them; and encourage innovations to address population needs, changing technology, and other factors.

There is broad consensus about the waning availability of primary care physicians in the United States, but estimates of the severity of the regional and local shortages vary. The AAFP supports the work of the Commission to analyze primary care shortages and propose innovations to help produce the physicians that our Nation needs and will need in the future. We request that the Committee provide \$3 million in fiscal year 2013 so that this important Commission can begin this important work.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

The American Association of Immunologists (AAI), a not-for-profit professional society comprised of more than 7,400 of the world’s leading experts on the immune system, appreciates this opportunity to submit this testimony regarding appropriations for the National Institutes of Health (NIH) for fiscal year 2013. AAI members work in academia, Government, and industry. Most of our members either receive funding from NIH to support their research¹ or depend on the basic research conducted by NIH-funded scientists in developing therapeutics to prevent or treat disease.² Whether public or private sector; basic, translational or clinical; American or international; most biomedical researchers rely on the leadership of, and funding from, the NIH—the world’s premier medical research organization.

NIH’s preeminence—and America’s dominance—in advancing medical research, discovering treatments and cures, and “growing” brilliant young scientists has been unchallenged for more than 50 years. However, continued erosion of NIH funding has already led to the loss of highly qualified scientists and the closures of labs.³ For those scientists who are able to continue, competing and securing research support increasingly occupies the time that could—and should—be dedicated to new advances and discoveries.

NIH funding is an important driver of our economy. Unlike many Federal agencies, NIH distributes most (>80 percent) of its \$30.7 billion budget to scientists in all 50 States, making NIH funding a formidable engine for local and national economic growth.⁴ NIH funding supports highly skilled jobs focused on improving human and animal health; less skilled jobs which support laboratories, academic in-

¹Many AAI members receive grants from the National Institute of Allergy and Infectious Diseases, the National Cancer Institute, and the National Institute on Aging, as well as other NIH Institutes and Centers.

²NIH funding has a definite impact on the private sector. “. . . [T]he National Bureau of Economic Research concluded that, in contrast to the pattern of public spending . . . displacing private activity in the economy, a dollar of NIH support for research leads to an increase of private medical research of roughly 32 cents.” Everett Ehrlich, *An Economic Engine: NIH Research, Employment and the Future of the Medical Innovation Sector*, http://www.unitedformedicalresearch.com/wp-content/uploads/2011/05/UMR_Economic-Engine.pdf.

³FASEB, “Federal Funding for Biomedical and Related Life Sciences Research FY 2013,” <http://www.faseb.org/LinkClick.aspx?fileticket=10Qs6teI4kY%3D&tabid=64>. Everett Ehrlich, *NIH’s Role in Sustaining the U.S. Economy*, <http://www.unitedformedicalresearch.com/wp-content/uploads/2012/03/NIHs-Role-in-Sustaining-the-US-Economy-2011.pdf>.

⁴NIH funding supports “almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every State and around the world.” <http://nih.gov/about/budget.htm>. (March 1, 2012).

stitutions, and a community of employees;⁵ and the training of our Nation's future researchers, inventors, and innovators. NIH-funded discoveries also fuel the success of our Nation's biotechnology and pharmaceutical industries.

The Broad Reach of the Immune System

All humans and other animals require a properly working immune system to survive. Optimally, this system defends against infectious agents which require a host to persist and propagate. Many infectious diseases, including influenza, HIV/AIDS, tuberculosis, malaria, and the common cold, challenge—and sometimes overcome—the defenses mounted by the immune system. Other malfunctions result in the immune system attacking our normal body tissues, causing “autoimmune” diseases or disorders, including Type 1 diabetes, multiple sclerosis, rheumatoid arthritis, asthma, allergies, inflammatory bowel diseases, and lupus.⁶ The immune system also impacts many other diseases and conditions, including cancer, Alzheimer's,⁷ obesity, Type II diabetes, psoriasis, alopecia areata, and pregnancy loss.

In addition, urgent public health challenges require understanding the immune response to pathogens that might cause the next pandemic; man-made and natural infectious organisms (including plague, smallpox and anthrax) that could be used for bioterrorism; and environmental threats that could cause or exacerbate disease.⁸ Although immunology is a relatively young field,⁹ research advances have already yielded remarkable progress.¹⁰ But solving key scientific questions that lead to prevention and cures cannot occur without a strong, sustained biomedical research enterprise, adequately funded through appropriations to NIH.

Recent Immunological Discoveries and Translation to Treatment

AIDS Vaccine.—Study of the immune system has helped lengthen the lives of those diagnosed with

HIV from months in the 1980s to as much as 50 years today.¹¹ Recently, several key advances have helped us understand how HIV evades immune recognition and how to generate more efficacious HIV vaccines. In one discovery, scientists were able to visualize neutralizing antibodies bound to HIV on a molecular level, determine the nature of the interaction, and find a broadly neutralizing antibody that combats several strains of HIV.¹² Such advances may lead to effective therapies and vaccines against many viruses, including HIV.

Universal Flu Vaccine.—Remarkable advances are also being made on improved seasonal influenza vaccines and “universal” flu vaccines that would provide protection against multiple strains of influenza.

Anti-Cancer Vaccines.—In testimony submitted to this subcommittee in 2009, AAI described a promising new cancer treatment that would redirect the immune system to attack cancer cells by manipulating the inhibitory molecule CTLA-4. In 2011, the Food and Drug Administration (FDA) approved CTLA-4 blockade (ipilimumab) for the treatment of metastatic melanoma after Phase III clinical trials showed that

⁵“One study estimates that every dollar of NIH support returns \$2.21 in goods and services in just 1 year, and that on average, every NIH grant creates seven high-quality jobs.” Testimony of Francis S. Collins, M.D., Ph.D., March 28, 2012, page 7, <http://www.appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=8a1dcace-6f68-4e35-ad94-4409966e2ffb>. See also Ehrlich, *NIH's Role in Sustaining the U.S. Economy* (see footnote 1, above).

⁶The immune system works by recognizing and attacking bacteria, viruses, and tumor cells inside the body. It is also responsible for the rejection response following transplantation of organs or bone marrow.

⁷Allison Bond, “Immune Response May Worsen Alzheimer's,” *Scientific American*, January 18, 2010, <http://www.scientificamerican.com/article.cfm?id=inflamed-neurons>.

⁸To best protect against emergent threats, AAI believes that scientists should focus on basic research, including understanding the immune response, identifying new pathogens, and developing tools (including vaccines) to protect against these pathogens. For example, to best protect against an influenza pandemic, scientists should focus on basic research to combat seasonal flu, including building capacity, pursuing new production methods, and seeking optimized flu vaccines and delivery methods.

⁹Most of our basic understanding of the immune system has developed in the last ~50 years, although the first vaccine (against smallpox) was developed in 1798.

¹⁰In 2011, three NIH-supported immunologists (the late Ralph Steinman, M.D., Bruce Beutler, M.D., and Jules Hoffman, Ph.D.) received the Nobel Prize in Medicine for their important contributions to the field.

¹¹Anthony S. Fauci, “After 30 years of HIV/AIDS, real progress and much left to do,” *Washington Post*, May 27, 2011, http://www.washingtonpost.com/opinions/after-30-years-of-hiv-aids-real-progress-and-much-left-to-do/2011/05/27/AGbimyCH_story.html.

¹²Robert Pejchal et al., “A Potent and Broad Neutralizing Antibody Recognizes and Penetrates the HIV Glycan Shield,” *Science* 334, (2011):1097.

ipilimumab improved survival for these patients.¹³ In 2010, the first therapeutic cancer vaccine (Provenge), for the treatment of prostate cancer, was approved by the FDA. This vaccine takes advantage of the immune system's ability to sense and then attack cancer cells.¹⁴ Both therapies were based on fundamental immunological discoveries of the past several decades and are now guiding the development of numerous other therapeutics which direct the immune system to specifically attack cancer cells.

Malaria Vaccine.—A recent phase III study for the malaria vaccine RTS,S showed that the progression of severe disease could be reduced by the vaccine by about half, promising data toward the development of a vaccine for a disease that is of urgent concern to people worldwide and to U.S. troops stationed abroad.

The Importance of Sustained National Institutes of Health Funding

AAI greatly appreciates this subcommittee's long history of strong bipartisan support for biomedical research. NIH funding has supported many excellent projects to advance human health and strengthen the Nation's research infrastructure. However, fiscal pressures in recent years have resulted in flat or reduced NIH funding. Together with increases in biomedical research inflation, these budgets have significantly eroded NIH's purchasing power; the President's fiscal year 2013 budget would reduce NIH's purchasing power to 2001 levels.¹⁵ AAI is deeply concerned that inadequate NIH funding will harm ongoing research, weaken the U.S. biomedical research enterprise, and enable global competitors to recruit our best scientists.

American Association of Immunologists Recommendation for National Institutes of Health Funding for Fiscal Year 2013

Although AAI believes that NIH needs a substantial infusion of funds, we realize that such an increase is unlikely this year. Therefore, AAI recommends a budget for NIH of at least \$32 billion to enable NIH to support existing research projects, fund a limited number of excellent new ones, and stabilize the research enterprise. More is needed, however, to grow the system or inspire confidence in it, particularly among the brightest young students who are increasingly hesitant to pursue careers in biomedical research.

American Association of Immunologists Priorities for Fiscal Year 2013

Biomedical innovation and discovery are best achieved through individual investigator-initiated research, i.e., researchers working all around the country, whose grant applications are peer-reviewed and funded by NIH. "Top-down" science, in which the Government specifies the type of research it wishes to fund, is less likely to achieve the desired goals than funding the best grant applications. AAI is concerned, therefore, that the President's budget reduces funding for research project grants (RPGs) by \$26 million. While NIH's new management plan anticipates funding a larger number (672) of new and competing RPGs, this reduced funding would require awards to be smaller and/or shorter in duration. Although this may be the best way for NIH to manage less RPG funding, it will not solve the fundamental problem caused by the erosion of the NIH budget: fewer scientists receiving the support they need to do their work.

The President's budget provides an increase of \$64 million to the National Center for Advancing Translational Sciences (NCATS), including an increase of \$40 million for the Cures Acceleration Network (CAN). Although AAI supports NIH's desire to facilitate the translation of basic research from "bench to bedside," AAI questions whether such large increases are wise when overall RPG funding is experiencing a significant and worrisome decline.

AAI is concerned about a new administration policy that limits the ability of Government scientists to attend privately sponsored scientific meetings and conferences.¹⁶ Government scientists are valued members of our organization and contribute significantly to scientific advancement in the field. It is as important to AAI to have them attend our meetings as it is for them to attend. Dialogue and information exchange among scientists from Government, academia, industry and private institutes are absolutely essential, and any barriers to the participation of Government scientists undermines the best interests of science.

¹³ Stephen Hodi et al., "Improved Survival with Ipilimumab in Patients with Metastatic Melanoma," *N Engl J Med* 363, (2010): 711–723.

¹⁴ See <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210174.htm>.

¹⁵ FASEB, *Predictable and Sustainable Funding for NIH Will Drive Innovation and Progress, 2012*, <http://www.faseb.org/LinkClick.aspx?fileticket=aDQlNW4adp0%3d&tabid=431>.

¹⁶ See <http://www.hhs.gov/travel/policies/2012%20policy%20manual.pdf>.

The National Institutes of Health Public Access Policy

As the owner and publisher of *The Journal of Immunology* (The JI), AAI believes that the NIH Public Access Policy (Policy) duplicates publishing services which are already provided cost-effectively and well by the private sector, including not-for-profit scientific societies. AAI and other scholarly publishers already publish, and make publicly available, thousands of scientific journals with millions of articles that report cutting-edge research. Many publishers make abstracts available online immediately and at no cost to the public. Most publishers who impose an embargo period (necessary to prevent the loss of subscriptions which defray publication costs) make available not only the articles supported by NIH funding, but all articles regardless of funding source. As a result, many publisher Web sites contain a more complete repository of relevant literature than does NIH, and often include the entire archives of the journal.

NIH should work with, rather than compete with, private publishers to enhance public access; address publishers' key concerns, including respecting copyright and ensuring journals' continued ability to provide quality, independent peer review of NIH-funded research; and publicly report on the cost of the Policy.

CONCLUSION

AAI thanks this subcommittee for its strong support for medical research, NIH and the thousands of researchers who devote their lives to scientific discovery and the prevention, treatment, and cure of disease.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF MUSEUMS

Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, thank you for inviting me to submit this testimony. My name is Ford Bell and I serve as President of the American Association of Museums (AAM). I also submit this testimony on behalf of the larger museum community—including the American Association for State and Local History, the Association of Art Museum Directors, the Association of Children's Museums, the American Public Gardens Association, and Heritage Preservation—to request that the subcommittee make a renewed investment in museums in fiscal year 2013. We urge your support for \$50 million for the Office of Museum Services (OMS) at the Institute of Museum and Library Services (IMLS).

AAM is proud to represent the full range of our Nation's museums—including aquariums, art museums, botanic gardens, children's museums, culturally specific museums, historic sites, history museums, maritime museums, military museums, natural history museums, planetariums, presidential libraries, science and technology centers, and zoos, among others—along with the professional staff and volunteers who work for and with museums. AAM is proud to work on behalf of the 17,500 museums that employ 400,000 people, spend more than \$2 billion annually on K–12 educational programming, receive more than 90 million visits each year from primary and secondary school students, and contribute more than \$20 billion to local economies.

IMLS is the primary Federal agency that supports the Nation's museums, and OMS awards grants to help museums digitize, enhance, and preserve their collections; provide teacher training; and create innovative, cross-cultural and multi-disciplinary programs and exhibits for schools and the public. The 2012–2016 IMLS Strategic Plan lists clear priorities: placing the learner at the center of the museum experience, promoting museums as strong community anchors, supporting museum stewardship of their collections, advising the President and the Congress on how to sustain and increase public access to information and ideas, and serving as a model independent Federal agency maximizing value for the American public. IMLS is indeed a model Federal agency.

In late 2010, a bill to reauthorize IMLS for 5 years was enacted (by voice vote in the House and unanimous consent in the Senate). The bipartisan reauthorization included several provisions proposed by the museum field, including enhanced support for conservation and preservation, emergency preparedness and response, and statewide capacity building. The reauthorization also specifically supports efforts at the State level to leverage museum resources, including statewide needs assessments and the development of State plans to improve and maximize museum services throughout the State. The bill (now Public Law 111–340) authorized \$38.6 million for the IMLS Office of Museum Services to meet the growing demand for museum programs and services. The fiscal year 2012 appropriation of \$30,859,000—equal to President Obama's fiscal year 2013 budget request—represents a nearly 15-

percent decrease from the fiscal year 2010 appropriation of \$35,212,000. We urge the subcommittee to provide \$50 million for the IMLS Office of Museum Services.

To be clear, museums are essential in our communities for many reasons:

Museums are Key Education Providers.—Museums already offer educational programs in math, science, art, literacy, language arts, history, civics and government, economics and financial literacy, geography, and social studies, in coordination with State and local curriculum standards. Museums also provide experiential learning opportunities, STEM education, youth training, and job preparedness. They reach beyond the scope of instructional programming for schoolchildren by also providing critical teacher training. There is a growing consensus that whatever the new educational era looks like, it will focus on the development of a core set of skills: critical thinking, the ability to synthesize information, the ability to innovate, creativity, and collaboration. Museums are uniquely situated to help learners develop these core skills.

Museums Create Jobs and Support Local Economies.—Museums serve as economic engines, bolster local infrastructure, and spur tourism. Both the U.S. Conference of Mayors and the National Governors Association agree that cultural assets such as museums are essential to attracting businesses, a skilled workforce, and local and international tourism. Museums pump more than \$20 billion into the American economy, creating many jobs.

Museums Address Community Challenges.—Many museums offer programs tailored to seniors, veterans, children with special needs, persons with disabilities, and more, greatly expanding their reach and impact. For example, some have programs designed specifically for children on the autism spectrum, some are teaching English as a second language, and some are serving as locations for supervised family visits through the family court system. In 2011, more than 1,500 museums participated in the Blue Star Museums initiative, offering free admission to all active duty and reserve personnel and their families from Memorial Day through Labor Day.

Digitization and Traveling Exhibitions Bring Museum Collections to Underserved Populations.—Teachers, students, and researchers benefit when cultural institutions are able to increase access to trustworthy information through online collections and traveling exhibits. Most museums, however, need more help in digitizing collections.

Grants to museums are highly competitive and decided through a rigorous, peer-reviewed process. Even the most ardent deficit hawks view the IMLS grantmaking process—the “regular process”—as a model for the Nation. It would take approximately \$124.6 million to fund all the grant applications that IMLS received from museums in 2011. But given the significant budget cuts, many highly rated grant applications go unfunded each year:

- Only 32 percent Museums for America/Conservation Project projects were funded;
- Only 15 percent National Leadership/21st Century Museum Professionals projects were funded;
- Only 64 percent Native American/Hawaiian Museum Services projects were funded; and
- Only 37 percent African American History and Culture projects were funded.

It should be noted that each time a museum grant is awarded, additional local and private funds are also leveraged. In addition to the required dollar-for-dollar match required of museums, grants often spur additional giving by private foundations and individual donors. A recent IMLS study found that 67 percent of museums that received Museums for America grants reported that their IMLS grant had positioned the museum to receive additional private funding.

Here are just a few examples of how Office of Museum Services funding is used:

- The Iowa Children’s Museum in Coralville will use its \$117,769 Museums for America grant awarded in 2011 to establish “MoneyWorks!”—a financial literacy project targeting children aged 4 to 10. The proposed project will empower children by adding active financial literacy experiences to the museum’s current CityWorks exhibit. “MoneyWorks!” enables children and their families to take on the roles of bank tellers, pizza chefs, doctors, and more in a pretend city environment where they can explore the concepts of earning, spending, saving, and giving. Through basic math skills, creative problem solving, and increased awareness of financial choices and consequences, kids will acquire a lifetime of essential financial literacy skills.
- The National Czech and Slovak Museum and Library in Cedar Rapids, Iowa, will use its \$148,351 Museums for America grant awarded in 2011 to capture the personal stories and family sagas of Czech and Slovak Cold War émigrés and recent (post-Velvet Revolution) Czech and Slovak immigrants to America.

Beginning in Cedar Rapids and then extending to New York, Chicago, the District of Columbia, Florida, and the San Francisco Bay Area, this project will involve a new permanent exhibition, a traveling exhibit, and an oral history recording booth to be designed, constructed, and implemented in the museum.

- The University of Northern Iowa Museums in Cedar Falls will use its \$149,684 Museums for America grant awarded in 2011 to protect and preserve the archive's resources (9,000 original documents relating to early Iowa education), ensuring public access to this valuable historical information. The historically important Marshall Center School, owned by UNI Museums, maintains a collection of more than 3,000 photographs, school board records, oral histories, teacher certificates and contracts, teaching materials, maps, diaries, letters, furnishings, and textbooks from the 1850s to the 1960s. With the addition of the statewide collection of official rural school documents, the UNI Museums' Center for the History of Rural Iowa Education and Culture is poised to become a significant national center for the study of educational, rural, and women's history.
- The McWane Science Center in Birmingham, Alabama, will use its \$140,020 Museums for America grant awarded in 2011 to partner with the W.J. Christian public school in Birmingham to provide teacher training workshops, classroom outreach programs, science laboratories and programs, and a school-based science resource center. The partnership is designed to pair a formal, public school with an informal education institution to provide low-income and disadvantaged students with the opportunity to access quality learning environments, equipment, and laboratories. The project will result in a revised science curriculum and professional development resources for science teachers. The project aims to engage students in science and inspire them to pursue opportunities for advanced science education. The Science Education Partnership will help further the museum's mission of "changing lives through science and wonder" by serving as an extension of the school-based science classroom.
- The Alabama Space Science Exhibit Commission in Huntsville, Alabama, will use its \$150,000 Museums for America grant awarded in 2011 to develop, "Carrying Out the Mission," an exhibit on astronaut training at its museum, the U.S. Space & Rocket Center. The center houses one of the world's largest collections of space artifacts and "Carrying Out the Mission" is one part of a 12-module exhibit plan that will use historical artifacts, hands-on interactive stations, two problem-solving computer simulators, and oral histories to explore human space exploration, and in the process inspire current and future generations to engage in science.
- The Birmingham Civil Rights Institute in Birmingham, Alabama, is using its \$129,830 Museum Grants for African American History and Culture awarded in 2010 to better engage its diverse audiences by enhancing the staff capacity to effectively utilize technology. With the recent installation of new interactive exhibits and a fiber optic network, the museum will now develop the skills of its staff to more fully utilize the museum's education programs and services. The museum will hire a computer and information systems assistant to provide technical support for exhibitions and staff functions, and a series of technology training programs will be offered to all staff. The project will promote greater efficiency between the various museum departments through improved communication and coordination, information sharing, data collection and analysis, and external communication with visitors and other stakeholders.

In closing, I would like to share with you for the record a letter to the subcommittee requesting \$50 million for the IMLS Office of Museum Services signed by 18 of your Senate colleagues. Thank you once again for the opportunity to submit this testimony.

UNITED STATES SENATE,
Washington, DC, March 29, 2012.

Hon. TOM HARKIN,
Chairman, Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education and Related Agencies, Washington, DC.

Hon. RICHARD C. SHELBY,
Ranking Member, Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education and Related Agencies, Washington, DC.

DEAR CHAIRMAN HARKIN AND RANKING MEMBER SHELBY: We are writing to thank you for your support for the Institute of Museum and Library Services (IMLS) Office of Museum Services (OMS) and to urge the subcommittee to support \$50 million for

OMS in the fiscal year 2013 Labor, Health and Human Services and Education Appropriations bill.

Museums are economic engines—spending more than \$20 billion in their communities, employing 400,000 Americans, and spurring local tourism. Museums are also fostering the kind of critical thinking skills and innovation that are necessary to keep our Nation competitive in the global economy.

The demand for museum services is greater than ever. At a time when school resources are strained and many families cannot afford to travel or make ends meet, museums are working overtime to fill the gaps—providing more than 18 million instructional hours to schoolchildren, bringing art and cultural heritage, dynamic exhibitions and living specimens into local communities, encouraging national service and volunteerism, collecting food and other resources for needy families and individuals, and offering free or reduced admission to military families. Unfortunately, museums are struggling significantly in these difficult economic times. They are being forced to cut back on hours, educational programming, community services, and jobs. And according to the 2005 Heritage Health Index, at least 190 million artifacts are at risk, suffering from light damage and harmful and insecure storage conditions.

The Institute of Museum and Library Services—the primary Federal agency that supports our Nation's 17,500 museums—was unanimously reauthorized in 2010 by both the House and Senate. The agency is highly accountable, and its competitive, peer-reviewed grants serve every State. Although the agency has been successful in creating and supporting advancements in areas such as technology, lifelong community learning and conservation and preservation efforts, only a small fraction of the Nation's museums are currently being reached, and many highly rated grant applications go unfunded each year. The re-authorization contained several provisions to further support museums, particularly at the State level, but much of the recently authorized activities cannot be accomplished without meaningful funding.

We therefore recommend a critical investment in our Nation's museums. Specifically, we are requesting \$50 million for IMLS Office of Museum Services for fiscal year 2013. Again, we appreciate the subcommittee's prior support for OMS and request this investment to strengthen and sustain the work of our Nation's museums.

Sincerely,

KIRSTEN E. GILLIBRAND; DANIEL K. AKAKA; MAX BAUCUS; JEFF BINGAMAN; RICHARD BLUMENTHAL; BENJAMIN L. CARDIN; RICHARD J. DURBIN; TIM JOHNSON; FRANK R. LAUTENBERG; PATRICK J. LEAHY; BARBARA A. MIKULSKI; JACK REED; BERNIE SANDERS; CHARLES E. SCHUMER; JEANNE SHAHEEN; DEBBIE STABENOW; TOM UDALL; SHELDON WHITEHOUSE.

U.S. Senators.

PREPARED STATEMENT OF THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

The Association of American Medical Colleges (AAMC) is a not-for-profit association representing all 137 accredited United States and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

The association appreciates the opportunity to address four Federal priorities that play essential roles in assisting medical schools and teaching hospitals to fulfill their missions of education, research, and patient care: the National Institutes of Health (NIH); the Agency for Healthcare Research and Quality (AHRQ); health professions education funding through the Health Resources and Services Administration (HRSA)'s Bureau of Health Professions; and student aid through the Department of Education and HRSA's National Health Service Corps. The AAMC appreciates the Subcommittee's longstanding, bipartisan efforts to strengthen these programs.

National Institutes of Health.—The NIH is one of the Federal Government's greatest achievements. Congress' long-standing support for medical research through the NIH has created a scientific enterprise that is the envy of the world and has contributed greatly to improving the health and well-being of all Americans—indeed of all humankind. The foundation of scientific knowledge built through NIH-funded research drives medical innovation that improves health through new and better diagnostics, improved prevention strategies, and more effective treatments.

The AAMC supports the recommendation of the Ad Hoc Group for Medical Research that the Subcommittee recognize NIH as a critical national priority by pro-

viding at least \$32 billion in funding in its fiscal year 2013 Labor-HHS-Education appropriations bill. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

More than 83 percent of NIH research funding is awarded to more than 3,000 research institutions in every State; at least half of this funding supports life-saving research at America's medical schools and teaching hospitals. This successful partnership not only lays the foundation for improved health and quality of life, but also strengthens the nation's long-term economy.

The AAMC opposes the administration's proposal to retain at Executive Level II of the Federal Executive Pay Scale the limit on salaries that can be drawn from NIH extramural awards. The reduction in the limit in the fiscal year 2012 appropriation comes at a time when medical schools' and teaching hospitals' discretionary funds from clinical revenues and other sources are increasingly constrained and less available to invest in research. As institutions and departments divert funds to compensate for the reduction in the salary limit, they will have less funding for critical activities such as bridge funding to investigators who may be between grants and seed grants and start-up packages for young investigators. The lower salary cap will disproportionately affect physician investigators, who will be forced to make up salaries from clinical revenues, thus leaving less time for research. This may serve as a deterrent to their recruitment into research careers. The AAMC urges the Subcommittee to restore the limit to Executive Level I, as it was for every year since fiscal year 2001.

Agency for Healthcare Research and Quality.—Complementing the medical research supported by NIH, AHRQ sponsors health services research designed to improve the quality of healthcare, decrease healthcare costs, and provide access to essential healthcare services by translating research into measurable improvements in the healthcare system. The AAMC firmly believes in the value of health services research as the Nation continues to strive to provide high-quality, efficient, and cost-effective healthcare to all of its citizens. The AAMC joins the Friends of AHRQ in recommending \$400 million in base discretionary funding for the agency in fiscal year 2013.

As the lead Federal agency to improve healthcare quality, AHRQ's overall mission is to support research and disseminate information that improves the delivery of healthcare by identifying evidence-based medical practices and procedures. The Friends of AHRQ funding recommendation will allow AHRQ to continue to support the full spectrum of research portfolios at the agency, from patient safety to patient-centered health research and other valuable research initiatives. These research findings will better guide and enhance consumer and clinical decisionmaking, provide improved healthcare services, and promote efficiency in the organization of public and private systems of healthcare delivery.

Health Professions Funding.—HRSA's Title VII health professions and Title VIII nursing education programs are the only Federal programs designed to improve the supply, distribution, and diversity of the Nation's healthcare workforce. Through loans, loan guarantees, and scholarships to students, and grants and contracts to academic institutions and nonprofit organizations, the Title VII and Title VIII programs fill the gaps in the supply of health professionals not met by traditional market forces. The AAMC joins the Health Professions and Nursing Education Coalition (HPNEC) in recommending \$520 million for these important workforce programs in fiscal year 2013.

This funding recommendation is necessary to ensure continuation of all Title VII and Title VIII programs at least at fiscal year 2012 base discretionary levels, while also supporting promising initiatives such as the Pediatric Subspecialty Loan Repayment program and other efforts to bolster the workforce. The AAMC strongly objects to the administration's proposal to eliminate the Area Health Education Centers (AHEC), which in 2010 alone, trained more than 50,000 health professions students in community-based settings, and the Health Careers Opportunity Program (HCOP), which research shows has helped students from disadvantaged backgrounds achieve higher grade point averages and matriculate into health professions programs. Continued support for these and the full spectrum of Title VII programs is essential to prepare our next generation of medical professionals to adapt to the evolving healthcare needs of the changing population.

In addition to funding for Title VII and Title VIII, HRSA's Bureau of Health Professions also supports the Children's Hospitals Graduate Medical Education program. This program provides critical Federal graduate medical education support for children's hospitals to prepare the future primary care workforce for our Nation's children and for pediatric specialty care. The AAMC has serious concerns about the President's plan to drastically reduce support for this essential program in fiscal

year 2013. At a time when the Nation faces a critical doctor shortage, any cuts to funding that supports physician training will have serious repercussions for Americans' health. We strongly urge restoration to the program's fiscal year 2010 level of \$317.5 million in fiscal year 2013.

Student Aid and the National Health Service Corps (NHSC).—The AAMC urges the committee to sustain student loan and repayment programs for graduate and professional students at the Department of Education. The average graduating debt of medical students currently exceeds \$160,000, and typical repayment can range from \$300,000 to \$450,000. The Budget Control Act (BCA, Public Law 112–25) adds another \$10,000 to \$20,000 to total repayment as a result of eliminating graduate and professional in-school subsidies, effective July 1, 2012.

The AAMC opposes any rescissions from the National Health Service Corps (NHSC) Fund created under the Affordable Care Act (ACA, Public Law 111–142 and Public Law 111–152). The steady, sustained, and certain growth established by this mandatory funding for the NHSC has resulted in program expansion and innovative pilots such as the Student to Service (S2S) Loan Repayment Program that incentivizes fourth year medical students to practice primary care in underserved areas after residency training. The AAMC further requests that any expansion of NHSC eligible disciplines or specialties be accompanied by a commensurate increase in NHSC appropriations so as to prevent a reduction of awards to current eligible health professions. Furthermore, the AAMC believes that such changes are best tested through the NHSC State Loan Repayment Program (SLRP), and that funds provided for this program should allow the States to define specialty and geographic shortages.

Once again, the AAMC appreciates the opportunity to submit this statement for the record and looks forward to working with the Subcommittee as it prepares its fiscal year 2013 spending bill.

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS

FISCAL YEAR 2013 APPROPRIATIONS REQUEST SUMMARY

	Fiscal year—			AANA fiscal year 2013 request
	2011 actual	2012 actual	2013 budget	
HHS/HRSA/BHPr Title VIII Advanced Education Nursing, Nurse Anesthetist Education Reserve.	Awards amounted to approx. \$3.5 million.	Grant allocations not specified.	Grant allocations not specified.	\$4 million for nurse anesthesia education
Total for Advanced Education Nursing, from Title VIII.	\$64.046 million for Advanced Education Nursing.	\$63.925 million for Advanced Education Nursing.	\$83.925 million for Advanced Education Nursing.	\$83.925 million for Advanced Education Nursing
Title VIII HRSA BHPr Nursing Education Programs.	\$242,387,000	\$231,948,000	\$251,099,000	\$251,099,000
CDC/Division of Healthcare Quality and Promotion.	Maintain level funding.	Maintain level funding

The American Association of Nurse Anesthetists (AANA) is the professional association for the 44,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists practicing today. CRNAs deliver approximately 32 million anesthetics to patients each year in the United States. CRNA services include administering the anesthetic, monitoring the patient's vital signs, staying with the patient throughout the surgery, and providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and ensure that rural medical facilities have access to obstetrical, surgical, and trauma stabilization, and pain management capabilities. In addition, CRNAs provide the lion's share of anesthesia care required by our U.S. Armed Forces through active duty and the reserves. Nurse anesthetists are experienced and highly trained anesthesia professionals whose record of patient safety in the field of anesthesia was bolstered by the Institute of Medicine report in 2000, which found that anesthesia is 50 times safer than in the 1980s. (Kohn L, Corrigan J, Donaldson M, ed. *To Err is Human*. Institute of Medicine, National Academy Press, Washington, DC, 2000.) Nurse anesthetists continue to set for themselves the most rigorous continuing education and re-certification requirements in the field of anesthesia. Relative anesthesia patient safety outcomes are comparable among nurse anesthetists and anesthesiologists, with a 2010 Health Affairs article, "No Harm Found When Nurse Anesthetists Work with-

out Supervision by Physicians” finding that adverse outcomes were no more prevalent in States that opted out of the Medicare physician supervision requirement of nurse anesthetists than those States that didn’t opt-out (Dulisse B, Cromwell J. No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians. *Health Aff.* 2010;29(8):1469–1475).

In addition, a study published in *Nursing Research* indicates that obstetrical anesthesia, whether provided by CRNAs or anesthesiologists, is extremely safe, and there is no difference in safety between hospitals that use only CRNAs compared with those that use only anesthesiologists. (Simonson, Daniel C et al. *Anesthesia Staffing and Anesthetic Complications During Cesarean Delivery: A Retrospective Analysis.* *Nursing Research*, Vol. 56, No. 1, pp. 9–17. January/February 2007).

Importance of Title VIII Nurse Anesthesia Education Funding

The nurse anesthesia profession’s chief request of the Subcommittee is for \$4 million to be reserved for nurse anesthesia education and \$83.925 million for advanced education nursing from the Title VIII program. We feel that this funding request is well justified, as we know that more baby boomers retiring will not only reduce our nurse workforce from retirements but will increase the demand from an aging population requiring care. The Title VIII program is an effective means to help address the nurse anesthesia workforce demand.

Increasing funding for advanced education nursing from \$63.93 million in fiscal year 2012 to \$83.925 million is necessary to meet the continuing demand for nursing faculty and other advanced education nursing services throughout the United States. The program provides for competitive grants that help enhance advanced nursing education and practice and traineeships for individuals in advanced nursing education programs.

There continues to be high demand for CRNA workforce in clinical and educational settings. Between 2000–2010, the number of nurse anesthesia educational program graduates doubled, with the Council on Certification of Nurse Anesthetists (CCNA) reporting 1,075 graduates in 2000 and 2,375 graduates in 2010. This growth is leveling off somewhat, but is expected to continue. The demand for nurse anesthetists continues to rise. The problem is not that our 112 accredited programs of nurse anesthesia are failing to attract qualified applicants. It is that they have to turn them away by the hundreds. The AANA has been working with the 112 accredited nurse anesthesia educational programs to increase the number of qualified graduates. To truly meet the nurse anesthesia workforce challenge, the capacity and number of CRNA schools must continue to grow. With the help of competitively awarded grants supported by Title VIII funding, the nurse anesthesia profession is making significant progress, expanding both the number of clinical practice sites and the number of graduates.

The AANA is pleased to report that this progress is extremely cost-effective from the standpoint of Federal funding. Anesthesia can be provided by nurse anesthetists, physician anesthesiologists, or by CRNAs and anesthesiologists working together. As mentioned earlier, the Health Affairs study by Dulisse and Cromwell indicates the safety of CRNA care. Another study published recently in *Nursing Economics* indicates that costs of educating and training a CRNA from undergraduate education through graduate education is roughly 15 percent of the cost of educating and training an anesthesiologist (Hogan, PF, Seifert RF, Moore CS, Simonson BE, *Cost Effectiveness Analysis of Anesthesia Providers, Nurs Econ.* 2010;28(3): 150–169.) This study also found that among anesthesia delivery models, CRNAs acting independently provide anesthesia services at the lowest economic cost; costs for this model are 25 percent less than the second lowest cost model in which an anesthesiologist supervises six CRNAs. Nurse anesthesia education represents a significant educational cost-benefit for supporting CRNA educational programs with Federal dollars vs. supporting other, more costly, models of anesthesia education.

We believe the Subcommittee should allocate \$4 million for nurse anesthesia education for several reasons. First, as this testimony has documented, the funding is cost-effective and needed. Second, this particular funding meets a distinct need not met elsewhere; nurse anesthesia is rural and medically underserved America is not affected by increases in the budget for the National Health Service Corps and community health centers, since those initiatives are for delivering primary and not surgical healthcare. Third, this funding meets an overall objective to increase access to quality healthcare in medically underserved America.

Title VIII Funding for Strengthening the Nursing Workforce

The AANA joins The Nursing Community and the Americans for Nursing Shortage Relief (ANSR) Alliance in support of the Subcommittee providing a total of \$251.099 million in fiscal year 2013 for nursing shortage relief through Title VIII.

AANA asks that of the \$251.099 million, \$83.925 million go to Advanced Education Nursing and \$4 million go to nurse anesthesia. The AANA appreciates the support for nurse education funding in fiscal year 2012 from this Subcommittee and from the Congress. In the interest of patients, we ask the Congress to invest in CRNA and nursing educational funding programs. Quality anesthesia care provided by CRNAs saves lives, promotes quality of life, and makes fiscal sense. This Federal support for Title VIII and advanced education nurses will improve patient access to quality services and strengthen the Nation's healthcare delivery system.

Safe Injection Practices

As a leader in patient safety, the AANA has been playing a vigorous role in the development and projects of the Safe Injection Practices Coalition, intended to reduce and eventually eliminate the incidence of healthcare facility acquired infections. Provider education and awareness, detection, tracking and response are all extremely important to preventing healthcare-associated infections. In the interest of promoting safe injection practice and reducing the incidence of healthcare facility acquired infections, we recommend the Committee maintain its level of funding for CDC's Division of Healthcare Quality and Promotion so they can address outbreaks and promote innovative ways to adhere to injection safety and infection control guidelines. We also hope the committee will support the CDC's efforts around provider education and patient awareness activities, as this issue transcends provider type and it's important to educate all types of providers and patients alike.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF OPHTHALMOLOGY

EXECUTIVE SUMMARY

The American Academy of Ophthalmology requests fiscal year 2013 NIH funding of at least \$32 billion, which reflects a \$1.38 billion, or 4.5 percent increase over fiscal year 2012, which consists of biomedical inflation of 2.8 percent plus modest growth, and is necessary since:

- After nearly a decade of budgets below biomedical inflation, NIH's inflation-adjusted funding is close to 20 percent lower than fiscal year 2003.
 - Even before adjusting for inflation, enacted spending bills in recent years have cut the NIH budget. The looming sequestration mandated by the Budget Control Act threatens further cuts, estimated by the Congressional Budget Office (CBO) at 8 percent in fiscal year 2013 alone.
- NIH, our Nation's biomedical research enterprise, is unique in that:
- Its basic and clinical research has helped to understand the basis of disease, thereby resulting in innovations in healthcare to save and improve lives.
 - Its research serves an irreplaceable role that the private sector could not duplicate.
 - It has been shown through several studies to be a major force in the economic health of communities across the Nation. The latest United for Medical Research report estimates that NIH funding supported more than 432,000 jobs in 2011, directly or indirectly, and generated more than \$62.1 billion in economic activity.

The American Academy of Ophthalmology requests National Eye Institute (NEI) funding at \$730 million, commensurate with the overall NIH funding increase, especially since:

- Fiscal year 2012 NEI funding of \$702 million reflects little more than 1 percent of the \$68 billion annual cost of eye disease and vision impairment in the United States.
- NEI has funded breakthrough research ranging from determining the genetic basis of eye disease to developing treatments that save and restore sight.
- In 2009, the Congress spoke volumes in passing S. Res. 209 and H. Res. 366, which designated 2010–2020 as The Decade of Vision, in which the majority of 78 million baby boomers will turn 65 years of age and face greatest risk of aging eye disease. A cut, level funding, or even an inflationary increase is not sufficient for NEI to meet the vision challenges presented by the "Silver Tsunami."

CONGRESS MUST IMPROVE UPON THE PRESIDENT'S FISCAL YEAR 2013 REQUEST, SINCE IT CUTS NEI FUNDING BY \$8.86 MILLION, OR 1.2 PERCENT BELOW FISCAL YEAR 2012, WHICH RESULTS IN FUNDING CLOSE TO THE BASE FISCAL YEAR 2009 LEVEL

Although the President's budget request level-funds NIH, it proposes to cut NEI by \$8.8 million. Although most of this cut reflects the NIH Office of AIDS Research pulling its funding from the NEI's Studies of Ocular Implications of AIDS (SOCA)

clinical trials, which established the efficacy of combination antiviral drug therapy in treating cytomegalovirus (CMV) retinitis, the resulting total NEI funding of \$693 million reflects a funding level just slightly higher than that in fiscal year 2009, prior to the addition of American Recovery and Reinvestment Act (ARRA) funding. Although the NEI's Congressional Justification (CJ) notes that this funding level will still enable NEI to increase Research Project Grant (RPG) funding by \$3 million, it will still cut training programs and Research and Development contracts.

NEI is already facing enormous challenges in this Decade of Vision 2010–2020. Each day, from 2011 to 2029, 10,000 citizens will turn 65 and be at greatest risk for eye disease, the fast growing African-American and Hispanic populations will experience a disproportionately higher incidence of eye disease, and the epidemic of obesity will significantly increase the incidence of diabetic retinopathy.

The Academy requests NEI funding at \$730 million, reflecting biomedical inflation plus modest growth commensurate with that of NIH overall, since our Nation's investment in vision health is an investment in overall health. NEI's breakthrough research is a cost-effective investment, since it is leading to treatments and therapies that can ultimately delay, save, and prevent health expenditures, especially those associated with the Medicare and Medicaid programs. It can also increase productivity, help individuals to maintain their independence, and generally improve the quality of life, especially since vision loss is associated with increased depression and accelerated mortality.

The very health of the vision research community is also at stake with a decrease in NEI funding. Not only will funding for new investigators be at risk, but also that of seasoned investigators, which threatens the continuity of research and the retention of trained staff, while making institutions more reliant on bridge and philanthropic funding. If an institution needs to let staff go, that usually means a highly-trained person is lost to another area of research or an institution in another State, or even another country.

FISCAL YEAR 2013 NIH FUNDING OF AT LEAST \$32 BILLION, NEI AT \$730 MILLION LETS
NEI BUILD UPON ITS PAST RECORD OF BASIC AND TRANSLATIONAL RESEARCH

In late June 2010, NIH Director Francis Collins, M.D., Ph.D. recognized NEI's leadership in translational research at an NEI-sponsored Translational Research and Vision Conference. Just 2 weeks earlier, Dr. Collins testified before the House Energy and Commerce Committee, stating that:

"Twenty years ago we could do little to prevent or treat AMD. Today, because of new treatments and procedures based on NIH/NEI research, 1.3 million Americans at risk for severe vision loss from AMD over the next 5 years can receive potentially sight-saving therapies."

With fiscal year 2013 funding at \$730 million, NEI can build upon its past research in several different areas, including:

Genetic Basis of Eye Disease.—As NEI Director Paul Sieving, M.D., Ph.D. has stated, of the more than 2,000 genes identified to date, more than 500, or one-quarter, are associated with both common and rare eye diseases. By further understanding the genetic basis of eye disease, NEI can study underlying disease mechanisms and develop appropriate diagnostic and therapeutic applications for such blinding eye diseases as AMD, glaucoma, and retinitis pigmentosa (RP).

—NEI's AMD Gene Consortium, which consolidates 15 international Genome Wide Association Studies (GWAS) representing more than 8,000 patients, has validated 8 previously known gene variants and identified 19 new variants.

—NEI's Glaucoma Human Genetics Collaboration (NEIGHBOR) has identified the first risk variant in a gene thought to play a role in the development of the optic nerve head, the degeneration of which leads to glaucoma and loss of peripheral vision, and then ultimately blindness.

—The NEI-led human gene therapy clinical trial for neurodegenerative eye disease Leber Congenital Amaurosis (LCA) has resulted to date in 15 patients being treated and experiencing visual improvement. NEI's pioneering work, as well as subsequent refinement of gene therapy techniques, is enabling further research into ocular gene therapy through the launch of NEI-funded clinical trials for AMD, choroideremia, Stargardt disease, and Usher Syndrome. The latter three neurodegenerative diseases occur in early childhood and progressively destroy the retina, leading to vision loss and blindness and resulting in a lifetime of direct medical and indirect support costs. NEI is also funding pre-clinical safety trials for human gene therapy for RP, juvenile retinoschisis ("splitting" of the retina, resulting in vision loss), and achromatopsia (affecting color perception and visual acuity).

Diabetic Eye Disease.—NEI's Diabetic Retinopathy Clinical Research (DRCR) Network found that laser treatment for diabetic macular edema, when combined with anti-angiogenic drug treatment, is more effective than laser treatment alone and will revolutionize the standard of care in place the past 25 years. With the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) leading a new NIH strategic plan to combat diabetes, NEI's research through its various diabetic eye disease networks over the past 40 years—in partnership with NIDDK—will be more important than ever. For example, about 1-in-5 individuals in the NEI-funded Los Angeles Latino Eye Study (LALES) was newly diagnosed with diabetes during the study, and of those newly diagnosed, 23 percent were found to already have diabetic retinopathy.

BLINDNESS AND VISION LOSS IS A GROWING PUBLIC HEALTH PROBLEM THAT INDIVIDUALS FEAR AND WOULD TRADE YEARS OF LIFE TO AVOID

The NEI estimates that more than 38 million Americans age 40 and older experience blindness, low vision, or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by year 2020. Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is \$68 billion, this number does not fully quantify the impact of indirect healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. NEI's fiscal year 2012 funding of \$702 million reflects just a little more than 1 percent of this annual costs of eye disease. The continuum of vision loss presents a major public health problem, as well as a significant financial challenge to the public and private sectors.

Vision loss also presents a real fear to most citizens:

- In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer.
- NEI's Survey of Public Knowledge, Attitudes, and Practices Related to Eye Health and Disease reported that 71 percent of respondents indicated that a loss of their eyesight would rate as a "10" on a scale of 1 to 10, meaning that it would have the greatest impact on their day-to-day life.
- In patients with diabetes, going blind or experiencing other vision loss rank among the top four concerns about the disease. These patients are so concerned about vision loss diminishing their quality of life that those with nearly perfect vision (20/20 to 20/25) would be willing to trade 15 percent of their remaining life for "perfect vision," while those with moderate impairment (20/30 to 20/100) would be willing to trade 22 percent of their remaining life for perfect vision. Patients who are legally blind from diabetes (20/200 to 20/400) would be willing to trade 36 percent of their remaining life to regain perfect vision.

The Academy urges the Congress to fund the NIH and NEI at funding levels of at least \$32 billion and \$730 million, respectively, which will ensure the momentum of breakthrough vision research and the retention of trained vision researchers.

ABOUT THE AMERICAN ACADEMY OF OPHTHALMOLOGY

The American Academy of Ophthalmology is the largest national membership association of Eye M.D.s. Eye M.D.s are ophthalmologists, medical and osteopathic doctors who provide comprehensive eye care, including medical, surgical and optical care. More than 90 percent of practicing U.S. Eye M.D.s are Academy members, and the Academy has more than 7,000 international members.

PREPARED STATEMENT OF THE AMERICAN ACADEMY OF PEDIATRICS

The American Academy of Pediatrics (AAP), a nonprofit professional organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates the opportunity to submit this statement for the record in support of strong Federal investments in children's health in fiscal year 2013 and beyond. AAP urges all Members of Congress to put children first when considering short and long-term Federal spending decisions.

Every adult was once a child. Many adult diseases have their origins in childhood. Early and continued investments in our children's health are needed to prevent obesity, heart disease, substance use, and other chronic conditions that threaten America's health and fiscal solvency. As clinicians we not only diagnose and treat our patients, we also promote preventive interventions to improve overall health. Likewise,

as policymakers, you have an integral role in ensuring the health of future generations through adequate and sustained funding of vital Federal programs.

The economic strength and prosperity of our Nation rests largely on the health and well-being of our children. Therefore, the Nation's pediatricians insist that the Congress prioritize funding for programs that support the healthy development of children and adolescents.

America's Children Deserve Better

Babies born in the United States are less likely to survive until their first birthday than those in 30 other industrialized nations. Twenty-two percent of children in the United States now live in poverty. Many children suffer from food insecurity, unstable housing, family dysfunction, abuse and neglect. Such adverse childhood experiences are linked with "toxic stress," a biologic phenomenon associated with profound and irreversible changes in brain anatomy and chemistry that have been implicated in the development of health-threatening behaviors and medical complications later in life including drug use, obesity, and altered immune function. Adults affected by such adverse childhood experiences are more likely to have experienced school failure, gang membership, unemployment, violent crime, and incarceration.

Of the world's richest 21 nations, the United States comes in dead last in terms of overall health and safety of its children due to poor indicators on child health at birth, infant mortality rates, prevalence of low birth weight, child immunization rates for children aged 12 to 23 months, and deaths from accidents or injuries among people aged 0 to 19 years. America's current generation of children is at risk of having shorter life expectancies than their parents. This is unacceptable. America's children deserve better. As a Nation we must rise above partisan politics and reclaim the health and well-being of our children through strong Federal investments in programs that promote and protect the health of all children.

Children's Healthcare Is Not the Cost Driver of Overall Healthcare Spending

The United States continues to spend less on our children's health, education, and general welfare than most other developed nations in the world. Children under age 18 represent 30 percent of the total United States population, yet healthcare services for infants, children, and young adults are only 12 percent of total annual healthcare spending. Children, including those with special healthcare needs, make up more than 50 percent of all Medicaid recipients, but account for less than 25 percent of Medicaid costs.

By contrast, currently over two-thirds of Medicare expenditures are for beneficiaries with five or more chronic conditions, conditions like diabetes, arthritis, and hypertension that are largely preventable over the course of a lifetime. Strong and continued investments during childhood are critical to curbing the onset of chronic conditions that are growing healthcare costs. Proposed cuts to prevention and public health initiatives, community health programs, and child safety net services are counterproductive to efforts to reduce Government spending and control the deficit in the long-term.

Children's Programs Are Cost-Effective and Improve Our Nation's Health and Economy

Every \$1 spent on childhood vaccines in the Section 317 immunization program saves the healthcare system \$16.50 in future medical costs. Every \$1 spent on preventative services for a pregnant woman in the Special Supplemental Nutrition Program for Women, Infants, and Children saves Medicaid up to \$4.20 by reducing the risk of pre-term birth and its associated costs. Every \$1 spent on high-quality home visiting programs saves up to \$5.70 as a result of improved prenatal health, decreased mental health and criminal justice costs, and fewer children suffering from abuse and neglect. Our Nation's sickest and most vulnerable children rely on Federal programs like these to support their physical and mental health needs. Reducing funding for vital child health programs during a time when many families are still struggling financially will disproportionately hurt children.

The Administration for Children and Families, Centers for Disease Control and Prevention, Health Resources and Services Administration, and other agencies within the Department of Health and Human Services and the Department of Education provide essential services, research, and surveillance that help our Nation's children grow into healthy and productive citizens. Federal and State partnerships like the Title V Maternal and Child Health block grants and Section 317 immunization program support families by providing newborn screenings, immunizations, preventive health services and medical care that children need to be healthy.

Devoting adequate resources to Federal health programs helps ensure children have safe and healthy food at home and school, homes and communities free of environmental toxins, and disaster preparedness and response systems that address

their unique health needs. Federal funds support critical programs that address pressing public health challenges including: efforts to prevent infant mortality and birth defects; healthy child development; antimicrobial resistance and infectious diseases; emergency medical services for children; mental health and substance abuse prevention; tobacco prevention and cessation; unintentional injury and violence prevention; child maltreatment prevention; childhood obesity; environmental and chemical exposures; poison control; teen pregnancy prevention and family planning; health promotion in schools; and medical research and innovation.

Meeting our children's health needs also requires a robust pediatric workforce. Children are not just little adults. Pediatricians, including medical and surgical specialists, are trained to diagnose and treat the unique healthcare needs of children and adolescents. Unlike the adult population, our Nation currently faces a shortage of pediatric subspecialists, resulting in many children with serious acute and chronic illnesses being forced to travel long distances—or wait several months—to see a needed pediatric subspecialist. Federal support for pediatric workforce programs—Public Health Service Act Title VII health professions programs, Children's Hospital Graduate Medical Education Program and the Pediatric Subspecialty Loan Repayment Program—is crucial to building the necessary supply of pediatricians to ensure all children, regardless of where they live or their insurance status, have access to timely and appropriate healthcare.

Healthier Children, Healthier Future

On behalf of the 75 million American children and their families that we serve and treat, the Nation's pediatricians expect the Congress to respond to mounting evidence that child health has life-long impacts and put children first during appropriations negotiations. Investing in children is not only the right thing to do for the long-term physical, mental, and emotional health of the population, but is imperative for the Nation's long-term fiscal health as well. At a time when States are facing unprecedented challenges with dwindling budgets yet rising demand for health services, Federal investments in the public health infrastructure could not be more important. Federal support for children's health programs, such as early brain and child development, parenting and health education, and preventive health services, will yield high returns for the American economy.

We fully recognize the Nation's fiscal challenges and respect that difficult budgetary decisions must be made; however, we do not support funding decisions made at the expense of the health and welfare of children and families. Rather, focus on the long-term needs of children and adolescents will ensure that the United States can compete in the modern, highly educated global marketplace. Strong and sustained financial investments in children's healthcare, research, and prevention programs will help keep our children healthy and pay extraordinary dividends for years to come.

The American Academy of Pediatrics looks forward to working with Members of Congress to prioritize the health of our Nation's children in fiscal year 2013 and beyond. If we may be of further assistance please contact the AAP Department of Federal Affairs at 202-347-8600 or aperencevich@aap.org. Thank you for your consideration.

PREPARED STATEMENT OF ACADEMYHEALTH

AcademyHealth is pleased to offer this testimony regarding the role of health services research in improving our Nation's health and the performance of the healthcare and public health systems. AcademyHealth's mission is to support research that leads to accessible, high value, high-quality healthcare, reduces disparities, and improves health. We represent the interests of more than 4,000 scientists and policy experts and 160 organizations that produce and use research to improve health and healthcare. We advocate for the funding to support health services research; a robust environment to produce this research; and its more widespread dissemination and use.

Health services research studies how to make the healthcare and public health systems work better and deliver improved outcomes for more people, at greater value. These scientific findings improve health systems by informing patient and healthcare provider choices; enhancing the quality, efficiency, and value of the care patients receive; improving patients' access to care, and supporting efficient community wide systems. Health services research both uncovers critical challenges confronting our Nation's healthcare system, and seeks ways to address them.

Finding new ways to get the most out of every healthcare dollar is critical to our Nation's long-term fiscal health. Like any corporation making sure it is developing

and providing high-quality products, the Federal Government has a responsibility to get the most value out of every taxpayer dollar it spends on Federal health programs, including Medicare, Medicaid, Children's Health Insurance Program, and veterans' and service members' health.

Funding for research on the quality, value, and organization of the health system will deliver real savings for the Federal Government, employers, insurers, and consumers. Research into the merits of different policy options for delivery system transformation, patient-centered quality improvement, community health, and disease prevention offers policymakers in both the public and private sectors the information they need to improve quality and outcomes, identify waste, eliminate fraud, increase efficiency and value, and promote personal choice.

Despite the positive impact health services research has had on the U.S. healthcare system, and the potential for future improvements in quality and value, the United States spends less than one cent of every healthcare dollar on this research; research that can help Americans spend their healthcare dollars more wisely and make more informed healthcare choices.

AcademyHealth greatly appreciates the subcommittee's historic efforts to increase the Federal investment in health services research. We respectfully ask that the subcommittee further strengthen the capacity of health services research to address the pressing challenges America faces in providing access to high-quality, efficient care. The following list summarizes AcademyHealth's fiscal year 2013 funding recommendations for agencies that support health services research and health data under the subcommittee's jurisdiction.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ funds health services research and healthcare improvement programs that are transforming people's health in communities in every State around the Nation. The science funded by AHRQ provides consumers and their healthcare professionals with valuable evidence to make the right healthcare decisions for themselves and their families. AHRQ's research also provides the basis for protocols that prevent medical errors and reduce hospital-acquired infections, and improve patient confidence, experiences, and outcomes in hospitals, clinics, and physician offices.

AcademyHealth joins the Friends of AHRQ—an alliance of more than 250 health professional, research, consumer, and employer organizations that support the agency—in recommending an overall funding level of \$400 million in base discretionary funding for AHRQ in fiscal year 2013.

In light of the need for increased funding of health services research, AcademyHealth is concerned about the President's use of the Patient-Centered Outcomes Research (PCOR) Trust Fund transfer to supplant AHRQ's discretionary budget. The PCOR Trust Fund transfer was intended to supplement AHRQ's base discretionary budget. In the President's fiscal year 2013 budget request, however, \$62 million from the PCOR Fund transfer is used to supplant AHRQ's existing programs. This de facto 10 percent funding cut further compromises AHRQ's ability to achieve its statutory mission: generating the broad evidence base on healthcare quality, costs, and access necessary to build a high-quality, high-value healthcare system.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency. Housed within the Centers for Disease Control and Prevention (CDC), it provides critical data on all aspects of our healthcare system through data cooperatives and surveys that serve as a gold standard for data collection around the world. AcademyHealth appreciates the subcommittee's leadership in securing steady and sustained funding increases for NCHS in recent years. Such efforts have allowed NCHS to reinstate some data collection and quality control efforts, continue the collection of vital statistics, and enhanced the agency's ability to modernize surveys to reflect changes in demography, geography, and health delivery.

We join the Friends of NCHS—a coalition of more than 250 health professional, research, consumer, industry, and employer organizations that support the agency—in endorsing the President's fiscal year 2013 request of \$162 million in base discretionary funding, to build on your previous investments and put the agency on track to become a fully functioning, 21st century, national statistical agency.

The Affordable Care Act recognizes the need for linking the medical care and public health delivery systems by authorizing a new CDC research program to identify effective strategies for organizing, financing, and delivering public health services in real-world community settings. AcademyHealth joins the CDC Coalition in seek-

ing \$7.8 billion for CDC in fiscal year 2013, and seeks new funding for public health services and systems research.

NATIONAL INSTITUTES OF HEALTH

NIH spends approximately \$1 billion on health services research annually—roughly 3 percent of its entire budget—making it the largest Federal sponsor of health services research. We join the Ad Hoc Group for Medical Research in seeking at least \$32 billion for NIH in fiscal year 2013. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation. AcademyHealth believes that NIH should increase the proportion of its overall funding that goes to health services research to ensure that discoveries from clinical trials are effectively translated into health services. We also encourage NIH to foster greater coordination of its health services research investment across its institutes, and to sustain investment in its Clinical and Translational Science Awards (CTSA) as the agency transitions to its new National Center for Advancing Translational Sciences (NCATS). The CTSA program enables innovative research teams to speed discovery and advance science aimed at improving our Nation's health. The program encourages collaboration in solving complex health and research challenges and finding ways to turn their discoveries into practical solutions for patients.

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Steady funding decreases for the Office of Research, Development and Information have hindered CMS's ability to meet its statutory requirements and conduct new research to strengthen public insurance programs, which together cover nearly 100 million Americans and comprise 45 percent of America's total health expenditures. As these Federal entitlement programs continue to pose significant budget challenges for both Federal and State governments, it is critical that we adequately fund research to evaluate the programs' efficiency and effectiveness and seek ways to manage their projected spending growth. AcademyHealth supports CMS's discretionary research and development budget to improve the effectiveness and efficiency of these programs.

In conclusion, the accomplishments of health services research would not be possible without the leadership and support of this subcommittee. We urge the subcommittee to accept our fiscal year 2013 funding recommendations for the Federal agencies funding health services research and health data.

PREPARED STATEMENT OF THE ADULT CONGENITAL HEART ASSOCIATION

Introduction

The Adult Congenital Heart Association (ACHA)—a national not-for-profit organization dedicated to improving the quality of life and extending the lives of adults with congenital heart disease (CHD)—is grateful for the opportunity to submit written testimony regarding fiscal year 2013 funding for congenital heart research and surveillance. We respectfully request \$2 million for CHD surveillance at the Centers for Disease Control and Prevention (CDC) as well as additional CHD research at the National Heart, Lung and Blood Institute (NHLBI).

Adult Congenital Heart Disease

Congenital heart defects are the most common group of birth defects occurring in nearly 1 percent of all live births, or 40,000 babies a year. These malformations of the heart and structures connected to the heart either obstruct blood flow or cause it to flow in an abnormal pattern. This abnormal heart function can be fatal if left untreated. In fact, congenital heart defects remain the leading cause of birth defect related infant deaths.

Many infants born with congenital heart problems require intervention in order to survive. Intervention often includes one or multiple open-heart surgeries; however, surgery is rarely a long-term cure. Children born with heart defects have a significantly decreased life expectancy. One in 10 won't survive to adulthood. Among those with the most complex heart defects, only half will make it to age 18.

The success of childhood cardiac intervention has created a new chronic disease—congenital heart disease (CHD). Thanks to the increase in survival, of the over 2 million people alive today with CHD, more than half are adults, increasing at an estimated rate of 5 percent each year. Few congenital heart survivors are aware of their high risk of additional problems as they age, facing high rates of neuro-cog-

nitive deficits, heart failure, rhythm disorders, stroke, and sudden cardiac death, and many survivors require multiple operations throughout their lifetime. Fifty percent of all congenital heart survivors have complex problems for which lifelong care from congenital heart specialists is recommended, yet less than 10 percent of adult congenital heart patients receive recommended cardiac care. Delays in care can result in premature death and disability. In adults, this often occurs during prime wage-earning years.

The public health burden of CHD has yet to be fully assessed. However, the limited available research suggests that medical costs associated with congenital heart defects are substantial. \$1.2 billion is the estimated lifetime cost for U.S. children born in a single year with one of four major heart defects. It is estimated that in 2009, the hospital cost for roughly 27,000 hospital stays for children treated primarily for CHD in the United States was nearly \$1.5 billion. In the same year, hospital costs for roughly 12,000 hospital stays of adults treated primarily for CHD was at least \$280 million. Investing in CHD surveillance and research will improve outcomes for CHD survivors, decreasing disability and improving productivity.

Adult Congenital Heart Association

ACHA serves and supports the more than 1 million adults with CHD, their families and the medical community—working with them to address the unmet needs of the long-term survivors of congenital heart defects through education, outreach, advocacy, and promotion of ACHD research.

In order to promote life-saving research and accessible, appropriate and quality interventions which, in turn, will reduce the public health burden of this chronic disease, ACHA advocates for adequate funding of CDC initiatives relating to CHD, and encourages funding within the National Institutes of Health (NIH) for CHD research. ACHA continues to work with Federal and State policymakers to advance policies that will improve and prolong the lives of those living with CHD.

ACHA is also a founding member of the Congenital Heart Public Health Consortium (CHPHC). The CHPHC is a group of organizations uniting resources and efforts to prevent the occurrence of CHD and enhance and prolong the lives of those with CHD through targeted public health interventions by enhancing and supporting the work of the member organizations. Representatives of Federal agencies serve in an advisory capacity. In addition to ACHA, the Alliance for Adult Research in Congenital Cardiology, American Academy of Pediatrics, American College of Cardiology, American Heart Association, March of Dimes Foundation, National Birth Defects Prevention Network, and the National Congenital Heart Coalition are all members of the CHPHC.

Federal Support for Congenital Heart Disease Research and Surveillance

Despite the prevalence and seriousness of the disease, CHD data collection and research are limited and almost non-existent for the adult CHD population. In 2004, the NHLBI convened a working group on CHD, which recommended developing a research network to conduct clinical research and establishing a national database of patients.

In March 2010, the first CHD legislation passed as part of Patient Protection and Affordable Care Act (ACA).¹ The ACA calls for the creation of The National Congenital Heart Disease Surveillance System, which will collect and analyze nationally representative, population-based epidemiological and longitudinal data on infants, children, and adults with CHD to improve understanding of CHD incidence, prevalence, and disease burden and assess the public health impact of CHD. It also authorized the NHLBI to conduct or support research on CHD diagnosis, treatment, prevention and long-term outcomes to address the needs of affected infants, children, teens, adults, and elderly individuals. These provisions included in the ACA were originally in the Congenital Heart Futures Act (H.R. 1570/S. 621, 111th Congress), which garnered bipartisan support in both the House and Senate and was championed by Senators Richard Durbin (D-IL) and Thad Cochran (R-MS), Representative Gus Bilirakis (R-FL) and former Representative Zack Space (D-OH).

Recently, the National Center on Birth Defects and Developmental Disabilities included preventing congenital heart defects and other major birth defects in its recently published 2011–2015 Strategic Plan, specifically recognizing the need for understanding the contribution of birth defects to longer term outcomes (i.e., beyond infancy) and the economic impact of specific birth defects.

¹Patient Protection and Affordable Care Act, § 10411(b).

The National Congenital Heart Disease Surveillance System at Centers for Disease Control and Prevention

As survival improves, so does the need for population-based surveillance across the lifespan. Funding to support the development of the National Congenital Heart Disease Surveillance System through both a pilot adult surveillance program, and the enhancement of the existing birth defects surveillance system, will be instrumental in driving research, improving interventional outcomes, improving loss to care, and assessing healthcare burden. In turn, the National Congenital Heart Disease Surveillance System can serve as a model for all chronic disease states.

The current surveillance system is grossly inadequate. There are only 14 States currently funded by the CDC to gather data on birth defects, presenting limitations in generalizing the information across the entire population. Thus, there are significant inconsistencies in the methods of collection and reporting across the various State systems, which limits the value of the data. Given the absence of population-based data across the lifespan, the data we do have excludes anyone diagnosed after the age of one, as well as those who are lost to care. It is this population, those lost to care, that is of greatest concern, and most difficult to identify. Evidence indicates that those with CHD are at significant risk for heart failure, rhythm disorders, stroke, and sudden cardiac death as they age, requiring ongoing specialized medical care. For those who are lost to care, for reasons such as limited access to affordable or appropriate care or poor education about the need for ongoing care, they often return to the system with preventable advanced illness and/or disability. Population-based surveillance across the lifespan is the only method by which these patients can be identified, and, as a result, appropriate intervention can be planned. ACHA is currently working with the CDC to address these concerns through the National Congenital Heart Disease Surveillance System.

The fiscal year 2012 appropriations bill provided \$2 million to the CDC for surveillance of congenital heart defects. In February 2013, the CDC announced a funding opportunity using these authorized funds. The CDC states that the “purpose of this program is to provide support through CDC cooperative agreements for non-research activities to develop robust, population-based estimates of the prevalence of CHDs focusing on adolescents and adults, and better understand the survival, healthcare utilization, and longer term outcomes of adolescents and adults affected by CHDs. The program is a pilot and designed as a learning collaborative effort between CDC and grantees with potentially unique and innovative approaches to monitoring CHDs among adolescents and adults.”

ACHA requests that the Congress provide the CDC \$2 million in fiscal year 2013 to continue to support data collection to better understand CHD prevalence and assess the public health impact of CHD. This level of funding will support a pilot adult surveillance system and allow for the enhancement of the existing birth defects surveillance system.

Funding of Research Related to Congenital Heart Disease at National Institutes of Health

Our Nation continues to benefit from the single largest funding source for CHD research, the NIH. Yet, as a leading chronic disease, congenital heart research is significantly underfunded.

The NHLBI supports basic and clinical research to establish a scientific basis for the prevention, detection, and treatment of CHD. The Bench to Bassinet Program is a major effort launched by the NHLBI to hasten the pace at which heart research on genetics and basic science can be developed into new treatments across the lifespan for people with CHD. The overall goal is to provide the structure to turn knowledge into clinical practice, and use clinical practice to inform basic research.

ACHA urges the Congress to support the NHLBI in efforts to continue its work with patient advocacy organizations, other NIH Institutes and Centers, and the CDC to expand collaborative research initiatives and other related activities targeted to the diverse lifelong needs of individuals living with congenital heart disease.

Summary

Thank you for the opportunity to highlight this important disease and the important work done by the CDC and NIH. We know that you face many difficult funding decisions for fiscal year 2013 and hope that you consider addressing the lifelong needs of those with CHD. By making an investment in the research and surveillance of CHD, the return will be seen through reduced healthcare costs, decreased disability and improved productivity in a population quickly approaching 3 million.

PREPARED STATEMENT OF THE AMERICAN CONGRESS OF OBSTETRICIANS AND
GYNECOLOGISTS

The American Congress of Obstetricians and Gynecologists, representing 57,000 physicians and partners in women's healthcare, is pleased to offer this statement to the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education. We thank Chairman Harkin, and the entire subcommittee for the opportunity to provide comments on some of the most important programs to women's health. Today, the United States lags behind other nations in healthy births, yet remains high in birth costs. ACOG's Making Obstetrics and Maternity Safer (MOMS) initiative seeks to improve maternal and infant outcomes through investment in all aspects of the cycle of research, including comprehensive data collection and surveillance, biomedical research, and translation of research into evidence-based practice and programs delivered to women and babies, and we urge you to make this a top priority in fiscal year 2013.

DATA COLLECTION AND SURVEILLANCE AT THE CENTERS FOR DISEASE CONTROL AND
PREVENTION (CDC)

In order to conduct robust research, uniform, accurate and comprehensive data and surveillance are critical. The National Center for Health Statistics is the Nation's principal health statistics agency and collects State data from records like birth certificates that give us raw, vital statistics. The birth certificate is the key to gathering vital information about both mother and baby during pregnancy and labor and delivery. The 2003 United States standard birth certificate collects a wealth of knowledge in this area, yet 25 percent of States are still not using it. States without these resources are likely underreporting maternal and infant deaths and complications from childbirth and causes of these deaths remains unknown. Use must be expanded to all 50 States, ensuring that uniform, accurate data is collected nationwide. ACOG supports the President's fiscal year 2013 budget request of \$16.45 million to modernize the National Vitals Statistics System, which would help States update their birth and death records systems.

The Pregnancy Risk Assessment Monitoring System (PRAMS) at CDC extends beyond vital statistics and surveys new mothers on their experiences and attitudes during pregnancy, with questions on a range of topics, including what their insurance covered to whether they had stressful experiences during pregnancy, when they initiated prenatal care, and what kinds of questions their doctor covered during prenatal care visits. By identifying trends and patterns in maternal health, researchers better understand indicators of preterm birth. This data allows CDC and State health departments to identify behaviors and environmental and health conditions that may lead to preterm births. Only 40 States use the PRAMS surveillance system today.

National data on maternal mortality is inconsistent and incomplete due to the lack of standardized reporting definitions and mechanisms. To capture the accurate number of maternal deaths and plan effective interventions, maternal mortality should be addressed through multiple, complementary strategies. ACOG recommends that Health and Human Services (HHS) fund States in implementing maternal mortality reviews that would allow them to conduct regular reviews of all deaths within the State to identify causes, factors in the communities, and strategies to address the issues. Combined with adoption of the recommended birth and death certificates in all States and territories, CDC could then collect uniform data to calculate an accurate national maternal mortality rate. Results of maternal mortality reviews will inform research needed to identify evidence based interventions addressing causes and factors of maternal mortality and morbidity.

ACOG urges the Congress to provide \$10 million to Health and Human Services to assist States in setting up maternal mortality reviews. ACOG also urges the Congress to provide \$50,000 to NIH to hold a workshop to identify definitions for severe maternal morbidity and \$100,000 to HHS to develop a research plan to identify and monitor severe maternal morbidity.

BIOMEDICAL RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH (NIH)

Biomedical research is critically important to understanding the causes of prematurity and developing effective prevention and treatment methods. Prematurity rates have increased almost 35 percent since 1981, and cost the Nation \$26 billion annually, \$51,600 for every infant born prematurely. Direct healthcare costs to employers for a premature baby average \$41,610, 15 times higher than the \$2,830 for a healthy, full-term delivery. A breakthrough study conducted by the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD)

last year showed a significant reduction in preterm delivery among women with short cervixes who are administered vaginal progesterone. The results were especially positive in reducing births pre-28 weeks. The results of this study are expected to save the healthcare system \$500 million a year. Additional research can help drive down our prematurity rates further, saving dollars and lives. Sustaining the investments at NIH is vital to achieving this goal, and therefore ACOG supports a minimum of \$32 billion for NIH in fiscal year 2013.

Adequate levels of research require a robust research workforce. The average investigator is in his/her forties before receiving their first NIH grant, a huge disincentive for students considering bio-medical research as a career. Complicating matters, there is a gap between the number of women's reproductive health researchers being trained and the need for such research. The NICHD-coordinated Women's Reproductive Health Research (WRHR) Career Development program seeks to increase the number of ob-gyns conducting scientific research in women's health in order to address this gap. To date 170 WRHR Scholars have received faculty positions, and 7 new and competing WRHR sites were added in 2010.

PUBLIC HEALTH PROGRAMS AT THE HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Projects at HRSA and CDC are integral to translating research findings into evidence-based practice changes in communities. Where NIH conducts research to identify causes of preterm birth, CDC and HRSA fund programs that provide resources to mothers to help prevent preterm birth, and help identify factors contributing to preterm birth and poor maternal outcomes. The Maternal Child Health Block Grant at HRSA is the only Federal program that exclusively focuses on improving the health of mothers and children. State and territorial health agencies and their partners use MCH Block Grant funds to reduce infant mortality, deliver services to children and youth with special healthcare needs, support comprehensive prenatal and postnatal care, screen newborns for genetic and hereditary health conditions, deliver childhood immunizations, and prevent childhood injuries.

These early healthcare services help keep women and children healthy, eliminating the need for later costly care. Every \$1 spent on preconception care for women with diabetes can reduce health costs by up to \$5.19 by preventing costly complications in both mothers and babies. Every \$1 spent on smoking cessation counseling for pregnant women saves \$3 in neonatal intensive care costs. The MCH block grant has seen an almost \$30 million decrease in funding in the past 5 years alone. ACOG urges you not to cut the MCH block grant any further and for fiscal year 2013 we request \$645 million for the block grant to maintain its current level of services.

Family planning is essential to helping ensure healthy pregnancies and reducing the risk of preterm birth. The Title X Family Planning Program provides services to more than 5 million low-income men and women at more than 4,500 service delivery sites. Every \$1 spent on family planning results in a \$4 savings to Medicaid. Services provided at Title X clinics accounted for \$3.4 billion in healthcare savings in 2008 alone. ACOG supports \$327 million for Title X in fiscal year 2013 to sustain its level of services.

The Healthy Start Program through HRSA promotes community-based programs that help reduce infant mortality and racial disparities in perinatal outcomes. These programs are encouraged to use the Fetal and Infant Mortality Review (FIMR) which brings together ob-gyn experts and local health departments to help specifically address local issues contributing to infant mortality. Today, more than 220 local programs in 42 States find FIMR a powerful tool to help reduce infant mortality, including understanding issues related to preterm delivery. For over 20 years, ACOG have partnered with the Maternal and Child Health Bureau to sponsor the designated resource center for FIMR Programs, the National FIMR Program. ACOG supports \$.5 million for HRSA to increase the number of Healthy Start programs that use FIMR.

The Safe Motherhood Initiative at CDC works with State health departments to collect information on pregnancy-related deaths, track preterm births, and improve maternal outcomes. The Initiative also promotes preconception care, a key to reducing the risk of preterm birth. For fiscal year 2013, we recommend a sustained funding level of at least \$44 million for the Safe Motherhood Program, and the inclusion of a \$2 million preterm birth sub-line to ensure continued support for preterm birth research, as authorized by the PREEMIE Act.

Regional quality improvement initiatives encourage use of evidence-based quality improvement projects in hospitals and medical practices to reduce the rate of preterm birth. Under the Ohio Perinatal Quality Collaborative, started in 2007 with

funding from CDC, 21 OB teams in 25 hospitals have decreased scheduled deliveries between 36 and 39 weeks gestation, in accordance with ACOG guidelines, significantly reducing pre-term births.

Finally, ACOG is proud to partner with the Department of Health and Human Services and the March of Dimes on Strong Start, a multi-faceted perinatal health campaign to reduce preterm births. Strong Start contains two strategies. The first is a public-private partnership to reduce elective deliveries prior to 39 weeks through a public awareness campaign and quality improvement efforts. The second is a funding opportunity to test innovative prenatal care approaches to reduce preterm births for women covered by Medicaid and at risk for preterm birth. Strong Start has the potential to make a huge difference in reducing the rate of pre-term birth. We urge the subcommittee to continue investing in programs like Strong Start.

Again, we would like to thank the subcommittee for its consideration of funding for programs to improve women's health, and we urge you to consider our MOMS Initiative in fiscal year 2013.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF PHYSICIANS

The American College of Physicians (ACP) is pleased to submit the following statement for the record on its priorities, as funded under the U.S. Department of Health and Human Services, for fiscal year 2013. ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 132,000 internal medicine specialists (internists), related subspecialists, and medical students.

As the Subcommittee begins deliberations on appropriations for fiscal year 2013, ACP is urging funding for the following proven programs to receive appropriations from the Subcommittee:

- Title VII, Section 747, Primary Care Training and Enhancement, at no less than \$71 million;
- National Health Service Corps, \$535,087,442 in discretionary funding, in addition to the \$300 million in enhanced funding through the Community Health Centers Fund;
- National Health Care Workforce Commission, \$3 million;
- Agency for Healthcare Research and Quality, \$400 million in base discretionary funding; and
- Centers for Medicare and Medicaid Services, Operations and Management of Exchanges, \$574.5 million.

The United States is facing a growing shortage of physicians in key specialties, most notably in general internal medicine and family medicine—the specialties that provide primary care to most adult and adolescent patients. With enactment of the Affordable Care Act (ACA), we expect the demand for primary care services to increase with the addition of 32 million Americans receiving access to health insurance, once the law is fully implemented. A recent study projects that there will be a shortage of up to 44,000 primary care physicians for adults, even before the increased demand for healthcare services that will result from near universal coverage is taken into account (Colwill JM, Cultice JM, Kruse RL. Will generalist physician supply meet demands of an increasing and aging population? *Health Aff (Millwood)*. 2008 May–June; 27(3):w232–41. Epub 2008 April 29. Accessed at <http://content.healthaffairs.org/content/27/3/w232.full> on January 14, 2011.). Without critical funding for vital workforce programs, this physician shortage will only grow worse. A strong primary care infrastructure is an essential part of any high-functioning healthcare system, with over 100 studies showing primary care is associated with better outcomes and lower costs of care (http://www.acponline.org/advocacy/where_we_stand/policy/primary_shortage.pdf).

The health professions education programs, authorized under Title VII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA), support the training and education of healthcare providers to enhance the supply, diversity, and distribution of the healthcare workforce, filling the gaps in the supply of health professionals not met by traditional market forces, and are critical to help institutions and programs respond to the current and emerging challenges of ensuring all Americans have access to appropriate and timely health services. Within the Title VII program, while we applaud the President's request for \$51 million for the Section 747, Primary Care Training and Enhancement, we urge the Subcommittee to fund the program at \$71 million, in order to maintain and expand the pipeline of primary care production and training. The Section 747 program is the only source of Federal training dollars available for general internal

medicine, general pediatrics, and family medicine. For example, general internists, who have long been at the frontline of patient care, have benefitted from Title VII training models that promoted interdisciplinary training that helped prepare them to work with other health professionals, such as physician assistants, patient educators and psychologists. Without a substantial increase of funding, HRSA will not be able to carry out a competitive grant cycle for the second year in a row for physician training; the Nation needs new initiatives relating to increased training in inter-professional care, the patient-centered medical home, and other new competencies required in our developing health system.

The College urges \$535,087,442 in appropriations for the National Health Service Corps (NHSC), the amount authorized for fiscal year 2013 under the ACA; this is in addition to the \$300 million in enhanced funding the Health and Human Services Secretary has been given the authority to provide to the NHSC through the Community Health Care Fund. Since enactment of the ACA, the NHSC has awarded nearly \$900 million in scholarships and loan repayment to healthcare professionals to help expand the country's primary care workforce and meet the healthcare needs of communities across the country and there are nearly three times the number of NHSC clinicians working in communities across America than there were 3 years ago, increasing Americans' access to healthcare. With field strength of more than 10,000 clinicians, NHSC provides healthcare services to about 10.5 million patients across the country; the increase in funds must be sustained to help address the health professionals' workforce shortage and growing maldistribution. The programs under NHSC have proven to make an impact in meeting the healthcare needs of the underserved, and with more appropriations, they can do more.

We urge the Subcommittee to fully fund the National Health Care Workforce Commission, as authorized by the ACA, at \$3 million. The Commission is authorized to review current and projected healthcare workforce supply and demand and make recommendations to the Congress and the administration regarding national healthcare workforce priorities, goals, and policies. Members of the Commission have been appointed but have not been able to do any work, due to a lack of funding. The College believes the Nation needs sound research methodologies embedded in its workforce policy to determine the Nation's current and future needs for the appropriate number of physicians by specialty and geographic areas; the work of the Commission is imperative to ensure the Congress is creating the best policies for our Nation's needs.

The Agency for Healthcare Research and Quality (AHRQ) is the leading public health service agency focused on healthcare quality. AHRQ's research provides the evidence-based information needed by consumers, providers, health plans, purchasers, and policymakers to make informed healthcare decisions. The College is dedicated to ensuring AHRQ's vital role in improving the quality of our Nation's health and recommends a base discretionary budget of \$400 million. This amount will allow AHRQ to continue its critical healthcare safety, quality, and efficiency initiatives; strengthen the infrastructure of the research field; reignite innovation and discovery; develop the next generation of scientific pioneers; and ultimately, help transform health and healthcare.

Finally, ACP is supportive of the Centers for Medicare and Medicaid Services, Operations and Management of Exchanges request for \$574.5 million. Such funding will allow the Federal Government to administer an insurance exchange, as authorized by the ACA, if a State declines to establish one by early 2013 that meets Federal requirements. If the Subcommittees decides to deny the requested funds, it may make it much more difficult for the Federal Government to organize a federally facilitated exchange in those States, raising questions about where and how their residents would get coverage. It is ACP's belief that all legal Americans—regardless of income level, health status, or geographic location—must have access to affordable health insurance.

In conclusion, the College is keenly aware of the fiscal pressures facing the Subcommittee today, but strongly believes the United States must invest in these programs in order to achieve a high performance healthcare system and build capacity in our primary care workforce and public health system. The College greatly appreciates the support of the Subcommittee on these issues and looks forward to working with the Congress as you begin to work on the fiscal year 2013 appropriations process.

PREPARED STATEMENT OF THE ASSOCIATION FOR CLINICAL RESEARCH TRAINING, THE ASSOCIATION FOR PATIENT-ORIENTED RESEARCH, THE CLINICAL RESEARCH FORUM, AND THE SOCIETY FOR CLINICAL AND TRANSLATIONAL SCIENCE

The Association for Clinical Research Training (ACRT), the Association for Patient-Oriented Research (APOR), the Clinical Research Forum (CR Forum), and the Society for Clinical and Translational Science (SCTS) represent a coalition of professional organizations dedicated to improving the health of the public through increased clinical and translational research and clinical research training. United by the shared priorities of the clinical and translational research community, ACRT, APOR, CR Forum, and SCTS advocate for increased clinical and translational research at the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), and other Federal science agencies.

On behalf of ACRT, APOR, CR Forum, and SCTS, I would like to thank the Subcommittee for its continued support of clinical and translational research and clinical research training. The translation of basic science to clinical treatment is an integral component of modern research and a necessity to developing the treatments and cures of tomorrow. We applaud the recent establishment of the National Center for Advancing Translational Sciences (NCATS) and its focus on the entire spectrum of translational research from the bench to implementation in the community. Housing translational research activities with a focus on translational science methods at a single Center at NIH will allow these programs to achieve new levels of success.

Today, I would like to address a number of issues that cut to the heart of the clinical and translational research community's priorities, including the Clinical and Translational Science Awards program (CTSA) at NIH, career development for clinical researchers, and support for comparative effectiveness research at the Federal level.

As our Nation's investment in biomedical research expands to provide more accurate and efficient treatments for patients, we must continue to focus on the translation of basic science to clinical research. The CTSA program at NIH is an invaluable resource in this area, and full funding is critical if we are truly to take advantage of the CTSA infrastructure.

Full Funding and Support for the Clinical and Translational Science Awards Program at National Institutes of Health

With its establishment in 2006, the CTSA program at NIH began to address the need for increased focus on translational research, or research that bridges the gap between basic scientific discoveries and the bedside. In 2011, the CTSA Consortium reached its expected size of 60 medical research institutions located throughout the Nation, linking them together to energize the discipline of clinical and translational science. The CTSA's have an explicit goal of improving healthcare in the United States by transforming the biomedical research enterprise to become more effectively translational. Specifically, the stated strategic goals of the CTSA program are to: (1) build national clinical and translational research capability, (2) provide training and career development of clinical and translational scientists, (3) enhance consortium-wide collaborations, (4) improve the health of our communities and the Nation through community engagement and comparative effectiveness research, and (5) advance T1 (bench-to-bedside) translational research, which transfers knowledge from basic research to clinical research.

Although the promise of the CTSA program is recognized both nationally and internationally, it has suffered from a lack of proper funding along with NIH and, in the past, the National Center for Research Resources (NCRR). In 2006, 16 initial CTSA's were funded, followed by an additional 12 in 2007, 14 in 2008, 4 in 2009, 9 in 2010, and 5 in 2011. Level-funding at NIH curtailed the growth of the CTSA's, preventing recipient institutions from fully implementing their programs and causing them to drastically alter their budgets after research had already begun. Without enough funding, the CTSA's risk jeopardizing not only new research but also the research begun by first, second, and third generation CTSA's. Professional judgments have determined full funding to be at a level of \$700 million.

We appreciate the difficult economic situation our country is currently experiencing, and greatly appreciate the commitment to healthcare the Congress has demonstrated in recent years. The CTSA's are currently funding 60 academic research institutions nationwide at a level of \$488 million. The translation of laboratory research to clinical treatment directly benefits patients suffering from complex diseases across all fields of medicine, and impacts all of NIH's Institutes and Centers (ICs). The CTSA program has created improved translational research capacity and processes from which all NIH's ICs stand to benefit.

In order to fully realize the promise of the CTSA in transforming biomedical research to improve its impact on health, it is imperative that the CTSA program receive funding at the level of \$700 million in fiscal year 2013. Without full funding, CTSA will be expected to operate with fewer resources, curtailing their transformative promise. It is also critical that the emphasis on the full spectrum of translational research be maintained during the program's transition to NCATS.

It is our recommendation that the Subcommittee support full funding of the CTSA program by providing \$700 million in fiscal year 2013, and that support for the full spectrum of translational research be protected during the transition of the CTSA program to NCATS.

Support for Research Training and Career Development Programs Through the K Awards

The future of our Nation's biomedical research enterprise relies heavily on the maintenance and continued recruitment of promising young investigators. Clinical investigators have long been referred to as an "endangered species," as financial barriers push medical students away from research. This trend must be reversed if we are to continue our pursuits of better treatments and cures for patients.

The T and K series Awards at NIH and AHRQ provide much-needed support for the career development of young investigators. As clinical and translational medicine takes on increasing importance, there is a great need to grow these programs, not to reduce them. Career development grants are crucial to the recruitment of promising young investigators, as well as to the continuing education of established investigators. Reduced commitment to the K-12, K-23, K-24, and K-30 awards would have a devastating impact on our pool of highly trained clinical researchers. Even with the full implementation of the CTSA program, it is critical for institutions without CTSA to retain their K-30 Clinical Research Curriculum Awards, as the K-30s remain a highly cost-effective method of ensuring quality clinical research training. ACRT, APOR, CRF, and SCTS strongly support the ongoing commitment to clinical research training through K Awards at NIH and AHRQ.

We urge the Subcommittee to continue its support for clinical research training and career development through the K Awards at NIH and AHRQ, in order to promote and encourage investigators working to transform biomedical science.

Continuing Support for Comparative Effectiveness Research

Comparative effectiveness research (CER) is the evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. This broad definition can include medications, behavioral therapies, and medical devices, among other interventions, and is an important facet of evidence-based medicine. Both AHRQ and NIH have long histories of supporting CER, and the standards for research instituted by these agencies serve as models for best practices worldwide. Not only are these agencies experienced in CER, they are universally recognized as impartial and honest brokers of information. Moreover, their approach is supplemental to, not duplicative of, that of the new Patient-Centered Outcomes Research Institute, and its continued support is critical.

We are pleased that the Congress recognizes the importance of these activities and believe that the peer review processes and infrastructure in place at NIH and AHRQ ensure the highest quality CER. We believe that collaboration between the Patient-Centered Outcomes Research Institute, NIH, and AHRQ will drive all Federal CER efforts. In addition to support for the CTSA program at NIH, we encourage the Subcommittee to provide continued support for Patient-Centered Health Research at AHRQ.

Thank you for the opportunity to present the views and recommendations of the clinical research training community.

PREPARED STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

Thank you for the opportunity to submit testimony on behalf of the American Diabetes Association (Association). As the Chair of the Board of the Association, I am proud to be a representative of the nearly 105 million American adults and children living with diabetes or prediabetes, including my 17-year-old daughter, Leah. My daughter was diagnosed with type 1 diabetes on March 16, 2001, at the age of 6, and is living a very full life today due in part to the Federal investment in diabetes research programs.

My family and many others have been affected by diabetes. Nearly 26 million Americans have diabetes, and 79 million have prediabetes, a condition that puts them at high risk for developing diabetes. Every 17 seconds, someone in this country is diagnosed with diabetes. Every day, 230 people with diabetes undergo an am-

putation, 120 people enter end-stage kidney disease programs and 55 people go blind from diabetes. If we do not take action, 1 of every 3 children today faces a life with diabetes. The diabetes epidemic should not be ignored by anyone, including the Congress and the administration.

As the Nation's leading nonprofit health organization providing diabetes research, information and advocacy, the Association knows how critical it is for our country to increase Federal funding for diabetes research and prevention. The Association acknowledges the challenging fiscal climate and supports fiscal responsibility, but our country cannot afford the consequences of failing to adequately fund diabetes research and prevention programs, a cost paid in painful and expensive complications. We cannot afford to turn our backs on the promising research that provides tools to prevent diabetes, better manage the disease, prevent complications, and bring us closer to a cure.

The rising epidemic of diabetes in America is daunting, but not insurmountable. The Association is pressing forward by supporting research and expanding education and awareness efforts. But we cannot do it alone. The millions of people living with, or at risk for, diabetes are looking to the Congress now more than ever to step up its response to the diabetes epidemic.

Accordingly, the Association urges the Subcommittee on Labor, Health and Human Services, Education and Related Agencies to invest in research and prevention efforts reflective of the magnitude of the burden diabetes has on our country to change the future of diabetes in America. The Association respectfully requests programs at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) and the Division of Diabetes Translation (DDT) at the Centers for Disease Control and Prevention (CDC) be top priorities in fiscal year 2013.

BACKGROUND

The CDC has warned diabetes is a disabling, deadly, and growing epidemic. Last year, the CDC identified the diabetes belt, which stretches across 644 counties in 15 States, including my State of South Carolina. According to the CDC, 1 in 3 adults in our country will have diabetes in 2050 if present trends continue. Among minority populations, this ratio will be nearly 1 in 2.

Diabetes is a chronic disease that impairs the body's ability to use food for energy. The hormone insulin, which is made in the pancreas, is needed for the body to change food into energy. In people with diabetes, either the pancreas does not create insulin, which is type 1 diabetes, or the body does not create enough insulin and/or cells are resistant to insulin, which is type 2 diabetes. If left untreated, diabetes results in too much glucose in the blood stream. Blood glucose levels that are too high or too low (as a result of medication to treat diabetes) can be life threatening in the short term. In the long term, diabetes is the leading cause of kidney failure, new cases of adult-onset blindness and non-traumatic lower limb amputations as well as a leading cause of heart disease and stroke. Additionally, an estimated 18 percent of pregnancies are affected by gestational diabetes, a form of glucose intolerance diagnosed during pregnancy that places both mother and baby at risk. In those with prediabetes, blood glucose levels are higher than normal and taking action to reduce their risk of developing diabetes is essential.

In addition to the physical toll, diabetes also tugs at our purse strings. A study by the Lewin Group found when factoring in the costs of undiagnosed diabetes, prediabetes, and gestational diabetes, the total cost of diabetes and related conditions in the United States in 2007 was \$218 billion. That same year, medical expenditures due to diabetes totaled \$116 billion, including \$27 billion for diabetes care, \$58 billion for chronic diabetes-related complications, and \$31 billion for excess general medical costs. Indirect costs resulting from increased absenteeism, reduced productivity, disease-related unemployment disability and loss of productive capacity due to early mortality totaled \$58 billion. Approximately \$1 out of every \$5 for healthcare is spent caring for someone with diagnosed diabetes, while \$1 in \$10 for healthcare is directly attributed to diabetes. Further, one-third of Medicare expenses are associated with treating diabetes and its complications.

A greater Federal investment in diabetes research at the NIDDK at the NIH, and prevention, surveillance, control, and research work currently being done by the DDT at the CDC is crucial for finding a cure and improving the lives of those living with, or at risk for, diabetes. Additionally, the National Diabetes Prevention Program is working to dramatically decrease the number of new diabetes cases in high-risk individuals.

Accordingly, for fiscal year 2013, the Association requests funding for the following programs:

- \$2.216 billion for the NIDDK. This level of funding will act to offset years of decreased or flat funding combined with bio-medical inflation that has led to cutbacks in promising research. It will also demonstrate the Congress' commitment to science and research in the face of this deadly epidemic.
- \$86.3 million for the DDT's critical prevention, surveillance and control programs. Even as proposals to consolidate the CDC's chronic disease programs, including the DDT circulate, expanded investment in the DDT will produce much larger savings in reduced acute, chronic, and emergency care spending.
- \$80 million for the implementation of the National Diabetes Prevention Program.

THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)
AT THE NIH

NIDDK is leading the way in supporting research across the country that moves us closer to a cure and better treatments for diabetes. Researchers are working on a variety of projects in each of your States representing hope for the millions of individuals with diabetes. The Association is extremely worried that without increased funding, the NIDDK will slow or halt promising research that would enable individuals with the disease to live healthier, more productive lives. It is our understanding the percentage of research grants NIDDK was able to fund decreased last year and is expected to decrease again this year without additional funding.

Thanks to research at the NIDDK, people with diabetes now manage their disease with a variety of insulin formulations and regimens far superior to those used in decades past. For example, the continuous glucose monitor and insulin pump my daughter uses allow her to better manage her blood glucose levels—and better pave the way to a healthier future.

Examples of NIDDK-funded breakthroughs include: new drug therapies for type 2 diabetes; the advent of modern treatment regimens that have reduced the risk of costly complications like heart disease, stroke, amputation, blindness and kidney disease; ongoing development of the artificial pancreas, a closed looped system combining continuous glucose monitoring with insulin delivery; and research showing modest weight loss through dietary changes and increased physical activity can reduce the risk of type 2 diabetes by 58 percent, the foundation for the National Diabetes Prevention Program at the DDT.

Increased fiscal year 2013 funding would allow the NIDDK to support additional research in order to build upon past successes, improve prevention and treatment, and close in on a cure. For example, additional funding will support a new comparative effectiveness clinical trial testing different medications for type 2 diabetes. Additionally, increased funding will continue to support researchers studying how insulin-producing beta cells develop and function, with an ultimate goal of creating therapies for replacing damaged or destroyed beta cells in people with diabetes. Funding will also support a clinical trial testing vitamin D in the prevention of type 2 diabetes, and support ongoing studies on the environmental triggers of disease, which could identify an infectious cause of type 1 diabetes and lead to a vaccine.

THE DIVISION OF DIABETES TRANSLATION (DDT) AT THE CDC

The President's fiscal year 2013 budget proposal includes a proposal to consolidate certain programs at CDC, including the DDT. While we think coordination across chronic disease programs at CDC is an important endeavor, the Congress must ensure the needs of people with, and at risk for, diabetes are adequately addressed. For such a coordinated effort to be successful, significant resources must be provided. In addition, there must be a clear design focusing precisely on chronic diseases with similar risk factors and populations, allowing for the delivery of primary, secondary and tertiary prevention, and ensuring performance measures result in improved prevention of chronic disease and complications.

Given that the DDT's funding has not kept pace with the magnitude of the growing diabetes epidemic, the Federal investment in DDT programs should be substantially increased to a minimum of \$86.3 million in fiscal year 2013 regardless of the organization of chronic disease programs at CDC and even as the evaluation of the administration's proposal continues. As the dialogue moves forward about how best to address chronic disease prevention, the DDT should be the centerpiece in the Federal Government's efforts in this regard and its State and national expertise should be maintained.

Preserving the DDT's expertise is vital. The DDT works to eliminate the preventable burden of diabetes through proven educational programs, best practice guidelines, and applied research. It performs vital work in both primary prevention of diabetes and in preventing its complications. Funding for the DDT must focus on

maintaining State-based Diabetes Prevention and Control Programs, supporting the National Diabetes Education Program, defining the diabetes burden through the use of public health surveillance, and translating research findings into clinical and public health practice.

The DDT's work in this regard is organized into several key components, which are also part of the part of the President's fiscal year 2013 budget proposal. As outlined in the Obama administration's budget these include: (1) the implementation of strategies that support and reinforce healthful behaviors and expand access to healthy choices; (2) health systems interventions to improve the delivery and use of clinical and other preventive services; and (3) community-clinical linkage enhancement to better support chronic disease self-management.

For example, the DDT's Diabetes Prevention and Control Programs (DPCPs), located in all 50 States, the District of Columbia, and all U.S. territories work to prevent diabetes, lower blood glucose and cholesterol levels, and reduce diabetes-related emergency room visits and hospitalizations. These activities are designed to improve education and awareness of diabetes by engaging health providers, health systems and community-based organizations to ensure that these outcomes are achieved. Additionally, DDT funding also supports vital and groundbreaking translational research like the Search for Diabetes in Youth study, a collaboration between the DDT and the NIDDK designed to determine the impact of type 2 diabetes in youth in order to improve prevention efforts aimed at young people. This work is illustrative of efforts at DDT to transform clinical research into cutting-edge tools to track the diabetes epidemic and prevent new cases and help individuals with diabetes to avoid complications.

With additional funding, the DDT will be able to expand the efforts of DPCPs to improve primary, secondary and tertiary prevention efforts at the State and local levels. Given the dramatic decreases in funding for State and local health departments, supporting the work of the DPCPs is more critical than ever to ensure access to diabetes care and services. Additionally, increased funding for the DDT is needed to allow it to build upon its work in reducing health disparities through vital programs such as the Native Diabetes Wellness Program, which furthers the development of effective health promotion activities and messages tailored to American Indian/Native Alaskan communities. These resources will also enable the DDT to expand its translational research studies, leading to improved public health interventions.

THE NATIONAL DIABETES PREVENTION PROGRAM

The CDC's National Diabetes Prevention Program (NDPP) supports the national network of community-based sites where trained staff will provide those at high risk for diabetes with cost-effective, group-based lifestyle intervention programs.

The NDPP is a proven and inexpensive means of combating a growing epidemic. Research has shown the NDPP can reduce the risk of type 2 diabetes by 58 percent for individuals with prediabetes. Furthermore, the NDPP costs approximately \$300 per participant, as compared to an average of \$6,649 in annual healthcare costs for the treatment of a person with diabetes. The Urban Institute has estimated a nationwide expansion of this type of diabetes prevention program will save a total of \$190 billion over 10 years. The Association urges the Congress to provide \$80 million for the NDPP in fiscal year 2013, funding needed to bring this program to scale nationwide using rigorous standards established by DDT.

CONCLUSION

Not a day passes that I don't imagine a world free of diabetes and all its burdens on my daughter. This future is possible and the Association is counting on the Congress to significantly expand its investment of programs to prevent, treat, and cure diabetes. As you consider the fiscal year 2013 funding levels for the NIDDK, the DDT, and the NDPP, we urge you to remember diabetes is an epidemic growing at an astonishing rate and will overwhelm the healthcare system with tragic consequences unless our elected officials take action. Thank you for the opportunity to submit this testimony. The Association looks forward to working with you to stop diabetes.

PREPARED STATEMENT OF THE AMERICAN DENTAL EDUCATION ASSOCIATION

The American Dental Education Association (ADEA), on behalf of all 61 dental schools in the United States, 700 dental residency training programs, nearly 600 allied dental programs, as well as more than 12,000 faculty who educate and train

the nearly 50,000 students and residents attending these institutions, submits this statement for the record and for your consideration as you begin to prioritize fiscal year 2013 appropriation requests.

ADEA urges you to preserve the funding and fundamental structure of Federal programs that provide access to oral healthcare for underserved populations, funding for cutting-edge oral research, access to careers in dentistry and oral health services and funding for programs that help promote diversity in the healthcare professions. Oral health services are provided through our campuses and offsite dental clinics where students and faculty provide patient care as dental homes to the uninsured and underserved populations. However, in order to continue to provide these services, there must be adequate funding.

We are asking the committee to protect and maintain adequate funding for the dental programs in Title VII of the Public Health Service Act; the National Institutes of Health (NIH) and the National Institute of Dental and Craniofacial Research (NIDCR); the Dental Health Improvement Act; Part F of the Ryan White HIV/AIDS Treatment and Modernization Act; the Dental Reimbursement Program and the Community-Based Dental Partnerships Program; and State-Based Oral Health Programs at the Centers for Disease Control and Prevention. These programs enhance and sustain State oral health departments, fund public health programs proven to prevent oral disease, fund research to eradicate dental disease, and fund programs to develop an adequate workforce of dentists with advanced training to serve all segments of the population including children, the elderly, and those suffering from chronic and life-threatening diseases. We elaborate below the merits of each program.

\$32 Million for Primary Oral Healthcare Workforce Improvements

ADEA, recognizing the constrained fiscal situation the Congress and the Nation face, does not request an increase in the President's request in these funds, but rather respectfully suggests a reallocation of the funds requested. Specifically, we ask for \$8 million for General Dental Residencies; \$8 million for Pediatric Dental Residencies; \$5.7 million for dental accounts under title VII; and, \$10.7 million for DHIA.

The dental programs in title VII, Section 748 of the Public Health Service Act that provide training in general, pediatric, and public health dentistry and dental hygiene are critical. Support for these programs will help to ensure there will be an adequate oral healthcare workforce to care for the American public. The funding supports pre-doctoral oral health education and postdoctoral pediatric, general, and public health dentistry training. The investment that Title VII makes not only helps to educate dentists and dental hygienists, but also expands access to care for underserved populations.

Additionally, Section 748 addresses the shortage of professors in dental schools with the dental faculty loan repayment program and faculty development courses for those who teach pediatric, general, or public health dentistry or dental hygiene. There are currently more than 300 open faculty positions in dental schools. These two programs provide schools with assistance in recruiting and retaining faculty. ADEA is increasingly concerned that the oral health research community is not growing and that the pipeline of new researchers is inadequate to address future needs.

The President's fiscal year 2013 request proposes \$228 million for Title VII health professions, a \$40 million (15 percent) cut below the current fiscal year. The budget request proposes no new funds for the Title VII Health Careers Opportunity Program (HCOP) and Area Health Education Centers (AHEC) program. HCOP helps schools provide opportunities to students from disadvantaged backgrounds to develop the skills needed to enter the health professions. While the AHEC program is focused on exposing medical students and health professions students to primary care and practice in rural and underserved communities. It is anticipated that the AHEC program grantees will continue their efforts to provide interprofessional/interdisciplinary training to health professions students with an emphasis on primary care.

ADEA is pleased that last year's committee report included language supporting opportunities for advanced training for dentists and dental educational institutional faculty loan repayment programs because of its recognition of the shortage of pediatric and public health dentists. Those who complete a general dentistry residency are eligible to receive additional training which allows them to take on complex cases of patients with autoimmune or systemic diseases. The Committee expressed its concern, shared by the academic dentistry community, about the growing aging population and agrees with the Committee's suggestion that HRSA create a grant program to provide access to unpaid, volunteer dental services for medically nec-

essary but otherwise uncovered and unaffordable dental treatment that would cover the salaries and other employment costs of professionals who verify the medical and financial needs, including the absence of other insurance coverage, of individual patients potentially eligible for such services.

During the current fiscal year HRSA anticipates providing nearly \$10.5 million in continuation funding for advanced training of dentists through the Postdoctoral and Dental Faculty Loan Repayment Programs. It will also provide \$10 million in new grants under the Dental Health Improvement Act, State Oral Health Workforce grant program, and the Faculty Development in General, Pediatric and Public Health Dentistry and Dental Hygiene Program.

These are important achievements. But momentum and focus cannot be lost by not funding, in fiscal year 2013, programs that assist in identifying and encouraging the future generations of dental professionals who will serve the most in need of access to adequate dental care. There is no higher priority in the allocation of Federal resources to training programs than to directly increase the number of primary care dental providers for these patients.

\$32 Billion for the National Institutes of Health, Including \$450 Million for the National Institute of Dental and Craniofacial Research

Discoveries stemming from dental research have reduced the burden of oral diseases, led to better oral health for millions of Americans, and uncovered important associations between oral and systemic health. Dental researchers are poised to make breakthroughs that can result in dramatic progress in medicine and health, such as repairing natural form and function to faces destroyed by disease, accident, or war injuries; diagnosing systemic disease from saliva instead of blood samples; and deciphering the complex interactions and causes of oral health disparities involving social, economic, cultural, environmental, racial, ethnic, and biological factors. Dental research is the underpinning of the profession of dentistry. With grants from NIDCR, dental researchers in academic dental institutions have built a base of scientific and clinical knowledge that has been used to enhance the quality of the Nation's oral health and overall health.

Also, dental scientists are putting science to work for the benefit of the healthcare system through translational research, comparative effectiveness research, health information technology, health research economics, and further research on health disparities. NIDCR continues to make disparities a priority with continued funding for the Centers for Research to Reduce Disparities in Oral Health at Boston University; the University of California at San Francisco; the University of Colorado at Denver; the University of Florida; and the University of Washington.

\$19 Million for Part F of the Ryan White HIV/AIDS Treatment and Modernization Act: Dental Reimbursement Program and the Community-Based Dental Partnerships Program

Patients with compromised immune systems are more prone to oral infections like periodontal disease and tooth decay. By providing reimbursement to dental schools and schools of dental hygiene, the Dental Reimbursement Program (DRP) provides access to quality dental care for people living with HIV/AIDS while simultaneously providing educational and training opportunities to dental residents, dental students, and dental hygiene students who deliver the care. DRP is a cost-effective Federal/institutional partnership that provides partial reimbursement to academic dental institutions for costs incurred in providing dental care to people living with HIV/AIDS.

\$107 Million for Title VII Diversity and Student Aid Programs

\$24 million for Centers of Excellence (COE).

\$60 million for Scholarships for Disadvantaged Students (SDS).

\$22 million for Health Careers Opportunity Program (HCOP).

\$1.2 million for Faculty Loan Repayment Program (FLRP).

Title VII Diversity and Student Aid programs play a critical role in helping to diversify the health profession's student body and thereby the healthcare workforce. For the last several years, these programs have not enjoyed adequate funding to sustain the progress that is necessary to meet the challenges of an increasingly diverse U.S. population. ADEA is most concerned that the administration did not request any funds for HCOP. HCOP helps schools provide opportunities to students from disadvantaged backgrounds to develop the skills needed to enter the health professions. These programs are significant because students from disadvantaged backgrounds are more likely to return to those areas to serve the communities.

\$25 Million for the Division of Oral Health at the Centers for Disease Control and Prevention

The CDC Division of Oral Health expands the coverage of effective prevention programs. The program increases the basic capacity of State oral health programs to accurately assess the needs of the State, organize and evaluate prevention programs, develop coalitions, address oral health in State health plans, and effectively allocate resources to the programs. This strong public health response is needed to meet the challenges of oral disease affecting children, and vulnerable populations.

We are disappointed that the President's request represents only a marginal increase over fiscal year 2012 appropriated levels, well below an amount needed to keep up with inflation. The appropriated level for fiscal year 2012 and the request for fiscal year 2013 are below the inadequate level of fiscal year 2011 appropriations. We look forward to sharing information with the committee in the coming weeks about the impact that the current path of funding will have on the overall health and preparedness of the Nation's States and communities.

Thank you for your consideration of this request. ADEA looks forward to working with you to ensure the continuation of congressional support for these critical programs. Please feel free to use us as a resource. We can be reached by contacting Yvonne Knight, J.D., Senior Vice President for Advocacy and Governmental Relations, ADEA Policy Center, at knighy@adea.org.

PREPARED STATEMENT OF THE AMERICAN DENTAL HYGIENISTS' ASSOCIATION

On behalf of the American Dental Hygienists' Association (ADHA), thank you for the opportunity to submit testimony regarding appropriations for fiscal year 2013. ADHA appreciates the subcommittee's past support of programs that seek to improve the oral health of Americans and to bolster the oral health workforce. Oral health is a part of total health and authorized oral healthcare programs require appropriations support in order to increase the accessibility of oral health services, particularly for the underserved.

ADHA is the largest national organization representing the professional interests of more than 150,000 licensed dental hygienists across the country. In order to become licensed as a dental hygienist, an individual must graduate from an accredited dental hygiene education program and successfully complete a national written and a State or regional clinical examination. Dental hygienists are primary care providers of oral health services and are licensed in each of the 50 States. Hygienists are committed to improving the Nation's oral health, a fundamental part of overall health and general well-being.

In the past decade, the link between oral health and total health has become more apparent and the significant disparities in access to oral healthcare services have been well documented. At the State and local level, policymakers and consumer advocates have been pioneering innovations to extend the reach of the oral healthcare delivery system and improve oral health infrastructure. At this time, when 130,000 million Americans struggle to obtain the oral healthcare required to remain healthy, the Congress has a great opportunity to support oral health prevention, infrastructure and workforce efforts that will make care more accessible and cost-effective.

ADHA urges full funding of all authorized oral health programs and describes some of the key oral health programs below:

Title VII Program Grants to Expand and Educate the Dental Workforce—Fund at a level of \$32 million in fiscal year 2013.—A number of existing grant programs offered under Title VII support health professions education programs, students, and faculty. ADHA is pleased dental hygienists are recognized as primary care providers of oral health services and are included as eligible to apply for several grants offered under the "General, Pediatric, and Public Health Dentistry" grants.

With millions more Americans eligible for dental coverage in coming years, it is critical that the oral health workforce is bolstered. Dental and dental hygiene education programs currently struggle with significant shortages in faculty and there is a dearth of providers pursuing careers in public health dentistry and pediatric dentistry. Securing appropriations to expand the Title VII grant offerings to additional dental hygienists and dentists will provide much needed support to programs, faculty, and students in the future.

ADHA recommends funding at a level of \$32 million for fiscal year 2013.

Alternative Dental Health Care Provider Demonstration Project Grants—Fund at a level of \$10 million in fiscal year 2013.—Congress recognized the need to improve the oral healthcare delivery system when it authorized the Alternative Dental Health Care Provider Demonstration Grants, Section 340G-1 of the Public Health Service Act. The Alternative Dental Health Care Providers Demonstration Grants

program is a Federal grant program that recognizes the need for innovations to be made in oral healthcare delivery to bring quality care to the underserved by pilot testing new models. This is an opportunity for dental education programs, health centers, public-private partnerships and other eligible entities to apply for funding that will allow for innovation, within the confines of State laws, to further develop the dental workforce and extend the reach of the oral healthcare system. This grant program, administered by the Health Resources and Services Administration (HRSA), would fund workforce innovations, including building on the existing dental hygiene workforce, utilizing medical providers, and pilot testing new providers, like dental therapists and advanced practice dental hygienists, who practice in accordance with State practice acts.

A number of dental hygiene-based models are listed as eligible for the grants, including advanced practice dental hygienists, public health hygienists and independent practice dental hygienists. Currently, 35 States have policies that allow dental hygienists to work in community-based settings (like public health clinics, schools, and nursing homes) to provide preventive oral health services without the presence or direct supervision of a dentist. Among the 35 direct access States are the Senators' home States of Iowa, Wisconsin, Washington State, Rhode Island, Arkansas, Ohio, Texas, South Carolina and Kansas. Direct access to dental hygiene services is especially critical for vulnerable populations like children, the elderly, and the geographically isolated who often struggle to overcome transportation, lack of insurance coverage, and other barriers to oral healthcare.

Dental workforce expansion is one of many areas that need to be addressed as we move forward with efforts to increase access to oral healthcare services to those who are currently not able to obtain the care needed to maintain a healthy mouth and body. The authorizing statute makes clear that pilots must "increase access to dental care services in rural and underserved communities" and comply with State licensing requirements. Such new providers are already authorized in Minnesota and are under consideration in Connecticut, Vermont, Kansas, Maine, New Hampshire, Washington State and several other States.

The fiscal year 2012 Labor, Health and Human Services funding bill included language designed to block funding for this important demonstration program. We seek your leadership in removing this unjustified prohibition on funding for the Alternative Dental Health Care Providers Demonstration Grants. This is a grant program to explore new ways of delivering oral healthcare in rural and underserved areas in compliance with State law. There is unanimity in the call for new types of dental providers and there simply is no health policy justification for the prohibition.

Please keep the following points in mind as you consider funding this dental workforce grant program for the underserved:

- The existing dental delivery model has increased in efficiency and is highly effective for those who have access to a dental office and are covered through insurance. However, the system fails the more than 80 million Americans who lack dental insurance, those who are geographically isolated, and those who are unable to travel to a private dental office for treatment.
- Reports that these workforce pilots will allow non-dentists to do dental surgery/irreversible procedures are unfounded. All grants must, by statute, be conducted in accordance with State law. The grant program cannot authorize or allow non-dentists to perform irreversible/surgical dental procedures unless State law allows for the provision of such services.
- All pilots must be specifically designed to increase access in rural and other underserved areas. This is a dental workforce grant program for the underserved.
- Nearly 48 million Americans live in dental health professional shortage areas according to the Health Resources and Services Administration (HRSA), and HRSA included funding for this program in its fiscal year 2012 and fiscal year 2013 budget justifications.
- An estimated 9,500 new dental practitioners are needed to end the Nation's dental care shortages. New types of models must be explored and, by statute, HRSA must contract with IOM to evaluate the demonstrations, which will yield valuable information to inform decisions about the dental workforce of the future.
- All evidence available demonstrates the safety and quality of care delivered by non-dentist providers, including for Dental Health Aide Therapists in Alaska. Dental therapists have successfully been in practice overseas for nearly a century. Funding to support pilot testing of new dental workforce models will yield additional data on the economic viability of new oral health providers.
- The Alternative Dental Health Care Providers Demonstration Program is a grant program to pilot dental workforce innovations that, by statute, must "in-

crease access to dental healthcare services in rural and other underserved communities” and must be compliant with “all applicable State licensing requirements.” New types of dental providers are essential to solving the Nation’s oral health access crisis and this grant program will help determine what types of providers are viable.

ADHA, along with more than 60 other oral healthcare organizations, advocated for funding of this important program. Without the appropriate supply, diversity and distribution of the oral health workforce, the current oral health access crisis will only be exacerbated.

ADHA recommends funding at a level of \$10 million for fiscal year 2013 to support these vital demonstration projects.

Oral Health Prevention and Education Campaign—Fund at a level of \$5 million in fiscal year 2013.—A targeted national campaign led by the Centers for Disease Control to educate the public, particularly those who are underserved, about the benefits of oral health prevention could vastly improve oral health literacy in the country. While significant data has emerged over the past decade drawing the link between oral health and systemic diseases like diabetes, heart disease, and stroke, many remain unaware that neglected oral health can have serious ramifications to their overall health. Data is also emerging to highlight the role that poor oral health in pregnant women has on their children, including a link between periodontal disease and low-birth weight babies.

ADHA advocates an allocation of \$5 million in fiscal year 2013 for a national oral health prevention and education campaign.

School-Based Sealant Programs—Fund at a level sufficient to ensure school-based sealant programs in all 50 States.—Sealants have long-proven to be low-cost and effective in preventing dental caries (cavities), particularly in children. While most dental disease is fully preventable, dental caries remains the most common childhood disease, five times more common than asthma, and more than half of all children age 5–9 have a cavity or filling.

The CDC noted that data collected in evaluations of school-based sealant programs indicates the programs are effective in stopping and preventing dental decay. Significant progress has been made in developing best practices for school-based sealant programs, yet most States lack well developed programs as a result of funding shortfalls. ADHA encourages the transfer of funding from the Public Health and Prevention Fund sufficient to allow CDC to meaningfully fund school-based sealant programs in all 50 States in fiscal year 2013.

Oral Health Programming Within the Centers for Disease Control—Fund at a level of \$25 million in fiscal year 2013.—ADHA joins with others in the dental community in urging \$25 million for oral health programming within the Centers for Disease Control. This funding level will enable CDC to continue its vital work to control and prevent oral disease, including vital work in community water fluoridation. Federal grants to facilitate improved oral health leadership at the State level, support the collection and synthesis of data regarding oral health coverage and access, promote the integrated delivery of oral health and other medical services, enable States to innovate new types of oral health programs and promote a data-driven approach to oral health programming.

ADHA advocates for \$25 million in funding for grants to improve and support oral health infrastructure and surveillance.

Dental Health Improvement Grants—Fund at a level of \$20 million in fiscal year 2013.—HRSA administered dental health improvement grants are an important resource for States to have available to develop and carry out State oral health plans and related programs. Past grantees have used funds to better utilize the existing oral health workforce to achieve greater access to care. Previously awarded grants have funded efforts to increase diversity among oral health providers in Wisconsin, promote better utilization of the existing workforce including the extended care permit (ECP) dental hygienist in Kansas, and in Virginia implement a legislatively directed pilot program to allow patients to directly access dental hygiene services.

ADHA supports funding of HRSA dental health improvement grants at a level of \$20 million for fiscal year 2013.

National Institute of Dental and Craniofacial Research—Fund at a level of \$450 million in fiscal year 2013.—The National Institute of Dental and Craniofacial Research (NIDCR) cultivates oral health research that has led to a greater understanding of oral diseases and their treatments and the link between oral health and overall health. Research breeds innovation and efficiency, both of which are vital to improving access to oral healthcare services and improved oral status of Americans in the future.

ADHA joins with others in the oral health community to support NIDCR funding at a level of \$450 million in fiscal year 2013.

CONCLUSION

ADHA appreciates the difficult task appropriators face in prioritizing and funding the many meritorious programs and grants offered by the Federal Government. In addition to the items listed, ADHA joins other oral health organizations in support for continued funding of the Dental Reimbursement Program (DRP) and the Community-Based Dental Partnerships Program established under the Ryan White HIV/AIDS Treatment and Modernization Act (\$14 million for fiscal year 2013) as well as block grants offered by HRSA's Maternal Child Health Bureau (\$8 million for fiscal year 2013). ADHA also supports full funding for community health centers, and urges HRSA be directed to further bolster the delivery of oral health services at community health centers, including through the use of new types of dental providers.

ADHA remains a committed partner in advocating for meaningful oral health programming that makes efficient use of the existing oral health workforce and delivers high quality, cost-effective care.

PREPARED STATEMENT OF THE ARTHRITIS FOUNDATION

On behalf of the more than 50 million Americans—or one and five adults who live with the heavy burden of arthritis—the pain, disability, cost and more; The Arthritis Foundation would like to provide recommendations for the Labor Health and Human Services (Labor HHS) budget for fiscal year 2013.

The Arthritis Foundation is committed to raising awareness and reducing the unacceptable impact of arthritis, which strikes one in every five adults and 300,000 children, and is the Nation's leading cause of disability. To conquer this painful, debilitating disease, we support education, research, advocacy and other vital programs and services.

The Arthritis Foundation would like to comment on three specific agencies of jurisdiction of the Labor-HHS Appropriations Subcommittee, the National Institutes of Health (NIH) and in particular the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the Health Services Resources Administration (HRSA) and the Centers for Disease Control (CDC).

SUMMARY REQUEST—ARTHRITIS RELATED FUNDING

The Arthritis Foundation strongly recommends that funding research funding at the National Institutes of Health and specifically at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) should both be increased at least 4.5 percent which would be the minimum level to maintain current research and account for inflation. NIH funding should be allocated \$32 billion for fiscal year 2013 and NIAMS should be funded at \$559 million to fund critical research on arthritis and other related diseases at the Institute. For the more than 300,000 children with Juvenile Arthritis (JA), access to a pediatric rheumatologist in most States is a challenge. A HRSA report to the Congress in 2007 highlighted the lack of a pediatric rheumatologist for most children with juvenile arthritis; in fact, many States have less than two pediatric rheumatologists who treat these patients. The Arthritis Foundation strongly urges the Congress to support the President's budget allocation of \$5 million significantly less than the \$30 million authorized to support loan repayment for pediatric specialists. Finally, the President' once again proposes to consolidate the Center for Disease Control's (CDC) disease programs including the CDC Arthritis Program into one chronic disease program. Last year the Congress rejected a similar proposal, and the Arthritis Foundation continues to have concerns about consolidation. We instead request that the Congress provide an increase (\$10 million) to expand the CDC Arthritis Program to \$23 million for fiscal year 2013. These additional funds would allow the Program to expand to 10 additional States.

ARTHRITIS RELATED RESEARCH INVESTMENTS AT THE NATIONAL INSTITUTES OF HEALTH (NIH): FUNDING FOR THE NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

Research holds the key to preventing, controlling, and curing arthritis, the Nation's leading cause of disability. The prevalence, impact and disabling pain continues to increase. 50 million Americans—one in five adults—have arthritis now. Within 20 years, the Centers for Disease Control and Prevention (CDC) estimate 67 million adults or 25 percent of the population will have arthritis. Arthritis limits the daily activities of 21 million Americans and accounts for \$128 billion annually in economic costs. The National Institute of Arthritis and Musculoskeletal and Skin

Diseases (NIAMS) supports research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases. The critical research done at NIAMS improves the quality of life for people with arthritis and decreases the overall burden of the disease. Two examples include:

- Cartilage regeneration studies for patients with osteoarthritis (OA), which afflicts 27 million Americans. This innovation could lead to the first disease-reversing drug to be available for patients with OA.
- A randomized, controlled trial on effectiveness of daily calcium supplementation for increasing bone mineral density in children with JA. The trial found that supplementation resulted in a small, but statically significant, increase in total body mineral density compared with a placebo in children with JA.

The Arthritis Foundation recommends at least \$32 billion for fiscal year 2013 (\$559 million for NIAMS) representing a 4.5 percent increase in funding, the minimum level to maintain current research and account for inflation.

HRSA PEDIATRIC SUBSPECIALTY LOAN REPAYMENT PROGRAM

Juvenile arthritis is one of the most common childhood diseases, affecting more children than cystic fibrosis and muscular dystrophy. Currently, there are less than 250 pediatric rheumatologists in the United States and about 90 percent of those are clustered in and around large cities. Pediatric rheumatology has one of the smallest numbers of doctors of any pediatric subspecialty. Of those children with juvenile arthritis, only one-fourth see a pediatric rheumatologist due to their scarcity. The other 75 percent of juvenile arthritis patients see either pediatricians (who tend not to be trained in how to care for juvenile arthritis) or adult rheumatologists, who aren't trained to deal with pediatric issues. Issues such as whether it's the stunted bone growth that can result from arthritis and its treatment, or the unwillingness of an adolescent to take his medicine. There are currently six States that do not have a single practicing pediatric rheumatologist and eight States with only one pediatric rheumatologist.

The pediatric subspecialty loan repayment program was authorized by Section 5203 of the Affordable Care Act (ACA) in March 2010. The program would incentivize training and practice in pediatric medical subspecialties, like pediatric rheumatology, in underserved areas across the United States. The program would offer up to \$35,000 in loan forgiveness for each year of service for a maximum of 3 years. The program was authorized for \$30 million for fiscal year 2010 through fiscal year 2014, but has yet to be appropriated any funding. The Arthritis Foundation supports the President's request of \$5 million to fund the Pediatric Subspecialty Loan Repayment Program.

CENTER FOR DISEASE CONTROL: CDC ARTHRITIS PROGRAM

Arthritis is a complex family of more than 100 different diseases or conditions that destroys joints, bones, muscles, cartilage and other connective tissues, hampering or halting physical movement. It is the most common cause of disability in the United States, striking people of all ages, races and ethnicities and currently affects 1 in 5 Americans. Its impact on the economy is about \$128 billion including more than \$81 billion in direct costs for expense like physicians visits and surgical interventions.

The goal of the CDC Arthritis Program is to improve the quality of life for people affected by arthritis and other rheumatic conditions by working with States and other partners to (1) increase awareness about appropriate arthritis self-management activities, (2) expanding the reach of programs proven to improve the quality of life for people with arthritis and (3) decrease the overall burden of arthritis as well as its associated disability, work and activity limitations.

Overall, the Foundation supports the public health community recommendation to fund the CDC at \$7.8 billion for fiscal year 2013. Unfortunately, the Foundation has concerns about the CDC Arthritis Program. The President's budget for fiscal year 2013 again, proposes to combine existing chronic disease programs (including those for diabetes, heart disease, arthritis, stroke and cancer) into a single consolidated program. Last year the Congress rejected a similar proposal, and the Arthritis Foundation continues to have concerns about consolidation. With the rising burden of arthritis and other chronic diseases, along with the mounting fiscal pressures your panel faces, now is not the time to undermine the extensive arthritis public health infrastructure which has been erected across the country.

We instead request that the Congress provide a slight increase (\$10 million) to expand the CDC Arthritis Program to \$23 million for fiscal year 2013. These additional funds would allow the Program to expand to 10 additional States. Additional funding would allow the CDC Arthritis Programs to expand into 10 new States.

These State-based programs would (1) increase evidence based interventions, such as the Arthritis Foundation's Walk with Ease Program, into more communities; (2) reach diverse populations by funding partnership activities; and (3) support the OA Action Alliance, a coalition committed to elevating OA as a national priority. www.oaactionalliance.org.

The Arthritis Foundation appreciates the opportunity to provide recommendations to the Senate Labor, Health and Human Services Committee on recommendations for fiscal year 2013.

If you have questions about these comments please don't hesitate to contact the Arthritis Foundation. Questions about HRSA requests—Kim Beer, Director, Government Relations, kbeer@arthritis.org or Maria Spencer, Director, Federal Affairs for NIH/CDC [mspencer@arthritis.org](mailto:m Spencer@arthritis.org).

PREPARED STATEMENT OF THE ALZHEIMER'S FOUNDATION OF AMERICA

On behalf of the Alzheimer's Foundation of America (AFA), a New York-based national nonprofit organization that unites more than 1,600 member organizations nationwide with the goal of providing optimal care and services to individuals confronting dementia, and to their caregivers and families, we are making the following appropriations requests for programs impacting Alzheimer's disease research and caregiving services in the fiscal year 2013 budget. These Federal programs and support services are vital to advancing promising clinical research, providing necessary respite care and promoting best practice tools to family caregivers.

Specifically, AFA makes the following appropriations requests for these specific agencies and programs:

National Institutes of Health (NIH).—Adequate investment in scientific research that could lead to new treatments and cures is critical in order to reduce long-term healthcare costs. The President's fiscal year 2013 budget calls for an additional \$80 million for clinical research into Alzheimer's disease. AFA urges the Subcommittee to honor the President's budget request to help fund effective pharmaceutical therapies to prevent, cure or slow the progression of Alzheimer's disease and provide the necessary seed money to implement and facilitate the ambitious and laudable goals of the National Plan to Address Alzheimer's Disease.

AFA also urges the Subcommittee to include \$32 billion in total funding for NIH, as recommended by the Ad Hoc Group for Medical Research, in the fiscal year 2013 appropriations bill. Even if funding remains flat, NIH's actual budget will still be effectively cut as spending will not be able to keep pace with the predicted 3.5 percent in biomedical inflation.

National Institute on Aging (NIA).—Since NIA is the primary agency responsible for Alzheimer's disease research, AFA urges that the Subcommittee include a minimum budget appropriation of \$1.4 billion, an increase of \$300 million for NIA.

NIA leads the national scientific effort to understand the nature of aging in order to promote the health and well-being of older adults, whose numbers are projected to rise dramatically in the coming years due to increased life expectancy and the aging of the baby boom generation.

This funding is essential to increase the NIA's baseline to a level consistent with comparable research initiatives conducted under the auspices of NIH, and to support additional research into Alzheimer's disease and related dementias.

Cures Acceleration Network (CAN).—AFA recommends \$100 million to fund this important program. CAN was established within the Office of the Director of the NIH to aid in speeding the translation of basic scientific discoveries into treatments for diseases like Alzheimer's and getting them faster to market.

U.S. Department of Health and Human Service's Prevention and Public Health Fund (PPHF).—The President's fiscal year 2013 budget request proposes \$1.25 billion from the PPHF to supplement the budgets of the Centers for Disease Control and Prevention (\$903 million), Substance Abuse and Mental Health Services Administration (\$105 million), and the Agency for Healthcare Research and Quality (\$12 million), among other agencies. The request also proposes \$80 million from the fund to support Alzheimer's disease research and related initiatives. However, the "extenders bill" (Public Law 112-96), amends the fund to allow \$1 billion in fiscal year 2013, rather than the original \$1.25 billion.

AFA urges the Subcommittee to maintain the President's proposed budget request of \$1.25 billion for PPHF and preserve the \$80 million earmarked for Alzheimer's disease grants. Utilizing public health funds to pay physicians is truly a case of "robbing Peter to pay Paul" and could increase overall healthcare costs if funding for preventive services and caregiver training are slashed.

Administration on Aging Programs (AoA).—AFA would like to single out the following programs within the AoA that are critical to individuals with Alzheimer's disease and their caregivers:

—*National Family Caregiver Support Program (NFCSP).*—NFCSP provides grants to States and territories, based on their share of the population aged 70 and over, to fund a range of supportive services that assist family and informal caregivers in caring for their loved ones at home for as long as possible, thus providing a more patient-friendly and cost-effective approach than institutional care. Last year's appropriation of \$153 million cannot possibly keep up with the need for respite care as our population ages. AFA urges that \$192 million be appropriated to support this important program.

—*Lifespan Respite Care Program (LRCP).*—AFA urges the Subcommittee to commit \$50 million of LRCP in fiscal year 2013. LRCP provides competitive grants to State agencies working with Aging and Disability Resource Centers and non-profit State respite coalitions or organizations to make quality respite care available and accessible to family caregivers regardless of age or disability by establishing State Lifespan Respite Systems. The Lifespan Respite Care Act was signed into law in 2006, but received no funding until 2009. Last year, only \$2 million was appropriated to this successful, yet deeply underfunded program.

—*Alzheimer's Disease Supportive Services Program (ADSSP).*—The President's budget requests an additional \$5.5 million to restore funding for the ADSSP, which was reduced in the fiscal year 2012 appropriation. In addition, the request complements the Alzheimer's Initiative recently announced by HHS, which calls for an additional \$26 million for caregiver support, provider education, public awareness and improvements in data infrastructure. AFA supports funding of \$12 million for this program; in addition, we ask the Subcommittee to build upon the administration's request for funding.

Food and Drug Administration (FDA).—AFA supports funding of the FDA at \$2.656 billion, an increase of \$150 million or 6 percent more than appropriated in fiscal year 2012. FDA activities are necessary to ensure proper evaluation and testing of pharmaceutical treatments for Alzheimer's disease before they enter the market. In addition, the science is becoming more complex, and FDA plays an increasingly important and often resource-intensive role in pharmaceutical innovation. AFA's request is in line with the appropriations request being recommended by the Alliance for a Stronger FDA and the coalition to Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD).

Taken together, these programs represent a lifeline to families who care for a loved one with Alzheimer's disease and provide hope to Americans living with the disease and those who face it in the future that there will be funding for a cure. AFA thanks the Subcommittee for the opportunity to present its recommendations and looks forward to working with you through the appropriations process. Please contact Eric Sokol, AFA's vice president of public policy, at esokol@alzfdn.org if you have any questions or require further information.

PREPARED STATEMENT OF THE AMERICAN FOUNDATION FOR SUICIDE PREVENTION

Chairman Harkin, Ranking Member Shelby and members of the subcommittee. The American Foundation for Suicide Prevention (AFSP) thanks you for the opportunity to provide testimony on the funding needs of Federal agencies and programs that play a critical role in suicide prevention efforts.

AFSP is the leading national not-for-profit organization exclusively dedicated to understanding and preventing suicide through research, education and advocacy, and to reaching out to people with mental disorders and those impacted by suicide. You can find more information at www.asfp.org.

Data from the Centers for Disease Control for 2009 (latest available) shows that suicide is the 10th leading cause of death in the United States (36,547) and the third leading cause of death in teens and young adults from ages 15–24. Nearly 1.1 million Americans attempt suicide each year and another 8 million have suicidal thoughts. Suicide in 1 year costs the United States \$36 billion in lost wages and work productivity.

In order to more effectively combat this public health crisis, AFSP urges the Committee approve funding at the levels requested for the following programs/agencies for fiscal year 2013:

Garrett Lee Smith Memorial Act Programs

We respectfully request that Garrett Lee Smith Memorial Act (GLSMA) youth suicide prevention grant programs receive \$48.2 million for fiscal year 2013.

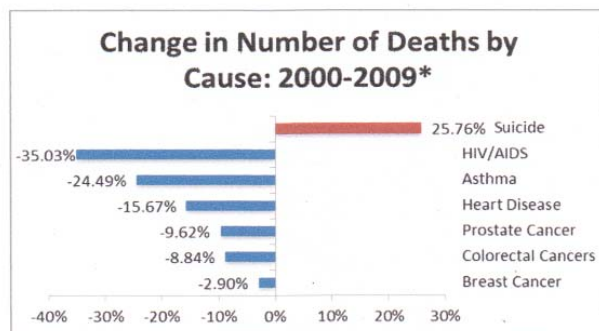
Since 2005, the Substance Abuse and Mental Health Services Administration (SAMHSA) has awarded GLSMA grants to 45 State programs, 12 tribal programs, and 78 colleges and universities for programs to help reduce youth suicides rates. State grantees include: Alaska, Arizona, Colorado, Connecticut, District of Columbia, Delaware, Florida, Georgia, Guam, Hawaii, Iowa, Idaho, Indiana, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Hampshire, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, and Wyoming.

Funding for the Act is directed to three programs administered by SAMHSA. We request \$5 million for the Suicide Prevention Technical Assistance Center to support its mission of providing technical assistance and support to grantees. We request \$35 million for the Youth Suicide Early Intervention and Prevention Strategies grant program. These grants help States and tribes develop and implement state-wide youth suicide early intervention and prevention strategies that will raise awareness and educate people about mental illness and the risk of suicide, help young people at risk of suicide take the first step toward seeking help, and allow States to expand access to treatment options. Finally, we request \$8.2 million to fund the Mental and Behavioral Health Services on Campus matching-grant program for colleges and universities to help raise awareness about youth suicide, as well as enable those institutions to train students and faculty to identify and intervene when youth are in crisis, and develop a system to refer students for care.

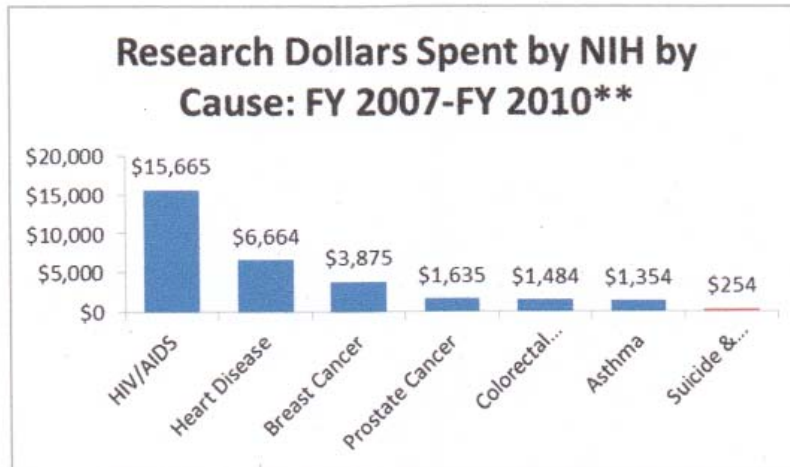
Support Federal Investment in Suicide Prevention Research at NIMH for Fiscal Year 2012

Strategic investments in disease research have produced declines in deaths, and the same types of investments are necessary to reduce deaths by suicide. In fiscal year 2011 (latest data) only \$41 million was devoted directly to suicide research. AFSP urges the Congress to increase the investment in suicide prevention research at the National Institutes of Mental Health by 15 percent, or \$6.15 million.

It is illuminating to compare the number of suicide deaths with the number of deaths in several major disease categories against the direct dollars spent on research in those areas (see below). In fact, the Institute of Medicine, in their 2002 report "Reducing Suicide: A National Imperative," stated the following: "There is every reason to expect that a national consensus to declare war on suicide and to fund research and prevention at a level commensurate with the severity of the problem will be successful, and will lead to highly significant discoveries as have the wars on cancer, Alzheimer's disease, and AIDS."



* Centers for Disease Control and Prevention (CDC)'s actual 2000 data versus preliminary final data from 2009; retrieved from http://www.cdc.gov/nchs/data/nvsr/nvsr50/nvsr50_15.pdf and http://www.cdc.gov/nchs/data/dvs/deaths_2009_release.pdf



**FY 2011 data is estimated; retrieved from <http://report.nih.gov/rcdc/categories/>

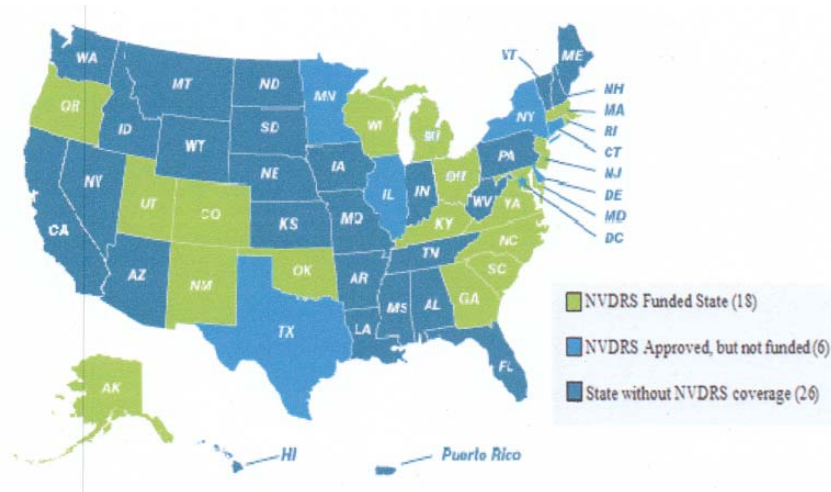
Maintain Vital Funding for SAMHSA Suicide Prevention Programs and Mental Health Services

As the lead Government agency charged with implementation of suicide prevention initiatives, AFSP urges this Committee to provide \$1.022 billion for SAMHSA's Center for Mental Health Services in fiscal year 2013. By this action the Congress will recognize the important role SAMHSA plays in healthcare delivery and mental health services.

As the lead Government agency charged with implementation of suicide prevention initiatives, SAMHSA has supported the establishment of a national toll-free hotline (the National Suicide Prevention Lifeline), a technical assistance center (the Suicide Prevention Resource Center), and a youth suicide prevention grant program for States and colleges (authorized and funded under the Garrett Lee Smith Memorial Act). Since its launch in January 2005, the Suicide Prevention Lifeline has answered more than 1 million calls and has 140 active crisis centers in 48 States. Beginning in 2008, SAMHSA's National Survey on Drug Use and Health asked respondents about suicide attempts and whether or not they had previously acknowledged major depression. This was an important first step forward in suicide surveillance, promoting greater attention to the interrelationship of suicide, substance abuse and depression. Moreover, the Agency also has been supporting the identification, development and promotion of best practices in suicide prevention, focusing on risk and protective factors related to suicide, with particular attention to mental health and substance abuse issues affecting suicide risk.

Support Federal Investment in Data Collection in Fiscal Year 2013

To design effective suicide prevention strategies, we must first have complete, accurate and timely information about deaths by suicide. The National Violent Death Reporting System (NVDRS) provides this information, which is essential to improve State and Federal suicide prevention activities. Current funding of \$3.5 million allows only 18 States to participate in this program. This Committee approved an additional \$1.5 million in fiscal year 2011; however, the bill never got signed into law. AFSP urges this Committee to appropriate \$5 million for the NVDRS in fiscal year 2013.



Provide Funding for Depression Centers of Excellence

This Committee included \$10 million for the DCOE in the fiscal year 2011 mark up as a down payment toward studying Depression, the most common psychiatric diagnosis associated with suicide. AFSP urges the Congress to appropriate funds to the DCOE at the highest levels possible in fiscal year 2013.

Depression Centers of Excellence would increase access to the most appropriate and evidence-based depression care and develop and disseminate evidence-based treatment standards to improve accurate and timely diagnosis of depression and bipolar disorders. Additionally, they would create a national database for large-sample effectiveness studies and a repository of evidence-based interventions and programs for depression and bipolar disorders. They would also utilize the network of centers as an ongoing national resource for public and professional education and training, with the goal of advancing knowledge and eradicating stigma of these mental disorders.

Chairman Harkin, Ranking Member Shelby and members of the subcommittee. AFSP once again thanks you for the opportunity to provide testimony on the funding needs of Federal Agencies and programs that play a critical role in suicide prevention efforts.

Suicide robs families, communities and societies of tens of thousands of its citizens. In a single year, in the United States alone, suicide is responsible for the deaths of nearly 37,000 people of all ages and costs an estimated \$36 billion annually in lost wages and work productivity. With your help, we can assure those tasked with leading the Federal Government's response to this public health crisis will have the resources necessary to effectively prevent suicide.

PREPARED STATEMENT OF THE AMERICAN HEART ASSOCIATION

Despite considerable progress in the fight against heart disease, stroke and other forms of cardiovascular disease, CVD remains our Nation's No. 1 and most costly killer, with one person dying from it every 39 seconds. CVD is also a major cause of disability, costing our country an estimated \$298 billion in medical expenses and lost productivity in 2008. Today, an estimated 83 million adults suffer from CVD. In addition, risk factors for CVD, such as obesity, diabetes, and high blood pressure, are on the rise. At age 40, the lifetime risk for CVD is 2 in 3 for men and more than 1 in 2 for women. Many are surprised to learn that CVD is the leading cause of death in women, outweighing cancer and other diseases.

Unfortunately, these startling statistics will likely worsen. A recent study projects that by the year 2030, more than 40 percent of adults in the United States will live with the effects of CVD at a cost exceeding \$1 trillion annually that would impoverish both the healthy and the ill. The graying of America's baby boomers along with the volatile growth in medical spending are the key drivers of these rising costs. Compounding this dire situation, heart disease and stroke prevention, re-

search, and treatment programs remain not only woefully underfunded, but there is no steady and dependable stream of resources for the National Institutes of Health (NIH) to mount a long-term strategy to fight this terrible disease, enhance prevention and foster best care.

CVD is the No. 1 killer in each State, except Alaska. Yet, research has shown that it is mostly preventable when treatable risk factors, such as high blood pressure and smoking, are addressed.

Where one lives can affect survival from a deadly type of heart disease—sudden cardiac arrest. Only 21 States received fiscal year 2010 funds for Health Resources and Services Administration's Rural and Community Access to Emergency Devices Program (HRSA) to save lives from SCA.

To avoid a looming CVD crisis, American Heart Association challenges the Congress to prioritize prevention. Evidence-based prevention programs must reach people where they live, work and play. Prevention must be a keystone to encourage early age heart healthy and stroke-free habits.

Thanks to the insight of Department of Health and Human Services, heart attack and stroke prevention will likely improve. AHA proudly partners with HHS to effect and achieve Million Hearts. Co-led by Centers for Disease Control and Prevention (CDC) and Centers of Medicare and Medicaid Services, this public-private partnership seeks to prevent 1 million heart attacks and strokes in 5 years.

In this time of budgetary belt-tightening, AHA lauds the Congress for providing a glimmer of hope to the 1-in-3 adult CVD sufferers in the United States by wisely investing in the NIH, HRSA, CDC, and in the Prevention and Public Health Fund for fiscal year 2012. While we advocated for higher increases, these funds will help improve our Nation's physical and fiscal health. Stable and sustained fiscal year 2013 funding is critical to advance heart disease and stroke research, prevention and treatment. However, the failure of the Joint Select Committee on Deficit Reduction to agree on a plan to reduce deficits will result in automatic across-the-board cuts in January 2013. Based on current projections, nearly every CVD research and prevention program will be cut by 9 percent.

FUNDING RECOMMENDATIONS: INVESTING IN THE HEALTH OF OUR NATION

Sadly, promising research remains unfunded that could stem the increase of heart disease and stroke risk factors. Also, too many Americans die from CVD while proven prevention efforts beg for resources for widespread implementation. Now is the time to boost research, prevention and treatment of our Nation's leading and most costly killer. If the Congress fails to capitalize on the progress of the past 50 years, Americans will pay more in lives lost and healthcare costs. Our recommendations below address the issues in a thorough and fiscally responsible way.

Capitalize on Investment for the National Institutes of Health

NIH-funded research prevents and cures disease, generates economic growth, fosters innovation, and preserves the U.S. role as the world leader in pharmaceuticals and biotechnology. NIH sponsored studies have revolutionized patient care. Further, NIH remains the single largest funder of basic research—the starting point for all medical advances and an essential function of the Federal Government. The private sector cannot fill this gap because there is no guarantee that this type of research will lead to an instant or profitable product or cure.

NIH research produces major returns on investment by developing new technologies that create high-paying jobs. Also, the typical NIH grant supported about seven mainly high-tech full-time or part-time jobs in fiscal year 2007. In fiscal year 2010, NIH created nearly a half million U.S. jobs and produced about \$70 billion in economic activity. Each dollar NIH distributes in a grant returns \$2.21 in goods and services to the local community in 1 year.

However, with sequestration looming, NIH faces an estimated 9 percent or \$2.8 billion cut, reducing its budget to the 2004 level. Since NIH invests in each State and in 90 percent of congressional districts, thousands of jobs will be lost, with a ripple effect on our fragile economic recovery. Such draconian budget cuts will both endanger NIH's role as the world leader in medical research—when our competitors are escalating their investment—and will severely delay research and development of disease treatments and cures.

American Heart Association Advocates.—We ask for a fiscal year 2013 appropriation of \$32 billion for NIH to build on successes to save lives, improve health, spur our economy and spark innovation. Also, we urge the Congress to protect NIH from across-the-board cuts for the aforesaid reasons.

Enhance Funding for National Institutes of Health Heart and Stroke Research: A Proven and Wise Investment

From 1998 to 2008, death rates for coronary heart disease and stroke fell nearly 29 percent and 35 percent respectively. Yet, more must be done to improve lives and to prevent these illnesses. Declines in these deaths are directly linked to NIH research, with scientists now on the verge of exciting discoveries that could lead to game-changing treatments and even cures. For example, the largest U.S. stroke rehabilitation study showed that intensive, home-based physical therapy as well as a more complex program using a body weight-supported treadmill can improve walking. Both programs resulted in superior walking ability as compared to usual care.

One of the largest-ever NIH-sponsored analyses of CVD lifetime risks demonstrated that middle-age adults with one or more classic CVD risk factors have a much greater chance of suffering a major CVD event. Further, it showed traditional risk factors predicted one's long-term development of CVD more than just age. Also, NIH studies identified 29 genetic variants that influence blood pressure, providing new clues for control, and demonstrated that those at highest risk of a second stroke should undergo aggressive medical treatment rather than with a stent.

In addition to saving lives, NIH research can cut healthcare costs. For example, the first NIH tPA drug trial resulted in a 10-year net \$6.47 billion drop in stroke healthcare costs. Also, the Stroke Prevention in Atrial Fibrillation Trial 1 produced a 10-year net savings of \$1.27 billion.

Cardiovascular Disease Research: National Heart, Lung, and Blood Institute

In spite of lower mortality rates and many promising avenues, there is still no cure for CVD. With an aging population, demand will only increase to find better ways for Americans to live healthy and productive lives, despite CVD. Stable and sustained NHLBI funding is needed to build on investments that provided grants to use genetics to identify and treat those at greatest risk of heart disease; hasten drug development to reduce high cholesterol and blood pressure; and create tailored strategies to treat, slow or prevent heart failure. Other key studies include an analysis of whether lower blood pressure than now recommended further reduces risk of heart disease, stroke, and cognitive decline. Sustained critical funding will allow for aggressive implementation of other priority initiatives in the cardiovascular strategic plan.

Stroke Research: National Institute of Neurological Disorders and Stroke

An estimated 795,000 Americans will suffer a stroke this year, and more than 134,000 will die from one. Many of the 7 million survivors face severe physical and mental disabilities and emotional distress. In addition to the physical and emotional toll, stroke cost a projected \$34 billion in medical expenses and lost productivity for 2008. The future does not bode well. A recent study projects stroke prevalence will increase 25 percent over the next 20 years, striking more than 10 million individuals with direct medical costs rising 238 percent over the same time period.

Stable and sustained NINDS funding is required to capitalize on investments to prevent stroke, protect the brain from damage and enhance rehabilitation. This includes initiatives to: (1) determine if MRI brain imaging can assist in selecting stroke victims who could benefit from the clot busting drug tPA beyond the 3-hour treatment window; (2) assess chemical compounds that might shield brain cells during a stroke; and (3) advance stroke rehabilitation by studying if the brain can be helped to "rewire" itself after a stroke. Enhanced funding will also allow for proactive initiation and implementation of the NINDS' novel stroke planning process to develop priorities to advance the most promising prevention, treatment and recovery research.

American Heart Association Advocates.—While AHA supports increased funding for all the 18 NIH Institutes and centers that conduct heart and stroke research, we specifically recommend that NHLBI be funded at \$3.214 billion and NINDS at \$1.698 billion for fiscal year 2013.

Increase Funding for the Centers for Disease Control and Prevention

Prevention is the best way to protect the health of Americans and reduce CVD's costs. Yet, effective prevention strategies are not being implemented due to inadequate funds. In addition to conducting research and evaluation and developing a surveillance system, the Division for Heart Disease and Stroke Prevention (DHDSP) manages Sodium Reduction Communities, Paul Coverdell National Acute Stroke Registry, and State Heart Disease and Stroke Prevention Program. The State program also promotes the "A-B-C-S" of prevention: appropriate aspirin therapy, blood pressure control, cholesterol management and smoking cessation.

The DHDSP manages WISEWOMAN that serves uninsured and under-insured low-income women ages 40 to 64. It helps them avoid heart disease and stroke by providing preventive health services, referrals to local healthcare providers—as needed—and lifestyle counseling and interventions tailored to risk factors to promote lasting behavior change. From July 2008 to June 2010, it served more than 70,000 women. In this timeframe, 89 percent of them were found to have at least one risk factor and 28 percent had three or more. Yet, more than 43,000 of them participated in at least one session to address them.

American Heart Association Advocates.—AHA concurs with the CDC Coalition in asking for \$7.8 billion for CDC's "core programs." We recommend \$75 million to bolster the DHDSP and \$37 million for WISEWOMAN to add States and serve more women. We also join with the Friends of the NCHS in asking for \$162 million for the National Center for Health Statistics.

Restore Funding for Rural and Community Access to Emergency Devices Program

About 90 percent of sudden cardiac arrest victims die outside of a hospital. However, prompt CPR and defibrillation, with an automated external defibrillator, can more than double their chances of survival. Communities with comprehensive AED programs have reached survival rates of about 40 percent. HRSA's Rural and Community AED Program provides competitive grants to States to buy AEDs, train lay rescuers and first responders in their use and place AEDs where SCA is likely to occur—and with tangible results. From September 2007 to August 2008, 3,051 AEDs were bought and 10,287 people were trained. Due to this effort, almost 800 patients were saved between August 1, 2009 and July 31, 2010. Requests for these AED grant dollars have exceeded available limited funds. In fiscal year 2009, less than 8 percent of the applicants were funded and only 21 States received funds in fiscal year 2010. We applaud the Congress for restoring this program to its fiscal year 2010 level for fiscal year 2012. However, HRSA transferred \$1.4 million to the AIDS Drug Assistance program, thereby diminishing the positive impact of the funding increase.

American Heart Association Advocates.—We ask for a fiscal year 2013 appropriation of \$8.927 million to restore the Rural and Community AED Program to its fiscal year 2005 level as 47 States were funded.

Increase Funding for the Agency for Healthcare Research and Quality

AHRQ develops scientific evidence to improve healthcare and provides patients and caregivers with vital evidence to make the right decisions about their care. AHRQ's research also enhances quality and efficiency of healthcare.

American Heart Association Advocates.—AHA joins Friends of AHRQ in advocating for \$400 million for AHRQ to preserve its vital initiatives.

CONCLUSION

Cardiovascular disease continues to wreak a deadly, disabling and costly toll on Americans. Our funding recommendations for NIH, CDC and HRSA outlined above will save lives and cut rising healthcare costs. We urge the Congress to seriously consider our proposals that represent a wise investment for our Nation and for the health and well-being of this and future generations.

PREPARED STATEMENT OF THE AD HOC GROUP FOR MEDICAL RESEARCH

The Ad Hoc Group for Medical Research is a coalition of more than 300 patient and voluntary health groups, medical and scientific societies, academic and research organizations, and industry. We appreciate the opportunity to submit this statement in support of enhancing the Federal investment in biomedical, behavioral, and population-based research conducted and supported by the National Institutes of Health (NIH).

We are deeply grateful to the Subcommittee for its long-standing and bipartisan leadership in support of NIH. These are difficult times for our Nation and for people all around the globe, but science and innovation are the key to a better future. To ensure continued improvement of our Nation's health and to sustain our global leadership in medical research, the Ad Hoc Group for Medical Research recommends at least \$32 billion for NIH in fiscal year 2013.

National Institutes of Health: A Public-Private Partnership to Save Lives and Provide Hope

The partnership between NIH and America's scientists, medical schools, teaching hospitals, universities, and research institutions is a unique and highly productive relationship, leveraging the full strength of our Nation's research enterprise to fos-

ter discovery, improve our understanding of the underlying cause of disease, and develop the next generation of medical advancements. More than 83 percent of NIH research funding is awarded to more than 3,000 research institutions located in every State. These are funded through almost 50,000 competitive, peer-reviewed grants and contracts to more than 350,000 researchers.

Research funded by NIH has contributed to nearly every medical treatment, diagnostic tool, and medical device developed in modern history, and we are all enjoying longer, healthier lives thanks to the Federal Government's wise investment in this lifesaving agency. From the major advances—including a nearly 70 percent reduction in the death rate for coronary heart disease and stroke—to moving stories of personalized medicine—such as children with rare diseases like dopa-responsive dystopia, whose prognosis has been transformed from severely disabled to happy and healthy through genomic medicine—NIH's role in improving human health has been extraordinary. For example:

- Between 1990 and 2007, death rates in the United States for all cancers combined decreased by 22 percent for men and 14 percent for women, resulting in 898,000 fewer deaths from the disease during this time period;
- Genomic advances have led us to the brink of approval for a new drug for cystic fibrosis, which tragically affects 30,000 Americans, whose current average life expectancy is only 37 years;
- Remarkable breakthroughs in HIV/AIDS announced within the past year have put the possibility of an AIDS-free world within sight; and
- We are within reach of a universal influenza vaccine, eliminating the need for annual flu shots.

NIH research impacts the full spectrum of the human experience, resulting in a 40 percent decline in infant mortality over the past 20 years, as well as a 30 percent decrease in chronic disability among seniors. For patients and their families, the scientific opportunities addressed by NIH provide hope.

NIH is the world's premiere supporter of peer-reviewed, investigator-initiated basic research. This fundamental understanding of how disease works and insight into the cellular, molecular, and genetic processes underlying life itself, including the impact of social environment on these processes, underpin our ability to conquer devastating illnesses. The application of the results of basic research to the detection, diagnosis, treatment, and prevention of disease is the ultimate goal of medical research. Ensuring a steady pipeline of basic research discoveries while also supporting the translational efforts absolutely necessary to bring the promise of this knowledge to fruition requires a sustained investment in NIH.

National Institutes of Health Supports Jobs, the Economy, and Innovation

The research supported by NIH drives not only medical progress but also local and national economic activity, creating skilled, high-paying jobs and fostering new products and industries. A report released in March by United for Medical Research showed NIH directly and indirectly supported more than 432,000 jobs nationwide, while generating \$62.1 billion in new economic activity. Another report, produced by Tripp Umbach, calculated a \$2.60 return on investment for every dollar spent on research at American medical schools and teaching hospitals.

At the same time, the private sector depends on the basic research funded by NIH to fuel the next generation of drugs, diagnostics, and devices. Chris Viehbacher, CEO of Sanofi, recently warned of the negative impact on the drug industry that withdrawal of support for NIH would have, saying, "I don't think there's enough appreciation in the United States about what a jewel the NIH is. It's fundamentally important to health everywhere in the world that the NIH be properly funded."

NIH also plays a significant role in supporting the next generation of innovators, the young and talented scientists and physicians who will be responsible for the breakthroughs of tomorrow. As competition for NIH grant funding reaches historically high levels, there is a real and present danger of losing our best and brightest minds at a time when scientific opportunity has never been better. Only with an increase in funding can NIH continue to attract the highest quality research talent from all over the world. The challenges of maintaining a cadre of physician-scientists to facilitate translation of basic research to human medicine, ensuring a biomedical workforce that reflects the racial and gender diversity of our citizenry, and maximizing our Nation's human capital to solve our most pressing health problems will only be addressed through continued support of NIH.

National Institutes of Health Is Critical to U.S. Competitiveness

While the United States maintains our preeminence in biomedical research, we must not take for granted the agency that established us as the world life sciences leader. Even as we have seen NIH's budget eroded by inflation—with a purchasing

power 20 percent lower than it was in fiscal year 2003—other nations have emulated our example and begun to invest in what can only be described as a life science revolution. A 2011 report by the Milken Institute warned that the United States was beginning to lose its competitive edge in the biomedical sciences, stating, “Europe and Japan are working to close the gap, while China, India, and Singapore have made impressive strides These efforts are part of larger economic development plans that increasingly focus on cultivating biomedical innovation for its economic contributions and high-wage jobs.” To illustrate this, a single Chinese company, BGI (formerly the Beijing Genomics Institute) has recently acquired more genomic sequencing capacity in terms of machines and people than the entire United States sequencing capacity combined.

In the past 6 months alone, we have heard ambitious pledges from India, the European Union, Russia, and China to commit substantial funding to research, even as the world struggles to recover from unprecedented fiscal challenges. Talented medical researchers from all over the world, who once flocked to the United States for training and stayed to contribute to our innovation-driven economy, are now returning to better opportunities in their home countries.

According to a new national public opinion poll commissioned by Research!America, more than half of likely voters doubt that the United States will be the world leader in science, technology, and healthcare by the year 2020. The findings reveal deep concerns among Americans about the country’s ability to maintain its world-class status in innovation, research and development before the next decade.

We cannot afford to lose that intellectual capacity, much less the jobs and industries fueled by medical research. The United States has been the leader in medical research because of bipartisan recognition of the critical role played by NIH. To maintain our dominance, we must reaffirm this commitment to provide NIH the funds needed to maintain our competitive edge.

National Institutes of Health: A Priority in Challenging Times

The Ad Hoc Group’s funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH’s budget to keep pace with biomedical inflation. Even before adjusting for inflation, enacted spending bills in recent years have imposed cuts on the NIH budget and the agency can now fund only one in six highly meritorious grant applications it receives—the lowest in history. Accordingly, NIH’s ability to sustain current research capacity and encourage promising new areas of science is significantly limited. More distressing, the looming sequestration mandated by the Budget Control Act threatens to continue this trend with further cuts estimated between 7 and 10 percent in fiscal year 2013 alone.

We recognize the tremendous challenges facing our Nation’s economy and acknowledge the difficult decisions that must be made to restore our country’s fiscal health. Nevertheless, we believe strongly that NIH is part of the solution to the Nation’s economic restoration, and we are thankful that the Subcommittee has recognized that role in its past support. Strengthening our commitment to medical research, through funding NIH, is a critical element in ensuring the health and well-being of the American people and our economy.

Therefore, the Ad Hoc Group for Medical Research respectfully requests that NIH be recognized as an urgent national priority as the Subcommittee prepares the fiscal year 2013 appropriations bill.

PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

This statement includes the fiscal year 2013 recommendations of the Nation’s Tribal Colleges and Universities (TCUs), covering three areas within the Department of Education.

HIGHER EDUCATION ACT PROGRAMS

Strengthening Developing Institutions.—Titles III and V of the Higher Education Act support institutions that enroll large proportions of financially disadvantaged students and that have low per-student expenditures. TCUs, funded under Title III—A Sec. 316, which are truly developing institutions, are providing quality higher education opportunities to some of the most rural, impoverished, and historically underserved areas of the country. The goal of HEA—Titles III/V programs is “to improve the academic quality, institutional management and fiscal stability of eligible institutions, in order to increase their self-sufficiency and strengthen their capacity to make a substantial contribution to the higher education resources of the Nation.”

The TCU Title III–A program is specifically designed to address the critical, unmet needs of their American Indian students and communities, in order to effectively prepare them to succeed in a global, competitive workforce. Yet, in fiscal year 2011 this critical program was cut by more than 11 percent and by another 4 percent in fiscal year 2012. The TCUs urge the Subcommittee to appropriate \$30 million in fiscal year 2013 for HEA Title III–A section 316, which is slightly less than the fiscal year 2010 appropriated funding level.

TRIO.—Retention and support services are vital to achieving the national goal of having the highest percentage of college graduates globally by 2020. TRIO programs, such as Student Support Services and Upward Bound were created out of recognition that college access is not enough to ensure advancement and that multiple factors work to prevent the successful completion of higher education for many low-income and first-generation students and students with disabilities. Therefore, in addition to maintaining the maximum Pell Grant award level, it is critical that the Congress also sustains student assistance programs such as Student Support Services and Upward Bound so that low-income and minority students have the support necessary to allow them to remain enrolled in and ultimately complete their postsecondary courses of study.

Pell Grants.—The importance of Pell Grants to TCU students cannot be overstated. A majority of TCU students receive Pell Grants, primarily because student income levels are so low and they have far less access to other sources of financial aid than students at State-funded and other mainstream institutions. Within the TCU system, Pell Grants are doing exactly what they were intended to do—they are serving the needs of the lowest income students by helping them gain access to quality higher education, an essential step toward becoming active, productive members of the workforce. However, beginning July 1, 2012, new Department of Education regulations will be imposed, limiting Pell eligibility to 12 full-time semesters. This change in policy will impede many TCU students from attaining a postsecondary degree, which is widely recognized as being critical for access to, and advancement in, today's highly technical workforce. Recent placement tests administered at TCUs indicated that 62 percent of first-time entering students required remedial math, 55 percent needed remedial writing, and 46 percent required remedial reading. Students requiring remediation can use as much as a full year of eligibility enhancing their math, and or reading/writing skills, thereby hampering their future postsecondary degree plans. A prior national goal was to provide access to quality higher education opportunities for all students regardless of economic means, at which TCUs have been extremely successful. While the new national goal is to produce the graduates with postsecondary degrees by 2020, this policy does not advance that goal. On the contrary, the new regulations will cause many low-income students to once again abandon their dream of a postsecondary degree, as they will simply not have the means to pursue it. The goal of a well-trained technical workforce will be greatly compromised. This new policy recalls the adage “penny wise-pound foolish.” The TCUs urge the Subcommittee to continue to fund this essential program at the highest possible level, and to direct the Secretary of Education to implement a process to waive the very restrictive 12 semester Pell Grant eligibility for TCU students.

PERKINS CAREER AND TECHNICAL EDUCATION PROGRAMS

Tribally Controlled Postsecondary Career and Technical Institutions.—Section 117 of the Carl D. Perkins Career and Technical Education Act provides a competitively awarded grant opportunity for tribally chartered and controlled career and technical institutions. AIHEC requests \$8,200,000 to fund grants under Sec. 117 of the Perkins Act, a modest increase of \$54,000 over the President's fiscal year 2013 budget request.

Native American Career and Technical Education Program (NACTEP).—NACTEP (Sec. 116) reserves 1.25 percent of appropriated funding to support American Indian career and technical programs. The TCUs strongly urge the Subcommittee to continue to support NACTEP, which is vital to the continuation of career and technical education programs offered at TCUs that provide job training and certifications to remote reservation communities.

AMERICAN INDIAN ADULT AND BASIC EDUCATION (OFFICE OF VOCATIONAL AND ADULT EDUCATION)

This program supports adult basic education programs for American Indians offered by State and local education agencies, Indian tribes, agencies, and TCUs. Despite a lack of funding, TCUs must find a way to continue to provide much-in-demand adult basic education classes for those American Indians that the present K–

12 Indian education system has failed. Before many individuals can even begin the course work needed to learn a productive skill, they first must earn a GED or, in some cases, even learn to read. There is an extensive need for adult basic educational programs, and TCUs must have adequate and stable funding to provide these essential activities. TCUs request that the Subcommittee direct that \$8 million of the funds appropriated annually for the Adult Education State Grants be made available to make competitive awards to TCUs to help meet the growing demand for adult basic education and remediation program services on their respective reservations.

JUSTIFICATIONS FOR FISCAL YEAR 2013 APPROPRIATIONS REQUESTS FOR TCUS

Tribal colleges and our students are already disproportionately impacted by efforts to reduce the Federal budget deficit and control Federal spending. The final fiscal year 2011 continuing resolution eliminated all of the Department of Housing and Urban Development's MSI community-based programs, including a critical TCU-HUD facilities program. TCUs were able to maximize leveraging potential, often securing even greater non-Federal funding to construct and equip Head Start and early childhood centers; student and community computer laboratories and public libraries; and student and faculty housing in rural and remote communities where few or none of these facilities existed. Important STEM programs, operated by the National Science Foundation and NASA were cut, and for the first time since the NSF program was established in fiscal year 2001, no new TCU-STEM awards were made in fiscal year 2011. Additionally, TCUs and their students suffer the impact of cuts to programs such as GEAR-UP, TRIO, SEOG, and are greatly impacted by the new highly restrictive Pell eligibility criteria more profoundly than mainstream institutions of higher education, which can realize economies of scale due to large endowments, alternative funding sources, including the ability to charge higher tuition rates and enroll more financially stable students, and access to affluent alumni. The loss of opportunity that cuts to DoEd, HUD, and NSF programs represent to TCUs, and to other MSIs, is magnified by cuts to workforce development programs within the Department of Labor, nursing and allied health professions tuition forgiveness and scholarship programs operated by the Department of Health and Human Services, and an important TCU-based nutrition education program planned by USDA. Combined, these cuts strike at the most economically disadvantaged and health-challenged Americans.

We respectfully ask the members of the subcommittee for their continued support of the nation's TCUs and full consideration of our fiscal year 2013 appropriations needs and recommendations.

PREPARED STATEMENT OF THE ALLIANCE OF INFORMATION AND REFERRAL SYSTEMS

The Alliance of Information and Referral Systems (AIRS) thanks you for providing the opportunity to submit testimony as you consider an fiscal year 2013 Labor-HHS, Education appropriations bill. AIRS is the national voice of Information and Referral/Assistance (I&R/A) and includes a membership of more than 1,200 I&R/A providers in both public and private organizations, which includes 2-1-1 providers. Our primary purpose for submitting this testimony is to urge you to support Title IIIB—Supportive Services funding of the Older Americans Act (OAA) as this provides Federal funding to the States for I&R/A.

As you know, in the President's fiscal year 2011 and fiscal year 2012 budget, an increase of \$48 million was proposed for Title IIIB of the OAA. AIRS was disappointed that an increase to IIIB was not recommended in the President's fiscal year 2013 budget. Given the economic climate, Information and Referral/Assistance (I&R/A) is a lifeline, bringing people and services together. Last year, AIRS members answered about 25 million calls for help. A top focus of the calls included housing, food, caregiver support, mental health, healthcare, transportation, employment, education and disaster services.

Comprehensive and specialized I&R/A programs help people in every community and operate as a critical component of the health and human services delivery system. I&R/A organizations have databases of programs and services and disseminate information through a variety of channels to individuals and communities.

While our preference is for an increase of \$48 million to be reflected in this year's appropriations, at a minimum, we encourage you to maintain the funding level of \$367 million for Title III B of the Older Americans Act. Thank you for your consideration as well as the opportunity to submit this testimony.

PREPARED STATEMENT OF THE AMERICAN LUNG ASSOCIATION

The American Lung Association is pleased to present our recommendations for fiscal year 2013 to the Labor, Health and Human Services, and Education Appropriations Subcommittee. The public health and research programs funded by this committee will prevent lung disease and improve and extend the lives of millions of Americans. Founded in 1904 to fight tuberculosis, the American Lung Association is the oldest voluntary health organization in the United States. The American Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through education, advocacy and research.

A SUSTAINED INVESTMENT IS NECESSARY

Mr. Chairman, investments in prevention and wellness pay near- and long-term dividends for the health of the American people. A recent study published in the American Journal of Public Health showed Washington State saved \$5 in tobacco-related hospitalization costs for every \$1 the State invested in its tobacco control and prevention program from 2000–2009. In order to save healthcare costs in the long-term, investments must be made in proven public health interventions including tobacco control, asthma programs and TB infrastructure.

Lung Disease

Each year, more than 400,000 Americans die of lung disease. It is America's number three killer, responsible for 1 in every 6 deaths. More than 33 million Americans suffer from a chronic lung disease and it costs the economy an estimated \$173 billion each year. Lung diseases include: lung cancer, asthma, chronic obstructive pulmonary disease (COPD), tuberculosis, pneumonia, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease and sarcoidosis.

Improving Public Health and Maintaining Our Investment in Medical Research

The American Lung Association strongly supports increasing overall CDC funding to \$7.8 billion in order for CDC to carry out its prevention mission and to assure an adequate translation of new research into effective State and local programs.

The United States must also maintain its commitment to medical research. While our focus is on lung disease research, we support increasing the investment in research across the entire NIH with particular emphasis on the National Heart, Lung and Blood Institute, the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, the National Institute of Environmental Health Sciences, the National Institute of Nursing Research, the National Institute on Minority Health and Health Disparities and the Fogarty International Center.

The Prevention and Public Health Fund

The American Lung Association strongly supports the Prevention and Public Health Fund established in the Affordable Care Act and asks the Committee to oppose any attempts to divert or use the Fund for any purposes other than what it was originally intended. The Prevention Fund provides funding to critical public health initiatives, like community programs that help people quit smoking, support groups for lung cancer patients, and classes that teach people how to avoid asthma attacks. Money from the Prevention Fund has also been used to pay for the new CDC media campaign "Tips from Former Smokers" which resulted in more than 33,000 people calling 1-800-QUIT-NOW during the campaign's first week of air. This represents a 128 percent increase in calls from the previous week.

Tobacco Use

Tobacco use is the leading preventable cause of death in the United States, killing more than 443,000 people every year. More than 46 million adults and 3.6 million youth in the United States smoke. Annual healthcare and lost productivity costs total \$193 billion in the United States each year.

Given the magnitude of the tobacco-caused disease burden and how much of it can be prevented, the CDC Office on Smoking and Health (OSH) should be much larger and better funded. Historically, the Congress has failed to invest in tobacco control—even though public health interventions have been scientifically proven to reduce tobacco use, the leading cause of preventable death in the United States. This neglect cannot continue if the Nation wants to prevent disease, promote wellness and reduce healthcare costs. The American Lung Association supports the President's budget request and urges that \$197.1 million be appropriated to OSH for fiscal year 2013.

Asthma

Asthma is highly prevalent and expensive. More than 25 million Americans currently have asthma, of whom 7 million are children. Asthma prevalence rates are more than 37 percent higher among African-Americans than whites. Asthma is also the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences from chronic disease. Asthma costs our healthcare system more than \$50.1 billion annually and indirect costs from lost productivity add another \$5.9 billion, for a total of \$56 billion annually.

The American Lung Association strongly opposes the proposal in the President's budget request that would merge the National Asthma Control Program with the Healthy Homes/Lead Poisoning Prevention Program and further reduce funding for both. The Lung Association asks this Committee to retain the National Asthma Control Program as a stand-alone program and appropriate \$25.3 million to it in fiscal year 2013. In addition, we recommend that the National Heart, Lung, and Blood Institute receive \$3.214 billion and the National Institute of Allergy and Infectious Diseases receive \$4.689 billion, and that both agencies continue their investments in asthma research in pursuit of treatments and cures.

Lung Cancer

More than 370,000 Americans are living with lung cancer. During 2011, approximately 221,000 new cases of lung cancer were diagnosed, and in 2008, more than 158,000 Americans died from lung cancer. Survival rates for lung cancer tend to be much lower than those of most other cancers. African-Americans are more likely to develop and die from lung cancer than persons of any other racial group.

Lung cancer receives far too little attention and focus. Given the magnitude of lung cancer and the enormity of the death toll, the American Lung Association strongly recommends that the NIH and other Federal research programs commit additional resources to lung cancer. The National Lung Screening Trial showed promising results for a small segment of the population at high risk for developing lung cancer but more research must be done in order to see if others would similarly benefit. We support a funding level of \$5.296 billion for the National Cancer Institute and urge more attention and focus on lung cancer.

Chronic Obstructive Pulmonary Disease

COPD is the third leading cause of death in the United States. It has been estimated that 13.1 million patients have been diagnosed with some form of COPD and as many as 24 million adults may suffer from its consequences. In 2008, 137,693 people in the United States died of COPD. The annual cost to the Nation for COPD in 2010 was projected to be \$49.9 billion. We strongly support funding the National Heart, Lung, and Blood Institute and its lifesaving lung disease research program at \$3.214 billion. The American Lung Association also asks the Committee to continue its support of the National Heart, Lung, and Blood Institute working with the CDC and other appropriate agencies to prepare a national action plan to address COPD, which should include public awareness and surveillance activities.

Influenza

Public health experts warn that 209,000 Americans could die and 865,000 would be hospitalized if a moderate flu epidemic hits the United States. To prepare for a potential pandemic, the American Lung Association supports funding the Federal CDC Influenza efforts at \$159.6 million.

Tuberculosis

There are an estimated 10 million to 15 million Americans who carry latent TB infection, and it is estimated that 10 percent of these individuals will develop active TB disease. In 2010, there were 11,182 cases of active TB reported in the United States. While declining overall TB rates are good news, the emergence and spread of multi-drug resistant TB and totally drug resistant TB also poses a significant public health threat. We request that the Congress increase funding for tuberculosis programs at CDC to \$243 million for fiscal year 2013.

Additional Priorities

We strongly encourage improved disease surveillance and health tracking to better understand diseases like asthma. We support an appropriations level of \$35 million for the Environment and Health Outcome Tracking Network. We strongly recommend at least \$52.8 million in funding for the Healthy Communities program and that it remain a separate, stand-alone program. This program supports investments in communities to identify and improve policies and environmental factors influencing health and reduce the burden of chronic diseases.

CONCLUSION

Mr. Chairman, lung disease is a continuing, growing problem in the United States. It is America's number three killer, responsible for 1 in 6 deaths. Progress against lung disease is not keeping pace with progress against other major causes of death and more must be done. The level of support this committee approves for lung disease programs should reflect the urgency illustrated by the impact of lung disease.

FISCAL YEAR 2013 REQUESTS

Centers for Disease Control and Prevention

Increase overall CDC funding—\$7.8 billion
 Funding Healthy Communities—\$52.8 million
 Office on Smoking and Health—\$197.1 million
 Asthma programs—\$25.3 million
 Environment and Health Tracking Network—\$35 million
 Tuberculosis programs—\$243 million
 CDC influenza preparedness—\$159.6 million
 NIOSH—\$522.3 million
 Prevention and Public Health Fund—Please Protect the Fund

National Institutes of Health

Increase overall NIH funding—\$32 billion
 National Heart, Lung, and Blood Institute—\$3.214 billion
 National Cancer Institute—\$5.296 billion
 National Institute of Allergy and Infectious Diseases—\$4.689 billion
 National Institute of Environmental Health Sciences—\$717.9 million
 National Institute of Nursing Research—\$151.178 million
 National Institute on Minority Health and Health Disparities—\$288.678 million
 Fogarty International Center—\$72.7 million

 PREPARED STATEMENT OF THE ASSOCIATION OF MATERNAL AND CHILD HEALTH PROGRAMS

The Association of Maternal and Child Health Programs (AMCHP), is pleased to submit testimony describing our request for \$645 million in funding for fiscal year 2013 for the Title V Maternal and Child Health (MCH) Services Block Grant. This funding request is level with fiscal year 2012 and represents an \$85 million decrease from its highest level of \$730 million in fiscal year 2003. While this request does not address all of the needs of pregnant women, children and children with special healthcare needs, we recognize that in the current budget climate a request for increased funding would come at the detriment of other public health programs designed to promote optimal health for the very populations our programs serve.

Additionally, we are gravely concerned about the proposed cuts to the Centers for Disease Control and Prevention (CDC). We urge you to recognize the value of health in improving the lives of American families. Further cuts to any programs that promote and protect the health of all Americans may seem penny wise but are definitely pound foolish.

In 2010 the Title V MCH Services Block Grant provided support and services to 41 million American women, infants and children, including children with special healthcare needs. It has been proven a cost effective, accountable, and flexible funding source used to address the most critical, pressing and unique MCH needs of each State. States and jurisdictions use the Title V MCH Services Block Grant to design and implement a wide range of maternal and child health programs that meet national and State needs. Although specific initiatives may vary among the States and jurisdictions, all of them work with local, State, and national partners to accomplish the following:

- Reduce infant mortality and incidence of disabling conditions among children.
- Increase the number of children appropriately immunized against disease.
- Increase the number of children in low-income households who receive assessments and follow-up diagnostic and treatment services.
- Provide and ensure access to comprehensive perinatal care for women; preventative and child care services; comprehensive care, including long-term care services, for children with special healthcare needs; and rehabilitation services for blind and disabled children.

—Facilitate the development of comprehensive, family centered, community-based, culturally competent, coordinated systems of care for children with special healthcare needs.

In addition to providing services to more than 40 million Americans, Title V MCH Services Block Grant programs save Federal and State governments' money by ensuring that people receive preventive services to avoid more costly chronic conditions later in life. Below are some examples of the cost effectiveness of maternal and child health interventions and the role of the Title V MCH Block Grant.

—Comprehensive prenatal care is associated with reduced incidence of low birth weight and infant mortality. State MCH programs link uninsured women to available prenatal services, and coordinate closely with State Medicaid programs to improve outreach and enrollment services to eligible women. Pre-conception health is a focus of many State MCH programs that work to improve women's health prior to pregnancy in order to improve pregnancy related outcomes.

—Total medical costs are lower for exclusively breastfed infants than never-breastfed infants since breastfed infants typically need fewer sick care visits, prescriptions and hospitalizations. State MCH programs promote breastfeeding by developing educational materials for new mothers on breastfeeding practices and providing information on breastfeeding to all residents of their States through websites, toll free telephone lines and coordinating with other local and State programs.

—Studies demonstrate that every \$1 spent on smoking cessation counseling for pregnant women saves \$3 in neonatal intensive care costs. State MCH programs fund state-wide smoking cessation or "quit lines" for pregnant women and provide education within their State about the dangers of smoking during pregnancy, helping moms and moms-to-be quit smoking and reducing their risk of premature birth.

—Every \$1 spent on preconception care programs for women with diabetes can reduce health costs by up to \$5.19 by preventing costly complications in both mothers and babies. Investing \$10 per person per year in community based disease prevention could save more than \$16 billion annually within 5 years. State MCH and Chronic Disease programs work together at the State and community levels to educate women, children and families about the importance of physical activity, nutrition and obesity prevention throughout the lifespan.

—Early detection of genetic and metabolic conditions can lead to reductions in death and disability as well as saved costs. For example, phenylketonuria (PKU) a rare metabolic disorder affects approximately 1 of every 15,000 infants born in the United States. Studies have found that PKU screening and treatment represent a net direct costs savings. State MCH programs are responsible for assuring that newborn screening systems are in place statewide and that clinicians are alerted when follow up is required.

—Early detection of physical and intellectual disabilities results in more efficient and effective treatment and support for children with special healthcare needs. High-quality programs for children at risk produce strong economic returns ranging from about \$4 per \$1 invested to more than \$10 per \$1 invested. State MCH programs administer the State and territorial Early Childhood Comprehensive Systems Initiative to support State and community efforts to strengthen, improve and integrate early childhood service systems.

—The injuries incurred by children and adolescents in 1 year create total lifetime economic costs estimated at more than \$50 billion in medical expenses and lost productivity. State MCH programs examine data and translate it into information and policy to positively impact the incidence of infant mortality and other factors that may contribute to child deaths. State MCH programs invest in injury prevention programs, including State and local initiatives to promote the proper use of child safety seats and helmets. Additionally State MCH programs promote safe sleeping practices to prevent Sudden Infant Death Syndrome (SIDS).

—The total cost of adolescent health risk behaviors is estimated to be \$435.4 billion per year. Risky behaviors have impact on the health and well-being of adolescents included smoking, binge drinking, substance abuse, suicide attempts and high risk sexual behavior. State MCH programs and their partners address access to healthcare, violence, mental health and substance use, reproductive health and prevention of chronic disease during adulthood. State MCH programs often support State adolescent health coordinators who work to improve the health of adolescents within their States and territories.

Members of Congress contend that savings in such as these will not be realized in the near future and therefore won't result in immediate savings in these tight

fiscal times. But today we can highlight a real-time example of how the Title V MCH Services Block Grant has played a role in helping save millions in annual healthcare costs. In Ohio, Title V played a lead role in providing funding for the Ohio Perinatal Quality Collaborative (OPQC). The OPQC is charged with reducing preterm births and improving outcomes of preterm newborns. Using the Institute for Healthcare Improvement Breakthrough Series, OPQC worked with 20 maternity hospitals (47 percent of all births in the State) through a collaborative focused on several obstetric improvement projects. OPQC reports that as a result of their efforts more than 9,000 births are full term and that approximately 250 NICU admissions have been avoided. OPQC estimates approximately \$10 million in annual healthcare cost savings. Other States have similar initiatives and we are tracking their successes.

The Title V MCH Services block grant is the foundation upon which State and territorial maternal and child health programs are built. Without a Federal investment the aforementioned savings will not be realized and our Nation's ability to address the most pressing needs of these vulnerable populations will not be possible. The Title V MCH Service Block Grant supports a system which treats a whole person, not by their specific disease and AMCHP therefore strongly urge you to sustain this investment at \$645 million in fiscal year 2013.

In addition to the Title V MCH block grant AMCHP is extremely concerned about current proposals to cut funding from other core programs designed to assure the health of our Nation's families. We strongly urge you to sustain funding for the Centers for Control and Prevention (CDC). It is short sighted and counterproductive to further cut discretionary funding for prevention in the interest of deficit reduction. CDC programs should be protected from further cuts that will have profound consequences on our capacity to address the needs of the most vulnerable.

PREPARED STATEMENT OF THE ASSOCIATION OF MINORITY HEALTH PROFESSIONS
SCHOOLS

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Wayne J. Riley, Chairman of the Board of Directors of the Association of Minority Health Professions Schools (AMHPS) and the President and Chief Executive Officer of Meharry Medical College. AMHPS, established in 1976, is a consortium of our Nation's 12 historically black medical, dental, pharmacy, and veterinary medicine schools. The members are two dental schools at Howard University and Meharry Medical College; four colleges of medicine at The Charles Drew University, Howard University, Meharry Medical College, and Morehouse School of Medicine; five schools of pharmacy at Florida A&M University, Hampton University, Howard University, Texas Southern University, and Xavier University; and one college of veterinary medicine at Tuskegee University. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, I speak for our institutions, when I say that the minority health professions institutions and the Title VII Health Professionals Training programs address a critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, even after the landmark passage of health reform, it is important to note that our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Mr. Chairman, I would like to share with you how your committee can help AMHPS continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need—even in austere financial times.

An October 2006 study by the Health Resources and Services Administration (HRSA)—during the Bush administration—entitled “The Rationale for Diversity in the Health Professions: A Review of the Evidence” found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race

or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

In fiscal year 2013, funding for the Title VII Health Professions Training programs must be robust, especially the funding for the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs). In addition, the funding for the National Institutes of Health (NIH)'s National Institute on Minority Health and Health Disparities (NIMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), should be preserved.

Minority Centers of Excellence.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions to the training of minorities in the health professions. Congress later went on to authorize the establishment of “Hispanic”, “Native American” and “Other” Historically black COEs. For fiscal year 2013, I recommend a funding level of \$24.602 million for COEs.

Health Careers Opportunity Program (HCOP).—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. For fiscal year 2013, I recommend a funding level of \$22.133 million for HCOPs.

National Institutes of Health

Research Centers at Minority Institutions.—The Research Centers at Minority Institutions program (RCMI), newly moved to the National Institute on Minority Health and Health Disparities has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2013.

National Institute on Minority Health and Health Disparities.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professions institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through its Centers of Excellence program. For fiscal year 2013, I recommend funded increases proportional with the funding of the overall NIH, with increased FTEs.

Department of Health and Human Services

Office of Minority Health.—Specific programs at OMH include: assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals; assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers; supporting conferences for high school and undergraduate students to interest them in health careers, and supporting cooperative

agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. For fiscal year 2013, I recommend a funding level of \$65 million for the OMH.

Department of Education

Strengthening Historically Black Graduate Institutions.—The Department of Education's Strengthening Historically Black Graduate Institutions (HBGI) program (Title III, Part B, Section 326) is extremely important to AMHPS. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2013, an appropriation of \$65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, AMHPS' member institutions and the Title VII Health Professions Training programs and the historically black health professions schools can help this country to overcome health disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. The Association seeks to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity everyday.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE AMERICAN NURSES ASSOCIATION

The American Nurses Association (ANA) appreciates the opportunity to comment on fiscal year 2013 appropriations for the Title VIII Nursing Workforce Development Programs and Nurse-Managed Health Clinics. Founded in 1896, ANA is the only full-service professional association representing the interests of the Nation's 3.2 million registered nurses (RNs) through its State nurses associations, and organizational affiliates. The ANA advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, and projecting a positive and realistic view of nursing.

As the largest single group of clinical healthcare professionals within the health system, licensed registered nurses are educated and practice within a holistic framework that views the individual, family and community as an interconnected system that can keep us well and help us heal. As the Nation works toward restructuring the healthcare system by focusing on expanding access, decreasing cost, and improving quality; a significant investment must be made in strengthening the nursing workforce.

ANA is grateful to the Subcommittee for your past commitment to Title VIII funding, and we understand the immense fiscal pressures the Subcommittee is facing. However, we respectfully request you support \$251 million for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act in fiscal year 2013. Additionally, we respectfully request \$20 million for the Nurse-Managed Health Clinics authorized under Title III of the Public Health Service Act in fiscal year 2013.

DEMAND FOR NURSES CONTINUES TO GROW

A sufficient supply of nurses is critical in providing our Nation's population with quality healthcare now and into the future. Registered Nurses (RNs) and Advanced Practice Registered Nurses (APRNs) are the backbone of hospitals, community clinics, school health programs, home health and long-term care programs, and serve patients in many other roles and settings. The Bureau of Labor Statistics' (BLS) Employment Projections for 2010–2020 state the expected number of practicing nurses will grow from 2.74 million in 2010 to 3.45 million in 2020, an increase of 712,000 or 26 percent.

Contrary to the good news that there are a growing number of nurses, the current nurse workforce is aging. According to the 2008 National Sample Survey of Registered Nurses, more than 1 million of the Nation's 2.6 million practicing RNs are over the age of 50. Within this population, more than 275,000 nurses are over the age of 60. As the economy continues to rebound, many of these nurses will seek retirement, leaving behind a significant deficit in the number of experienced nurses in the workforce. According to Douglas Staiger, author of a New England Journal

of Medicine study, the nursing shortage will “re-emerge” from 2010 and 2015 as 118,000 nurses will stop working full time as the economy grows.

Furthermore, as of January 1, 2011 baby boomers began turning 65 at the rate of 10,000 a day. With this aging population, the healthcare workforce will need to grow as there is an increase in demand for nursing care in traditional acute care settings as well as the expansion of non-hospital settings such as home care and long-term care.

The BLS projections explain a need for 495,500 replacements in the nursing workforce, bringing the total number of job openings for nurses due to growth and replacements to 1.2 million by 2020. A shortage of this magnitude would be twice as large as any shortage experienced by this country since the 1960s. Cuts to Title VIII funding would be detrimental to the healthcare system and the patients we serve.

TITLE VIII: NURSING WORKFORCE DEVELOPMENT PROGRAMS

The Nursing Workforce Development programs, authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.), include programs such as Nursing Loan Repayment Program and Scholarships Program, (Sec. 846, Title VIII, PHSA); Advanced Nursing Education (ANE) Grants; (Sec. 811), Advanced Education Nursing Traineeships, (AENT); Nurse Anesthetist Traineeships (NAT); Comprehensive Geriatric Education Grants, (Sec. 855, Title VIII, PHSA); Nurse Faculty Loan Program, (Sec. 846A, Title VIII, PHSA); and Nursing Workforce Diversity Grants, (Sec. 821). These programs support the supply and distribution of qualified nurses to meet our nation’s healthcare needs.

Without support for Title VIII funding and nursing education; there will be a shortage of nurse educators. With a shortage of nurse educators, schools will have to turn away nursing students. With less financial assistance to deserving nursing students; there will be fewer nursing students. With fewer nursing students, there will be fewer nurses. As noted above, the nursing shortage will have a detrimental impact on the entire healthcare system.

Numerous studies have shown that nursing shortages contribute to medical errors, poor patient outcomes, and increased mortality rates. A study published in the March 17, 2011 issue of the *New England Journal of Medicine* shows that inadequate staffing is tied to higher patient mortality rates. The study supports findings of previous studies and finds that higher than typical rates of patient admissions, discharges, and transfers during a shift were associated with increased mortality—an indication of the important time and attention needed by RNs to ensure effective coordination of care for patients at critical transition periods.

Over the last 48 years, Title VIII programs have provided the largest source of Federal funding for nursing education; offering financial support for nursing education programs, individual students, and nurse educators. These programs bolster nursing education at all levels, from entry-level preparation through graduate study and in many areas including rural and medically underserved communities.

The American Association of Colleges of Nursing’s (AACN) Title VIII Student Recipient Survey gathers information about Title VIII dollars and its impact on nursing students. The 2011–2012 survey, which included responses from more than 1,600 students, stated that Title VIII programs played a critical role in funding their nursing education. The survey showed that 68 percent of the students receiving Title VIII funding are attending school full-time. Between fiscal year 2005 and 2010 alone, the Title VIII programs supported more than 400,000 nurses and nursing students as well as numerous academic nursing institutions, and healthcare facilities.

However, current funding levels are falling short of the growing need. In fiscal year 2008 (most recent year statistics are available), the Health Resources and Services Administration (HRSA) was forced to turn away 92.8 percent of the eligible applicants for the Nurse Education Loan Repayment Program (NELRP), and 53 percent of the eligible applicants for the Nursing Scholarship program due to a lack of adequate funding. These programs are used to direct RNs into areas with the greatest need—including community health centers, departments of public health, and disproportionate share hospitals. Additionally according to the AACN Title VIII Student Recipient Survey, a record 58,327 qualified applicants were turned away due to insufficient clinical teaching sites, a lack of faculty, limited classroom space, insufficient preceptors and budget cuts.

Monies you appropriate for these programs help move nurses into the workforce without delay. Your investment in programs, and the nurses that participate, is returned by more students entering into the profession and serving in rural and underserved areas; by nurses continuing with their education and studying to be nurse practitioners, thereby addressing our Nation’s growing need for primary care pro-

viders; or by going on to become a nurse faculty member and teaching the next generation of nurses. While the ANA appreciates the continued support of this Subcommittee, we are concerned that Title VIII funding levels have not been sufficient to address the growing nursing shortage. Registered Nurses (RNs) and Advanced Practice Nurses (APRNs) are key providers whose care is linked directly to the availability, cost, and quality of healthcare services. For these reasons and many more, we again respectfully request you appropriate \$251 million for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act in fiscal year 2013.

NURSE-MANAGED HEALTH CLINICS

A healthcare system must value primary care and prevention to achieve an improved health status of individuals, families and the community. Nurses are strong supporters of community and home-based models of care. We believe that the foundation for a wellness-based healthcare system is built in these settings and reduces the amount of both financial expenditures and human suffering. ANA supports the renewed focus on new and existing community-based programs such as Nurse Managed Health Centers (NMHCs).

Currently, there are more than 200 Nurse Managed Health Centers (NMHCs) in the United States which have provided care to more than 2 million patients annually. ANA believes that Nurse Managed Health Centers (NMHCs) are an efficient, cost-effective way to deliver primary healthcare services. NMHCs are effective in disease prevention and early detection, management of chronic conditions, treatment of acute illnesses, health promotion, and more. These clinics are also used as clinical sites for nursing education.

The ANA again respectfully requests the committee provide \$20 million for the Nurse-Managed Health Clinics authorized under Title VIII of the Public Health Service Act in fiscal year 2013.

Thank you for your time and your attention to this matter.

PREPARED STATEMENT OF THE AMERICAN NATIONAL RED CROSS AND UNITED NATIONS FOUNDATION

Chairman Tom Harkin, Ranking Member Richard Shelby, and Members of the Subcommittee, the American Red Cross and the United Nations Foundation appreciate the opportunity to submit testimony in support of measles control activities of the U.S. Centers for Disease Control and Prevention (CDC). The American Red Cross and the United Nations Foundation recognize the leadership that the Congress has shown in funding CDC for these essential activities. We sincerely hope that the Congress will continue to support the CDC during this critical period in measles control.

In 2001, CDC—along with the American Red Cross, the United Nations Foundation, the World Health Organization, and UNICEF—founded the Measles Initiative, a partnership committed to reducing measles deaths globally. The current U.N. goal is to reduce measles deaths by 95 percent by 2015 compared to 2000 estimates. The Measles Initiative is committed to reaching this goal by providing technical and financial support to governments and communities worldwide.

The Measles Initiative has achieved “spectacular” results by supporting the vaccination of more than 1 billion children. Largely due to the Measles Initiative, global measles mortality dropped 74 percent, from an estimated 535,300 deaths in 2000 to 139,300 in 2010 (the latest year for which data is available). During this same period, measles deaths in Africa fell by 85 percent.

FIGURE 1.—ESTIMATED NUMBER OF GLOBAL MEASLES DEATHS, 2000–2010

	Number
2000	535.3
2001	528.8
2002	373.8
2003	484.3
2004	331.4
2005	384.8
2006	227.7
2007	130.1
2008	137.5
2009	177.9

FIGURE 1.—ESTIMATED NUMBER OF GLOBAL MEASLES DEATHS, 2000–2010—Continued

	Number
2010	139.3

Working closely with host governments, the Measles Initiative has been the main international supporter of mass measles immunization campaigns since 2001. The Initiative mobilized more than \$870 million and provided technical support in more than 60 developing countries on vaccination campaigns, surveillance and improving routine immunization services. From 2000 to 2010, an estimated 9.6 million measles deaths were averted as a result of these accelerated measles control activities at a donor cost of less than \$200/death averted, making measles mortality reduction one of the most cost-effective public health interventions.

Nearly all the measles vaccination campaigns have been able to reach more than 90 percent of their target populations. Countries recognize the opportunity that measles vaccination campaigns provide in accessing mothers and young children, and “integrating” the campaigns with other life-saving health interventions has become the norm. In addition to measles vaccine, Vitamin A (crucial for preventing blindness in under nourished children), de-worming medicine (reduces malnutrition), and insecticide-treated bed nets (ITNs) for malaria prevention are distributed during vaccination campaigns. The scale of these distributions is immense. For example, more than 42 million ITNs were distributed in vaccination campaigns in the last few years. The delivery of multiple child health interventions during a single campaign is far less expensive than delivering the interventions separately, and this strategy increases the potential positive impact on children’s health from a single campaign.

The extraordinary reduction in global measles deaths contributed nearly 25 percent of the progress to date toward Millennium Development Goal #4 (reducing under five child mortality). However, since 2009, Africa has experienced outbreaks affecting 28 countries, resulting in a four-fold increase in reported measles cases and in 2011, Europe experienced more than 30,000 cases with half of these cases in one country—France. These outbreaks highlight the fragility of the last decade’s progress. If mass immunization campaigns are not continued, measles deaths will increase rapidly with more than half a million deaths estimated for 2013 alone.

To achieve the 2015 goal and avoid a resurgence of measles the following actions are required:

- Fully implementing activities, both campaigns and strengthening routine measles coverage, in India since it is the greatest contributor to the global burden of measles.
- Sustaining the gains in reduced measles deaths, especially in Africa, by strengthening immunization programs to ensure that more than 90 percent of infants are vaccinated against measles through routine health services before their first birthday as well as conducting timely, high quality mass immunization campaigns.
- Acceleration of MCV2 introduction in eligible countries with support from the GAVI Alliance.
- Securing sufficient funding for measles-control activities both globally and nationally. The Measles Initiative faces a funding shortfall of an estimated United States \$112 million for 2012–2015. Implementation of timely measles campaigns is increasingly dependent upon countries funding these activities locally. The decrease in donor funds available at global level to support measles elimination activities makes increased political commitment and country ownership of the activities critical for achieving and sustaining the global goal of reducing measles mortality by 95 percent and supporting regional measles elimination goals.

If these challenges are not addressed, the remarkable gains made since 2000 will be lost and a major resurgence in measles deaths will occur.

By controlling measles cases in other countries, U.S. children are also being protected from the disease. Measles can cause severe complications and death. A resurgence of measles occurred in the United States between 1989 and 1991, with more than 55,000 cases reported. This resurgence was particularly severe, accounting for more than 11,000 hospitalizations and 123 deaths. Since then, measles control measures in the United States have been strengthened and endemic transmission of measles cases have been eliminated here since 2000. However, importations of measles cases into this country continue to occur each year. The costs of these cases and outbreaks are substantial, both in terms of the costs to public health departments and in terms of productivity losses among people with measles and parents

of sick children. Studies show that a single case of measles in the United States can cost between \$100,000 and \$200,000 to control. The United States had 222 measles cases in 2011, the highest in 15 years and Canada experienced a large outbreak of more than 800 cases.

The Role of the Centers for Disease Control and Prevention in Global Measles Mortality Reduction

Since fiscal year 2001, the Congress has provided between \$43.6 and \$49.3 million annually in funding to CDC for global measles control activities. These funds were used toward the purchase of measles vaccine for use in large-scale measles vaccination campaigns in more than 80 countries in Africa and Asia, and for the provision of technical support to Ministries of Health. Specifically, this technical support includes:

- Planning, monitoring, and evaluating large-scale measles vaccination campaigns;
- Conducting epidemiological investigations and laboratory surveillance of measles outbreaks; and
- Conducting operations research to guide cost-effective and high quality measles control programs.

In addition, CDC epidemiologists and public health specialists have worked closely with WHO, UNICEF, the United Nations Foundation, and the American Red Cross to strengthen measles control programs at global and regional levels. While it is not possible to precisely quantify the impact of CDC's financial and technical support to the Measles Initiative, there is no doubt that CDC's support—made possible by the funding appropriated by the Congress—was essential in helping achieve the sharp reduction in measles deaths in just 10 years.

The American Red Cross and the United Nations Foundation would like to acknowledge the leadership and work provided by CDC and recognize that CDC brings much more to the table than just financial resources. The Measles Initiative is fortunate in having a partner that provides critical personnel and technical support for vaccination campaigns and in response to disease outbreaks. CDC personnel have routinely demonstrated their ability to work well with other organizations and provide solutions to complex problems that help critical work get done faster and more efficiently.

In fiscal year 2011 and fiscal year 2012, the Congress appropriated approximately \$49 million each year to fund CDC for global measles control activities. This amount represents a \$2.7 million decrease from 2010. The American Red Cross and the United Nations Foundation respectfully request a return to fiscal year 2010 funding levels (\$52 million) for fiscal year 2013 for CDC's measles control activities to protect the investment of the last decade, and prevent a global resurgence of measles and a loss of progress toward Millennium Development Goal #4.

Your commitment has brought us unprecedented victories in reducing measles mortality around the world. In addition, your continued support for this initiative helps prevent children from suffering from this preventable disease both abroad and in the United States.

Thank you for the opportunity to submit testimony.

PREPARED STATEMENT OF AMERICANS FOR NURSING SHORTAGE RELIEF

The undersigned organizations of the ANSR Alliance greatly appreciate the opportunity to submit written testimony regarding fiscal year 2013 appropriations for the Title VIII Nursing Workforce Development Programs at the Health Resources and Services Administration (HRSA) and the Nurse Managed Health Clinics as authorized under Title III of the Public Health Service Act. We represent a diverse cross-section of healthcare and other related organizations, healthcare providers, and supporters of nursing issues that have united to address the national nursing shortage. ANSR stands ready to work with the Congress to advance programs and policy that will ensure our Nation has a sufficient and adequately prepared nursing workforce to provide quality care to all well into the 21st century. The Alliance, therefore, urges the Congress to:

- Appropriate \$251 million in funding for Nursing Workforce Development Programs under Title VIII of the Public Health Service Act at the Health Resources and Services Administration (HRSA) in fiscal year 2013.
- Appropriate \$20 million in fiscal year 2013 for the Nurse Managed Health Clinics as authorized under Title III of the Public Health Service Act.

The Nursing Shortage

Nursing is the largest healthcare profession in the United States. According to the National Council of State Boards of Nursing, there were nearly 3.854 million licensed RNs in 2010. Nurses and advanced practice nurses (nurse practitioners, nurse midwives, clinical nurse specialists, and certified registered nurse anesthetists) work in a variety of settings, including primary care, public health, long-term care, surgical care facilities, schools, and hospitals. The March 2008 study, *The Future of the Nursing Workforce in the United States: Data, Trends, and Implications*, calculates an adjusted projected demand of 500,000 full-time equivalent registered nurses by 2025. According to the U.S. Bureau of Labor Statistics, employment of registered nurses is expected to grow by 26 percent from 2010 to 2020 resulting in 711,900 new jobs. Based on these scenarios, the shortage presents an extremely serious challenge in the delivery of high quality, cost-effective services.

Build Capacity of Nursing Education Programs and Enhance Nursing Research

New models of overall healthcare delivery are being developed to address a range of challenges in healthcare and impact the structure of the workforce and care delivery. Government estimates indicate the nursing shortage only promises to worsen due to an insufficient supply of individuals matriculating in nursing schools, an aging existing workforce, and the inadequate availability of nursing faculty to educate and train the next generation of nurses. At the exact same time that the nursing shortage is expected to worsen, the baby boom generation is aging and the number of individuals with serious, life-threatening, and chronic conditions requiring nursing care will increase. Consequently, more must be done today by the Government to help ensure an adequate nursing workforce for the patients of today and tomorrow.

A particular focus on securing and retaining adequate numbers of faculty is essential to ensure that all individuals interested in—and qualified for—nursing school can matriculate in the year that they are accepted. The National League for Nursing found that in the 2009–2010 academic year,

- 42 percent of qualified applications to prelicensure RN programs were turned away.
- One in four (25.1 percent) of prelicensure RN programs turned away qualified applicants.
- Four out of five (60 percent) of prelicensure RN programs were considered “highly selective” by national college admissions standards, accepting less than 50 percent of applications for admission.

Aside from having a limited number of faculty, nursing programs struggle to provide space for clinical laboratories and to secure a sufficient number of clinical training sites at healthcare facilities.

ANSR supports the need for sustained attention on the efficacy and performance of existing and proposed programs to improve nursing practices and strengthen the nursing workforce. The support of research and evaluation studies that test models of nursing practice and workforce development is integral to advancing healthcare for all in America. Investments in research and evaluation studies have a direct effect on the caliber of nursing care. Our collective goal of improving the quality of patient care, reducing costs, and efficiently delivering appropriate healthcare to those in need is served best by aggressive nursing research and performance and impact evaluation at the program level.

Strengthen the Capacity of the National Nursing Public Health Infrastructure

Nurses make a difference in the lives of patients from disease prevention and management to education to responding to emergencies. Nearly half of Americans suffer from one or more chronic conditions and chronic disease accounts for 70 percent of all deaths. An October 2008 report issued by Trust for America’s Health entitled “Blueprint for a Healthier America” found that the health and safety of Americans depends on the next generation of professionals in public health. Further, existing efforts to recruit and retain the public health workforce are insufficient. New policies and incentives must be created to make public service careers in public health an attractive professional path, especially for the emerging workforce and those changing careers.

Public health nursing is the critical resources for healthy communities. Nurses are key healthcare workers that can help our Nation achieve its public health goals and protect our Nation from the full impact of disasters, both natural and man-made. Data from the 2000 National Sample Survey of Registered Nurses (conducted by the Health Resources Services Administration, Division of Nursing) indicate that the number of registered nurses (RNs) employed in public/community health settings with the title “public health nurse” has decreased from 39 percent in 1980 to

just 17.6 percent in 2000. Even in the overall public/community nursing group, there was a decrease of almost 16 percent between 1996 and 2000.

The shortage of school nurse positions contributes to holes in the healthcare safety net for all children. The Institute of Medicine report, "The Future of Nursing: Leading Change, Advancing Health", points out that with an expected increase in the number of children who have complex medical, genetic and mental/behavioral health conditions that require more nursing oversight, school nursing provides the expertise and coordination to assure that children receive the care they need.

Summary

RNs, advanced practice registered nurses, and nursing faculty are all critically necessary to sustain an adequate supply of nurses available to deliver quality healthcare. The U.S. nursing shortage is part of a larger worldwide nursing shortage. The international scope of this problem makes it an immediate and critical need for our Nation to develop additional strategies to appeal to men and women to pursue nursing and teaching nursing as a profession. Congress specifies the mission of Title VIII is to ensure a sufficient national supply of nurses; Title VIII programs must be adequately funded to fulfill that important mission. ANSR requests \$251 million in funding for Nursing Workforce Development Programs under Title VIII of the Public Health Service Act at HRSA and \$20 million for the Nurse Managed Health Clinics under Title III of the Public Health Service Act in fiscal year 2013.

LIST OF ANSR MEMBER ORGANIZATIONS

Academy of Medical-Surgical Nurses	National Association of Clinical Nurse Specialists
American Academy of Ambulatory Care Nursing	National Association of Hispanic Nurses
American Academy of Nurse Practitioners	National Association of Neonatal Nurses
American Academy of Nursing	National Association of Neonatal Nurse Practitioners
American Association of Nurse Anesthetists	National Association of Nurse Massage Therapists
American Association of Nurse Assessment Coordination	National Association of Nurse Practitioners in Women's Health
American Association of Occupational Health Nurses	National Association of Orthopedic Nurses
American College of Nurse-Midwives	National Association of Registered Nurse First Assistants
American Organization of Nurse Executives	National Association of School Nurses
American Psychiatric Nurses Association	National Black Nurses Association
American Society for Pain Management Nursing	National Council of State Boards of Nursing
American Society of PeriAnesthesia Nurses	National Council of Women's Organizations
American Society of Plastic Surgical Nurses	National Gerontological Nursing Association
Association for Radiologic & Imaging Nursing	National League for Nursing
Association of Pediatric Hematology/Oncology Nurses	National Nursing Centers Consortium
Association of State and Territorial Directors of Nursing	National Nursing Staff Development Organization
Association of Women's Health, Obstetric & Neonatal Nurses	National Organization for Associate Degree Nursing
Citizen Advocacy Center	National Student Nurses' Association, Inc.
Dermatology Nurses' Association	Nurses Organization of Veterans Affairs
Developmental Disabilities Nurses Association	Pediatric Endocrinology Nursing Society
Emergency Nurses Association	Preventive Cardiovascular Nurses Association
Infusion Nurses Society	RN First Assistants Policy & Advocacy Coalition
International Association of Forensic Nurses	Society of Gastroenterology Nurses and Associates, Inc.
International Nurses Society on Addictions	Society of Pediatric Nurses
International Society of Nurses in Genetics, Inc.	Society of Trauma Nurses
Legislative Coalition of Virginia Nurses	Women's Research & Education Institute
	Wound, Ostomy and Continence Nurses Society

PREPARED STATEMENT OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION

The American Psychological Association (APA) appreciates that the Committee is accepting outside witness testimony addressing the fiscal year 2013 Labor-HHS-Education appropriations bill. APA is a scientific and professional organization representing psychology in the United States, with 154,000 members and affiliates. APA's mission is to advance the creation, communication, and application of psychological knowledge to benefit society and improve people's lives. Although APA and its members have broad interests in many of the programs under the Subcommittee's jurisdiction, in this statement we highlight critical activities and funding needs in five agencies: the National Institutes of Health, Administration on Aging, Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the Substance Abuse and Mental Health Services Administration.

Substance Abuse and Mental Health Services Administration (SAMHSA).—SAMHSA's three component agencies have the primary Federal responsibility to mobilize and improve mental health and addiction services in the United States. The Center for Mental Health Services promotes improvements in mental health services that enhance the lives of adults who experience mental illnesses and children with serious emotional disorders; fills unmet and emerging needs; bridges the gap between research and practice; and strengthens data collection to improve quality and enhance accountability.

APA strongly recommends that the Congress allocate the fully authorized amount (\$50 million) for SAMHSA's National Child Traumatic Stress Network (NCTSN) program which works to aid the recovery of children, families, and communities impacted by a wide range of trauma, including physical and sexual abuse, natural disasters, sudden death of a loved one, the impact of war on military families, and much more. Specifically, APA recommends that SAMHSA increase the number of NCTSN grantees and maintain the collaborative model envisioned in the original authorization.

Racial and ethnic minorities represent 30 percent of our Nation's population, but only 23 percent of doctoral recipients in psychology, social work and nursing. The Minority Fellowship Program (MFP) is a unique workforce development initiative that trains ethnic minority mental and behavioral healthcare professionals to provide services to underserved communities. APA urges the Congress to maintain level funding for MFP (\$5.1 million). This funding is needed given the recent expansion of the program by granting eligibility to additional disciplines to participate.

Administration on Aging (AoA).—Older adults are one of the fastest growing segments of the U.S. population and approximately 25 percent of older Americans have a mental or behavioral health problem. In particular, older white males (age 85 and over) currently have the highest rates of suicide of any group in the United States. Accordingly, APA urges an expanded effort to address the mental and behavioral health needs of older adults including implementation of the mental and behavioral health provisions in the Older Americans Act Amendments of 2006, to provide grants to States for the delivery of mental health screening, and treatment services for older individuals and programs to increase public awareness and reduce the stigma associated with mental disorders in older individuals. APA also recommends that AoA designate an officer to administer mental health services for older Americans.

Family caregivers play an essential role in providing long-term services and supports for the chronically ill and aging. For this reason APA supports the Lifespan Respite Care Program and urges the Congress to appropriate \$5 million for this initiative.

National Institutes of Health (NIH).—The APA supports the recommendation of the Ad Hoc Group for Medical Research that the Subcommittee recognize the National Institutes of Health (NIH) as a critical national priority by providing at least \$32 billion in funding in fiscal year 2013. This recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

While there are many programs at NIH worthy of being highlighted, we want to mention some initiatives that are critically important to APA's member scientists. Regarding the proposed reorganization of substance use, abuse and addiction research at NIH, APA has long been concerned that substance use, abuse and addiction research is significantly underfunded when weighed against the public health and public safety impact associated with alcohol, tobacco, and illicit substance use. Any newly reorganized entity must be greater than the sum of its parts. This Committee should encourage NIH to fully integrate the substance use and related research portfolios of all other NIH Institutes and Centers in order to develop a new infrastructure for conducting that research with particular attention to tobacco, co-

morbid mental health disorders, and other compulsive use behaviors. NIH should establish rigorous and transparent baselines to define current funding levels, and the allocation of those funds across the existing NIH Institutes and Centers to ensure the ability to assess the evolution of the portfolios and effectiveness of any organizational change. This Committee should encourage the continued active involvement of extramural scientists at every stage of this process as well as the Office of Behavioral and Social Sciences Research.

To its credit NIH is moving quickly to identify the reasons, documented in a recent Science article, that black investigators are significantly less likely to receive RO1 awards than investigators from other racial groups. The Committee should encourage NIH to devote all necessary resources to this investigation and subsequent corrective action. Additional efforts should go toward enhancing the pipeline of minority investigators. The Office of Behavioral and Social Sciences Research should be commended for its support of a workshop addressing ways to establish a comprehensive and cohesive process to track the efforts of Government, universities, private foundations and associations to enhance minority participation in the sciences.

APA is concerned that the budget of the Office of Behavioral and Social Sciences Research has been flat, at \$27 million, for 3 years, and urges the Committee to provide an inflationary increase at a minimum.

The National Institute on Aging (NIA) has been the focus of additional resources from the administration so that it may push forward its research on Alzheimer's disease, now that the Congress has passed legislation authorizing a National Plan for Alzheimer's research, care and services. The Committee is encouraged to give full support to the NIA budget.

Biomedical approaches to HIV prevention are most effective when they are combined with behavioral approaches. With recent scientific advances demonstrating the promise of biomedical HIV prevention interventions, behavioral research is needed more than ever to bolster medication adherence and treatment uptake, to document real-world decisionmaking processes associated with biomedical interventions, and to better understand potential unintended and/or undesired consequences of biomedical interventions. APA encourages the Committee to continue to press the National Institute on Mental Health to support a robust HIV/AIDS behavioral prevention research agenda that examines these factors, and includes operations research to optimize combination HIV prevention.

Health Resources and Services Administration (HRSA), Bureau of Health Professions.—The APA requests that the Subcommittee include \$4.5 million for the Graduate Psychology Education Program (GPE) within HRSA. An exemplary “two-for-one” Federal activity, this nationally competitive grant program supports the training of psychology graduate students while they provide mental and behavioral health services. In rural and urban underserved communities, services are provided under supervision at no charge to underserved populations, such as children, older adults, chronically ill persons, victims of abuse or trauma, including returning military personnel, veterans and their families, and the unemployed. To date there have been 125 grants in 32 States to universities and hospitals throughout the Nation. All psychology graduate students who benefited from GPE funds are expected to work with underserved populations and more than 80 percent will work in underserved areas immediately after completing the training.

The GPE Program is specifically authorized at between \$10 million and \$12 million per year by the Public Health Service Act [Section 756(a)(2)]. Also Section 755(b)(1)(J) provides broader additional authority. HRSA receives appropriations for the program under its “Mental and Behavioral Health” account in the Labor-HHS appropriations bill. GPE was included in the President's budget at its current funding level of \$3 million.

Established in 2002, GPE grants have supported the interdisciplinary training of more than 3,000 graduate students of psychology and other health professions to provide integrated healthcare services to underserved populations. The fiscal year 2013 GPE funding request will focus especially on providing services to returning military personnel, veterans and their families, unemployed persons and others affected by the economic downturn, and older adults in underserved communities. Also the GPE funding request will also be used to create training opportunities at our Nation's Federally Qualified Health Centers, which play a critical role in meeting the healthcare needs of our nation's underserved persons.

Centers for Disease Control and Prevention (CDC).—As a member of the Centers for Disease Control and Prevention (CDC) Coalition, APA supports a minimum budget of \$7.8 billion for CDC core programs in fiscal year 2013. CDC programs play a key role in maintaining a strong public health infrastructure, protecting Americans from public health threats and emergencies, and in reducing healthcare costs and strengthening the Nation's health system. The Prevention and Public

Health Fund and other fund transfers heavily supplant program budgets in the fiscal year 2013 President's budget. The proposed \$664 million cut to CDC's budget authority in the President's budget request would amount to a \$1.4 billion decrease in CDC's budget authority since fiscal year 2010. APA urges the Subcommittee to restore this cut.

APA is disappointed to see a decrease in funding of more than 10 percent for the Prevention Research Centers (PRC) program in the President's budget request. A focus on prevention is essential to improving health in America and the PRC network of community, academic, and public health partners makes significant contributions to research on evidenced based approaches in health promotion. APA urges the Congress to designate specific funding for the program again in fiscal year 2013, including the resources necessary to support the Prevention Research Centers so that this network of academic institutions and organizations can continue to contribute widely and effectively to prevention science.

As a member of the Friends of the National Center for Health Statistics (NCHS), APA endorses the President's fiscal year 2013 request of \$162 million in funding for the agency's base discretionary budget. The health data collected by NCHS, on chronic disease prevalence, healthcare disparities, emergency room use, teen pregnancy, infant mortality, causes of death, and rates of insurance, to name a few, are essential to the Nation's statistical and public health infrastructure. Your leadership in securing steady and sustained funding increases for NCHS over the last 5 fiscal years has helped NCHS rebuild after years of underinvestment and restored the collection of essential health data. In particular, APA is pleased with the Center's progress in the past year field testing data collection methods for sexual orientation, and hopes for the expedient incorporation of this data, as well as that on gender identity, into the National Health Interview Survey and other appropriate surveys.

APA is pleased to see the increase in funding for the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention in the President's fiscal year 2013 budget, and in particular the \$40.2 million increase in funding for domestic HIV/AIDS prevention and research in line with the National HIV/AIDS Strategy. APA supports the maximum possible funding for HIV/AIDS prevention for fiscal year 2013 to scale up combination HIV prevention. APA urges CDC to make additional funds available for screening for mental health and substance use disorders in HIV testing programs; behavioral interventions to optimize biomedical interventions; and operations research to inform implementation of high impact HIV prevention.

As a member of the Injury and Violence Prevention Stakeholder Coalition, convened by the Safe States Alliance, APA supports restoration of the CDC Injury Center to its fiscal year 2011 level of \$147 million and restoration of the Preventive Health and Health Services Block Grant to its fiscal year 2011 level of \$100 million. The Injury Center and the Preventive Health and Health Services Block Grant are critical to the State and local injury and violence prevention efforts.

Again, APA is grateful for the opportunity to present these recommendations for fiscal year 2013.

PREPARED STATEMENT OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

The American Public Health Association is the oldest and most diverse organization of public health professionals and advocates in the world dedicated to promoting and protecting the health of the public and our communities. We are pleased to submit our views regarding fiscal year 2013 funding for the Centers for Disease Control and Prevention, the Health Resources and Services Administration and school-based health programs. We urge you to take our recommendations into consideration as you work to develop the fiscal year 2013 Labor-HHS-Education appropriations bill.

Centers for Disease Control and Prevention

APHA believes that the Congress should support CDC as an agency—not just the individual programs that it funds. In our best judgment—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and reemerging infectious diseases and our many unmet public health needs and missed prevention opportunities—CDC will require funding of at least \$7.8 billion for CDC's programs in fiscal year 2013. We are deeply disappointed with the proposed \$664 million cut to CDC's budget authority contained in the President's fiscal year 2013 budget proposal. In fact, when including the President's fiscal year 2013 request, CDC's budget authority would have been decreased by a staggering \$1.4 billion since fiscal year 2010. While CDC has received and the President's fiscal year 2013 budget proposal directs significant funding from

the Prevention and Public Health Fund to CDC, we believe this funding is essentially supplanting many of the cuts made to CDC's budget authority. We urge you to restore this cut to CDC's budget authority and to support the \$1 billion available through Prevention and Public Health Fund in fiscal year 2013.

By translating research findings into effective intervention efforts, CDC is a critical source of funding for many of our State and local programs that aim to improve the health of our communities. Perhaps more importantly, Federal funding through CDC provides the foundation for our State and local public health departments, supporting a trained workforce, laboratory capacity and public health education communications systems. We urge you to restore the proposed elimination of the Preventive Health and Health Services Block grant in the President's budget, which is a critical source of funding for State and local public health agencies.

CDC also serves as the command center for our Nation's public health defense system against emerging and reemerging infectious diseases. With the potential onset of a worldwide influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center. States and communities rely on CDC for accurate information and direction in a crisis or outbreak.

CDC serves as the lead agency for bioterrorism and other public health emergency preparedness and response and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. Given the challenges of terrorism and disaster preparedness, and our many unmet public health needs and missed prevention opportunities we urge you to provide adequate funding for State and local capacity grants. Unfortunately, this is not a threat that is going away.

The President's fiscal year 2013 budget proposes to consolidate a number of chronic disease programs within CDC to promote better coordination. If it is to be effective, we believe this proposal, the Coordinated Chronic Disease Prevention and Health Promotion program, must receive the resources needed to provide our States and communities increased and sustainable funding to effectively improve efforts to reduce the burden of chronic disease.

We encourage the Subcommittee to restore funding for CDC's National Center for Environmental Health. Since 2009, NCEH funding has been cut by 25 percent. We urge the committee to restore funding for the Healthy Homes and Lead Poisoning Prevention program and to main the program and Asthma program as separate and distinct programs. We ask the Subcommittee to continue its recent efforts to maintain CDC's capacity to help the Nation prepare for and adapt to the potential health effects of climate change by providing CDC with level funding for climate change and health activities.

We also urge you to restore funding for the Education and Research Centers and for the Agriculture, Forestry and Fishing Program (AFF) within the budget for the National Institute for Occupational Safety and Health which are proposed for elimination in the President's budget. These programs play an important role in protecting the health and safety of American workers.

Health Resources and Services Administration

HRSA operates programs in every State and territory and thousands of communities across the country and is a national leader in providing health services for individuals and families. The agency serves as a health safety net for the medically underserved, including the nearly 50 million Americans who were uninsured in 2010 and 60 million Americans who live in neighborhoods where primary healthcare services are scarce. To respond to these challenges, APHA believes that the agency will require an overall funding level of at least \$7 billion for fiscal year 2013.

Our request of \$7 billion represents the amount necessary for HRSA to continue to meet the healthcare needs of the American public. Anything less will undermine the efforts of HRSA programs to improve access to quality healthcare for millions of our neediest citizens. Additionally, we remain concerned about the deep cuts the agency has endured over the past few years; HRSA's discretionary budget has been reduced by more than \$1.2 billion since fiscal year 2010. Cuts of this magnitude have had a serious negative impact on the agency's ability to carry out critical public health programs and services for millions of Americans. Therefore, our requested level of funding is necessary to ensure HRSA is able to implement public health programs including training for public health and healthcare professionals, providing primary care services through community health centers, improving access to care for rural communities, supporting maternal and child healthcare programs and providing healthcare to people living with HIV/AIDS.

Some of the major healthcare initiatives conducted by HRSA include:

- Health Professions programs that support the education and training of primary care physicians, nurses, dentists, optometrists, physician assistants, public health personnel and other allied health providers; improve the distribution and diversity of health professionals in medically underserved communities and ensure a sufficient and capable health workforce able to provide care for all Americans and respond to the growing demands of our aging and increasingly diverse population. In addition, the Patient Navigator Program helps individuals in underserved communities, who suffer disproportionately from chronic diseases, navigate the health system.
- Primary Care programs that support more than 7,000 community health centers and clinics in every State and territory, improving access to preventive and primary care in geographically isolated and economically distressed communities. In addition, the health centers program targets populations with special needs, including migrant and seasonal farm workers, homeless individuals and families, and those living in public housing.
- Maternal and Child Health programs including the Title V Maternal and Child Health Block Grant, Healthy Start and others support a myriad of initiatives designed to promote optimal health, reduce disparities, combat infant mortality, prevent chronic conditions, and improve access to quality healthcare for more than 40 million women and children, including children with special healthcare needs.
- HIV/AIDS programs that provide assistance to metropolitan and other areas most severely affected by the HIV/AIDS epidemic; support comprehensive care, drug assistance and support services for people living with HIV/AIDS; provide education and training for health professionals treating people with HIV/AIDS; and address the disproportionate impact of HIV/AIDS on women and minorities.
- Family Planning Title X services that ensure access to a broad range of reproductive, sexual, and related preventive healthcare for more than 5.2 million poor and low-income women, men and adolescents at nearly 4,400 health centers nationwide. This program helps improve maternal and child health outcomes and promotes healthy families.
- Rural Health programs improve access to care for the more than 60 million Americans who live in rural areas. These programs support community-based disease prevention and health promotion projects, help rural hospitals and clinics implement new technologies and strategies, and build health system capacity in rural and frontier areas.
- Special Programs that include the Organ Procurement and Transplantation Network, the National Marrow Donor Program, the C.W. Bill Young Cell Transplantation Program, and National Cord Blood Inventory, which help people who need potentially life-saving transplants by connecting patients, doctors, donors, and researchers to the resources they need to live longer, healthier lives.

School Health

Nearly one-third of students in the United States do not graduate from high school, and for Black, Latino and American Indian students, the number is half. As indicated in Healthy People 2020, the leading indicator determining health status in the United States is graduation from high school. Thus, graduation from high school is not only a predictor of economic success but also of long-term health.

Some of the social factors that influence whether or not a student remains in school and graduates simultaneously influence their health and vice versa. That is why these factors are also included in the adolescent health objectives of Healthy People 2020. A number of studies now recognize the cause and effect between social determinants of health and achievement. The October 2011 issue of the *Journal of School Health* identified seven educationally related health disparities that contribute to the achievement gap and ultimately school dropout: (1) hunger, (2) aggression and violence, (3) teen pregnancy, (4) asthma, (5) vision, (6) physical, and (7) inattention and hyperactivity.

SBHCs can address these issues and improve educational success of at-risk students. Studies have also shown that SBHCs create the conditions needed for educational success by meeting student's physical and mental healthcare needs. They have been shown to reduce absenteeism, improve grade point average, and improve the overall school climate.

We urge you to provide the \$50 million in fiscal year 2013 for operation of school-based health centers as authorized in the Patient Protection and Affordable Care Act. We also urge you to consider the social factors that influence health and ultimately graduation and ask you to provide \$120 million for programs in the Office of Safe and Healthy Students in the U.S. Department of Education.

Conclusion

In closing, we emphasize that public health programs require stronger financial investments at every stage. Funding for these programs makes up only a fraction of Federal spending and continued cuts to public health and prevention programs will not balance our budget, it will only lead to increased costs to our healthcare system. Successes in biomedical research must be translated into tangible prevention opportunities, screening programs, lifestyle and behavior changes and other population-based interventions that are effective and available for everyone. Without a robust and sustained investment in our Nation's public health programs and agencies, we will fail to meet the mounting health challenges facing our Nation.

 PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) appreciates the opportunity to submit this statement supporting funding for the Low-Income Home Energy Production Assistance Program (LIHEAP) for fiscal year 2013.

APPA has consistently supported an increase in the authorization level for LIHEAP. The administration's fiscal year 2013 budget requests \$3 billion for LIHEAP—a cut of \$452 million from fiscal year 2012 levels. APPA supports extending the current level of \$5.1 billion for the program.

APPA is the national service organization representing the interests of more than 2,000 municipal and other State and locally owned utilities throughout the United States (all but Hawaii). Collectively, public power utilities deliver electricity to 1 of every 7 electricity consumers (approximately 46 million people), serving some of the Nation's largest cities. However, the vast majority of APPA's members serve communities with populations of 10,000 people or less.

APPA is proud of the commitment that its members have made to their low-income customers. Many public power systems have low-income energy assistance programs based on community resources and needs. Our members realize the importance of having in place a well-designed, low-income customer assistance program combined with energy efficiency and weatherization programs in order to help consumers minimize their energy bills and lower their requirements for assistance. While highly successful, these local initiatives must be coupled with a strong LIHEAP program to meet the growing needs of low-income customers. In the last several years, volatile home-heating oil and natural gas prices, severe winters, high utility bills as a result of dysfunctional wholesale electricity markets and the effects of the economic downturn have all contributed to an increased reliance on LIHEAP funds. Even at \$5.1 billion, LIHEAP cannot provide assistance to all who qualify for the program. Cutting this program by \$2.5 billion would have very serious consequences for those who rely on the program.

Also, when considering LIHEAP appropriations this year, we encourage the subcommittee to provide advanced funding for the program so that shortfalls do not occur in the winter months during the transition from one fiscal year to another. LIHEAP is one of the outstanding examples of a State-operated program with minimal requirements imposed by the Federal Government. Advanced funding for LIHEAP is critical to enabling States to optimally administer the program.

Thank you again for this opportunity to relay our support for increased LIHEAP funding for fiscal year 2013.

 PREPARED STATEMENT OF THE ASSOCIATION OF PUBLIC TELEVISION STATIONS AND THE PUBLIC BROADCASTING SERVICE

On behalf of America's 361 public television stations, we appreciate the opportunity to submit testimony for the record on the importance of Federal funding for local public television stations.

Corporation for Public Broadcasting—Fiscal Year 2015 Request: \$445 Million, 2-Year Advance Funded

More than 40 years after the inception of public broadcasting, local stations continue to serve as the treasured educational and cultural institutions envisioned by their founders, reaching America's local communities with unique, essential and unsurpassed programming and services.

Public television treats its audience as citizens rather than mere consumers. We provide essential services to all Americans, not just the 18–49 year olds to whom advertisers hope to appeal to because of that age group's spending habits. We serve everyone, everywhere, every day, for free.

Public broadcasting serves the public good—in education, public affairs, public safety, the preservation of the national memory and celebration of the American culture, and many other areas—and richly deserves public support. The overwhelming majority of Americans agree. In a recent bipartisan poll conducted by Hart Research Associates/American Viewpoint, nearly 70 percent of American voters, including majorities of self-identifying Republicans, Independents, and Democrats support continued Federal funding for public broadcasting. In addition, the same poll shows that Americans consider PBS to be the second most appropriate expenditure of public funds, behind only national defense.

Federal support for CPB and local public television stations has resulted in a nationwide system of locally owned and controlled, trusted, community-driven and community responsive media entities.

We seek Federal funding for public broadcasting because we are part of the Nation's public service infrastructure, just like public libraries, public schools and public highways.

Furthermore, the power of digital technology has enabled stations to greatly expand their delivery platforms to reach Americans where they are increasingly consuming media—online and on-demand—in addition to on-air. At the same time that stations are expanding their services and the impact they have in their communities, stations are also facing unprecedented funding challenges—presenting them with the greatest financial hurdles in their 40 year history. Funding from traditional sources such as individuals, corporate underwriters, foundations and State governments has become increasingly more challenging to secure in this difficult economy. Continued Federal support for public broadcasting is more important now than ever before.

Funding through CPB is absolutely essential to public television stations. Stations rely on the Federal investment to develop local programming, operate their facilities, pay their employees and provide community resources on-air, online and on-the-ground. This funding is particularly important to rural stations that struggle to raise local funds from individual donors due to the smaller and often economically strained population base. At the same time it is often more costly to serve rural areas due to the topography and distances between communities.

More than 70 percent of funding appropriated to CPB reaches local stations in the form of Community Service Grants (CSGs). On average, Federal spending makes up approximately 15 percent of local television station's budgets. However, for many smaller and rural stations, Federal funding represents more than 30–50 percent (and in a handful of instances, an even larger percentage) of their total budget. For all stations, this Federal funding is the “lifeblood” of public broadcasting, providing critical seed money to local stations which leverage each \$1 of the Federal investment to raise more than \$6 from State legislatures, private foundations and corporations, and “viewers like you.”

A 2007 GAO report concluded that Federal funding, such as CSGs, is an irreplaceable source of revenue, and that “substantial growth of non-Federal funding appears unlikely.” It also found that “cuts in Federal funding could lead to a reduction in staff, local programming or services.” This study was conducted before the severe economic recession that struck in 2008, and its findings may be even more acute today.

At an annual cost of about \$1.37 per year for each American—compared with \$68 in Japan and \$83 in Great Britain—public broadcasting is a smart investment. This successful public-private partnership creates important economic activity while providing an essential educational and cultural service. Public broadcasting directly supports more than 24,000 jobs, and the vast majority of them are in local public television and radio stations in hundreds of communities across America.

In addition, the advent of digital technology has created enormous potential for stations, allowing them to bring content to Americans in new, innovative ways while retaining our fundamental public service mission. Public television stations are now utilizing a wide array of digital tools to expand their current roles as educators, local conveners and vital sources of trusted information at a time when their communities need them most. For example, in an effort to confront the dropout crisis in America's high schools, CPB has developed the American Graduate initiative, a significant investment and partnership with local stations and their communities to address this daunting problem that could have disastrous effects on America's future if it is not soon addressed. Together with schools and organizations that are already addressing the dropout crisis, the stations are providing their resources and services to raise awareness, coordinate action with community partners, and work directly with students, parents, teachers, mentors, volunteers and leaders to lower the drop-out rate in their respective communities.

Public television is the Nation's largest classroom. Local stations provide free, cutting edge, educational content for all Americans so that regardless of their family's income, children have access to safe, non-commercial media that helps prepare them for success in school and has been proven to help close the achievement gap.

Stations are also responding to the needs of the 21st century classroom by expanding digital educational resources for teachers, students and parents alike. For example, stations are working together with PBS to create an online portal, PBS Learning Media, where educators can access standards-based, curriculum-aligned digital learning objects created from public television content as well as material from the Library of Congress, National Archives, and other contributors to the Department of Education's Learning Registry. Stations are also building homegrown learning platforms like Maryland Public Television's Thinkport online system, which the State superintendent of schools has credited with helping raise Maryland's students to the top of the student achievement rankings nationwide.

Local public television stations have also embraced the opportunities of digital technology as a way to help address emergency response and homeland security issues in their communities. Stations like Las Vegas PBS have integrated their digital technology with local public safety officials to provide enhanced emergency communications that better aide the responders and provide citizens with needed information during a crisis. Vegas PBS is also the largest job trainer in Nevada, and this manifold mission of service is being emulated by public television stations nationwide.

Local public television stations serve as essential communications hubs in their communities providing unparalleled local coverage of news, current events, and State legislatures that encourages every American to become a more informed citizen. Public television is the place for real public affairs programming, real news, real history, real science, real art that makes us think, teaches us useful things, and inspires us to be a better, more sophisticated, more civilized, more successful people. We bring the wonders of the world—Broadway shows, the finest museums, the best professors and much more—to the most remote places in our country.

In order for our stations to continue playing this vital role in their communities, APTS and PBS respectfully request \$445 million for CPB, 2-year advance funded for fiscal year 2015.

Two-year advance funding is essential to the mission of public broadcasting. This longstanding practice, which was proposed by President Ford and embraced by the Congress in 1976, establishes a firewall insulating programming decisions from political interference, enables the leveraging of funds to ensure a successful public-private partnership, and provides stations with the necessary lead time to plan in-depth programming.

The 2-year advance funding mechanism insulates programming decisions from political influence, as President Ford and the Congress intended in their initial proposal for advance funding.

Public television's history of editorial independence has paid off in unprecedented levels of public trust—for the ninth consecutive year, the American people have ranked public broadcasting as one of the most trusted national institutions. Advance funding and the firewall it provides is vital to maintaining this credibility among the American public.

In addition, local public broadcasting stations are able to leverage the 2-year advance funding to raise State, local and private funds, ensuring the continuation of this strong public-private partnership. These Federal funds act as essential seed money for fundraising efforts at every station, no matter its size.

Finally, the 2-year advance funding mechanism also gives stations and producers the critical lead time needed to plan and produce high-quality programs. The signature series that demonstrate the depth and breadth of public television, like Ken Burns' "The Civil War" and Henry Hampton's "Eyes on the Prize", take several years to produce. Ken Burns's documentary schedule is already planned through 2019, and it will educate the Nation on subjects ranging from the Dust Bowl to the Vietnam war to the history of country music.

The fact that stations know they will have funding to support projects like these in advance is critical for producers to be able to actively develop groundbreaking projects. In addition to national programming, 2-year advance funding is essential to the creation of local programming over multiple fiscal years as stations convene the community to identify needs, recruit partners, conduct research, develop content and deliver services.

The 2-year advance funding is essential for stations as they continue to plan the production of the unparalleled programming and local services that educate, inspire, inform and entertain the American people in the unique way only public broadcasting can.

Ready To Learn—Fiscal Year 2013 Request: \$27.3 Million (Department of Education)

The Ready to Learn Television competitive grant program's success in improving children's literacy and preparing them for school is proven and unquestioned. Ready to Learn combines the power of public media's on-air and online educational content with on-the-ground local station community engagement to build the literacy skills of children between the ages of two and eight, especially those from low-income families or those most lacking reading skills.

Over the last 5 years, 60 independent studies have proven the effectiveness of public media's Ready to Learn approach. In one study pre-schoolers who were exposed to a curriculum composed of programming and interactive games from top Ready to Learn programs, including "SUPER WHY!," "Between the Lions" and "Sesame Street", outscored children who received a comparison (science) curriculum in all five measures of early literacy. In addition, use of Ready to Learn curriculum has been proven to help close the achievement gap by enabling low-income students to catch up to their peers from high-income households as shown when comparing standardized reading assessments.

Pivoting off of this success in literacy, public media will expand its Ready to Learn effort to include early math skills to continue helping bridge the achievement gap by further innovating educational media content, educating kids inside and outside the classroom, and engaging local communities. This will include developing new content like a PBS KIDS TV math series and three new math TV pilots. In addition to the content, new tools will be provided including a sophisticated progress tracking system that equips parents and educators with the means to measure student progress, in real time. Ready to Learn will continue to be rigorously evaluated for its appeal and efficacy, so that the program can continue to offer America's youngest citizens the tools they need to succeed in school and in life.

In addition to being research-based and teacher tested, the Ready to Learn Television program also provides excellent value for our Federal dollars. In the last 5-year grant round, public broadcasting leveraged an additional \$50 million in funding to augment the \$73 million investment by the Department of Education for content production. Without the investment of the Federal Government, this supplemental funding would likely end.

The President's budget proposes consolidating Ready to Learn into a larger grant program. APTS and PBS are concerned that the consolidation of this program could lead to the elimination of this critical program that has been the driving force behind the creation of public television's unparalleled children's educational programming. The proposed budget would significantly weaken Ready to Learn's unique local-national partnership between communities and their public media stations and PBS with its national scope and resources. This local-national partnership has made Ready to Learn tremendously efficient and effective and is a key element of the successful operation of the program. Consolidation or elimination of the Ready to Learn Television program would severely affect the ability of local stations to respond to their communities' educational needs, removing the critical resources provided by this program for children, parents and teachers.

Ready to Learn symbolizes the mission of public media and is a shining example of a public-private partnership as Federal funds are leveraged to create the most appealing and impactful children's educational content that is supplemented by on-line and on-the-ground resources. Without the Ready to Learn program, millions of families would lose access to this incredible high-quality education content, especially low-income and underserved households for whom this program is targeted.

We urge the Committee to maintain the Ready to Learn Television program as a stable line-item in the fiscal year 2013 budget and resist the calls for consolidation. APTS and PBS respectfully request level funding of \$27.3 million for the Ready to Learn Television program in fiscal year 2013.

One hundred seventy million Americans regularly rely on public broadcasting—on television, on the radio, online, and in the classroom—because we provide them something they need that no one else in the media world provides: A place to think. A place to learn. A place to grow. A tool for the citizen. None of this would be possible without the Federal investment in public broadcasting.

We request that the Congress continue its commitment to this highly successful public-private partnership by continuing to provide level funding for the 2-year advance of the Corporation for Public Broadcasting and the Ready to Learn Program.

PREPARED STATEMENT OF THE ASSOCIATION OF REHABILITATION NURSES

INTRODUCTION

On behalf of the Association of Rehabilitation Nurses (ARN), I appreciate having the opportunity to submit written testimony to the Senate LHHs Appropriations Subcommittee regarding funding for nursing and rehabilitation related programs in fiscal year 2013. ARN represents nearly 12,000 rehabilitation nurses that work to enhance the quality of life for those affected by physical disability and/or chronic illness. ARN understands that the Congress has many concerns and limited resources, but believes that chronic illnesses and physical disabilities are heavy burdens on our society that must be addressed.

REHABILITATION NURSES AND REHABILITATION NURSING

Rehabilitation nurses help individuals affected by chronic illness and/or physical disability adapt to their condition, achieve their greatest potential, and work toward productive, independent lives. We take a holistic approach to meeting patients' nursing and medical, vocational, educational, environmental, and spiritual needs. Rehabilitation nurses begin to work with individuals and their families soon after the onset of a disabling injury or chronic illness. We continue to provide support and care, including patient and family education, which empowers these individuals when they return home, or to work, or school. The rehabilitation nurse often teaches patients and their caregivers how to access systems and resources.

Rehabilitation nursing is a philosophy of care, not a work setting or a phase of treatment. We base our practice on rehabilitative and restorative principles by: (1) managing complex medical issues; (2) interprofessional collaboration with other specialists; (3) providing ongoing patient/caregiver education; (4) setting goals for maximum independence; and (5) establishing plans of care to maintain optimal wellness. Rehabilitation nurses practice in all settings, including freestanding rehabilitation facilities, hospitals, long-term subacute care facilities/skilled nursing facilities, long-term acute care facilities, comprehensive outpatient rehabilitation facilities, home health, and private practices, just to name a few.

As we celebrate the 2 year anniversary of the Affordable Care Act (ACA)—which focused on creating a system that will increase access to quality care, emphasizes prevention, and decreases costs—it is critical that a substantial investment be made in the nursing workforce programs and in the scientific research that provides the basis for nursing practice. To ensure that patients receive the best quality care possible, ARN supports Federal programs and research institutions that address the national nursing shortage and conduct research focused on nursing and medical rehabilitation, e.g., traumatic brain injury. Therefore, ARN respectfully requests that the Subcommittee provide increased funding for the following programs:

NURSING WORKFORCE AND DEVELOPMENT PROGRAMS AT THE HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

ARN supports efforts to resolve the national nursing shortage, including appropriate funding to address the shortage of qualified nursing faculty. Rehabilitation nursing requires a high-level of education and technical expertise, and ARN is committed to assuring and protecting access to professional nursing care delivered by highly educated, well-trained, and experienced registered nurses for individuals affected by chronic illness and/or physical disability.

According to the Health Resources and Services Administration (HRSA), in 2010, our healthcare workforce experienced a shortage of more than 400,000 nurses.¹ The demand for nurses will continue to grow as the baby-boomer population ages, nurses retire, and the need for healthcare intensifies. Implementation of the new health reform law will also increase the need for a well-trained and highly skilled nursing workforce. The Institute of Medicine has released recommendations on how to help the nursing workforce meet these new demands, but we are destined to fall short of these lofty goals if there are not enough nurses to facilitate change.

According to the U.S. Bureau of Labor Statistics, nursing is the Nation's top profession in terms of projected job growth, with more than 581,500 new nursing positions being created through 2018.² These positions are in addition to the existing jobs that healthcare employers have not been able to fill. Educating new nurses to fill these gaping vacancies is a great way to put Americans back to work and simultaneously enhance an ailing healthcare system.

¹ <http://bhpr.hrsa.gov/healthworkforce/reports/nursing/rnbehindprojections/4.htm>.

² <http://www.bls.gov/oco/ocos083.htm#outlook>.

ARN strongly supports the national nursing community's request of \$251 million in fiscal year 2013 funding for Federal Nursing Workforce Development programs at HRSA.

NATIONAL INSTITUTE ON DISABILITY AND REHABILITATION RESEARCH (NIDRR)

The National Institute on Disability and Rehabilitation Research (NIDRR) provides leadership and support for a comprehensive program of research related to the rehabilitation of individuals with disabilities. As one of the components of the Office of Special Education and Rehabilitative Services at the U.S. Department of Education, NIDRR operates along with the Rehabilitation Services Administration and the Office of Special Education Programs.

The mission of NIDRR is to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community, and also to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. NIDRR conducts comprehensive and coordinated programs of research and related activities to maximize the full inclusion, social integration, employment and independent living of individuals of all ages with disabilities. NIDRR's focus includes research in areas such as: employment, health and function, technology for access and function, independent living and community integration, and other associated disability research areas.

ARN strongly supports the work of NIDRR and encourages the Congress to provide the maximum possible fiscal year 2013 funding level.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

ARN understands that research is essential for the advancement of nursing science, and believes new concepts must be developed and tested to sustain the continued growth and maturation of the rehabilitation nursing specialty. The National Institute of Nursing Research (NINR) works to create cost-effective and high-quality healthcare by testing new nursing science concepts and investigating how to best integrate them into daily practice. Through grants, research training, and inter-professional collaborations, NINR addresses care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life for those with chronic illness, and care for individuals at the end of life. NINR's broad mandate includes seeking to prevent and delay disease and to ease the symptoms associated with both chronic and acute illnesses. NINR's recent areas of research focus include the following:

- End of life and palliative care in rural areas;
- Research in multi-cultural societies;
- Bio-behavioral methods to improve outcomes research; and
- Increasing health promotion through comprehensive studies.

ARN respectfully requests \$150 million in fiscal year 2013 funding for NINR to continue its efforts to address issues related to chronic and acute illnesses.

TRAUMATIC BRAIN INJURY (TBI)

According to the Brain Injury Association of America, 1.7 million people sustain a traumatic brain injury (TBI) each year.³ This figure does not include the 150,000 cases of TBI suffered by soldiers returning from wars in Afghanistan and conflicts around the world.

The annual national cost of providing treatment and services for these patients is estimated to be nearly \$60 million in direct care and lost workplace productivity. Continued fiscal support of the Traumatic Brain Injury Act will provide critical funding needed to further develop research and improve the lives of individuals who suffer from traumatic brain injury.

Continued funding of the TBI Act will promote sound public health policy in brain injury prevention, research, education, treatment, and community-based services, while informing the public of needed support for individuals living with TBI and their families.

ARN strongly supports the current work being done by the Centers for Disease Control and Prevention (CDC) and HRSA on TBI programs. These programs contribute to the overall body of knowledge in rehabilitation medicine.

ARN urges the Congress to support the following fiscal year 2013 funding requests for programs within the TBI Act: \$10 million for CDC's TBI registries and surveillance, prevention and national public education and awareness efforts; \$8

³<http://www.biausa.org/living-with-brain-injury.htm>.

million for the HRSA Federal TBI State Grant Program; and \$4 million for the HRSA Federal TBI Protection and Advocacy Systems Grant Program.

CONCLUSION

ARN appreciates the opportunity to share our priorities for fiscal year 2013 funding levels for nursing and rehabilitation programs. ARN maintains a strong commitment to working with Members of Congress, other nursing and rehabilitation organizations, and other stakeholders to ensure that the rehabilitation nurses of today continue to practice tomorrow. By providing the fiscal year 2013 funding levels detailed above, we believe the Subcommittee will be taking the steps necessary to ensure that our Nation has a sufficient nursing workforce to care for patients requiring rehabilitation from chronic illness and/or physical disability.

PREPARED STATEMENT OF THE ASSOCIATION FOR RESEARCH IN VISION AND OPHTHALMOLOGY

Biomedical Research Investment

Fiscal year 2013 is a pivotal time for the United States as the Nation's leaders work hard toward the goal of recovering from an historic economic recession. We agree with the President that education and innovation are crucial investments for growing the economy and creating jobs. We understand that difficult decisions have to be made about fiscal year 2013 appropriation priorities, with imposed counter pressures from the Budget Control Act. We urge the Congress to carefully consider the long term impact of not investing in research and development (R&D) while other nations (e.g., China and India) increase their investment, and while the United States faces a critical need to control inflating healthcare costs. We were happy to see the importance of R&D investment reflected in the President's budgets for the National Science Foundation, the Department of Energy, and the Department of Agriculture. We think the Presidential budget for NIH, which did not maintain funding levels, is a mistake. Our Nation faces unprecedented aging eye disease costs; these will radically increase without proper investment in research that leads to treatments and cures.

Americans Want Biomedical Research Investment

The American public recognizes the importance of biomedical research and is more likely to support candidates who support Federal biomedical research.¹ Specifically, "85 percent of likely voters are concerned about the impact of a decreased Federal investment in research, including the possibility of scientists leaving their profession or moving abroad to countries with a stronger research investment."¹ Biomedical research investment is a long term strategy to ensure economic competitiveness of the United States. Each dollar NIH spends on research results in a two-fold economic return to local economies. NIH funding supports half a million U.S. jobs, including extramural research supported by 325,000 scientists at more than 3,000 institutions.² In 2010, NIH funding "directly and indirectly supported 487,900 jobs nationwide, leading to 15 States experiencing job growth of 10,000 or more."² The spending results in complementary private investments,² not even accounting for local growth near new research infrastructure (e.g., restaurants/other services). Unfortunately, 55,000 jobs were lost when American Recovery and Reinvestment Funding ended.² Research is a marathon, not a sprint. Sustained investment over time is needed for progress. We urge elected representatives to consider what constituents value when making decisions about NIH funding appropriations.

ARVO has two major requests for the Senate:

- To recognize funding for the NIH as a national priority by funding NIH in fiscal year 2013 at least \$32 billion.
- To recognize vision health as a national priority by funding the NEI at \$730 million.

The requested funding levels will enable NIH and NEI to keep pace with inflation and continue extraordinary progress made toward improving vision health of the American public. Blindness prevention and vision restoration are crucial for reducing healthcare costs, maintaining productivity, ensuring independence, enhancing quality of life, enabling safe mobility and navigation of affected individuals and the community (e.g., driving safety). The \$730 million requested for NEI is a small amount, considering the annual cost of eye disease (estimated in U.S. adults at

¹ Research!America March 14, 2012 public opinion poll.

² United for Medical Research, May 2011, *NIH Role in Sustaining the U.S. Economy*.

\$51.4 billion/year in 2007).³ The annual economic cost did not account for child eye care costs or the baby boomer demographic entered this decade, when the number of people turning 65-years-old each day rose from 1,000 people per day to 6,000 people per day, continuing until 2029. Future eye care costs will be in proportion to the number of children affected by diabetic and other eye disease and the number of adults affected by aging eye diseases.⁴

Biomedical Infrastructure in Crisis

Rep. Paul Ryan (R-WI) outlined a 10-year Federal spending reduction plan earlier this month that did not recognize the crucial role that biomedical research spending plays for the economic growth and well-being of our country. Meanwhile, the biomedical research institutions of our Nation, whose goal it is to address the national health needs through research are economically stressed from a variety of sources including: State budget restrictions, decreased availability of bridge and philanthropic funding, and added expenses from increased regulatory administrative costs detailed below.

Salary Caps Derail Clinical Research, New Research Programs and Junior Researchers

On January 20, 2012 NIH issued guidance on congressionally imposed salary caps, effectively reducing Executive Level II salaries by \$20,000. This decision might look like an insignificant 1 percent budget reduction from a policy perspective. However, from a local perspective on individual institutions, this decision generated more interest than any other policy report by our organization in the past 4 years. Below are some preliminary institutional administrative reports on the local impact.

- The cap disproportionately affects clinician-scientists, who already make lower salaries than their colleagues in private practice and industry settings. Effectively, this cap pushes them out of research at a time when the United States is placing more emphasis on translational research.
- Clinical departments are ceasing to offer seed money for new faculty to jumpstart new research programs.
- Post-doctoral researchers in clinical departments are being let go (at the most vulnerable stage in their career) to address lost NIH salary reimbursements. Post-docs are highly trained, relatively poorly paid (around \$40,000/year) junior investigators, who frequently fall between the cracks as they are not faculty, staff, or students.
- John's Hopkins alone estimates the current salary cap will result in a loss of \$6.8 million per year in recoverable facility and administration (F&A) costs, in addition to an earlier cap that resulted in a \$10 million per year loss in recoverable F&A.

Increased Costs and Reduced Capacity

A set of new guidelines for the care and use of animals is being implemented by NIH. The spirit and intent of the guidelines are currently being followed in a manner consistent with the scientific community concerns to limit the number of animals used and ensure they are not subjected to unnecessary discomfort and pain. However, the prescriptive nature of the new guidelines have the potential to be interpreted as regulations that leave little room for professional judgment based on local infrastructure and study specific variables. An uncertainty about interpretation of the guidelines by inspectors is certain to initiate changes in housing at great expense and loss of capacity to individual institutions.

Transportation of animals is also being targeted. Non-human primates, while infrequently used in vision research, are very important and critical for certain studies. Members are starting to rely on expensive charters to ship research animals, as airlines are being targeted by passionate anti-animal research advocates.

The regulatory, public policies and transportation issues for animal research are initiating a shift for pharmaceutical companies to move pharmaceutical testing to countries with less stringent regulations and easier access to research animals, which will be unfortunate for the humane treatment of animals and will mean a loss of jobs in the United States.

Approval Path to a Product Graveyard

Members who conduct translational studies report that the Food and Drug Administration (FDA) has a lack of a defined approval process for ophthalmic drugs. They report that it is difficult to attract investors for clinical trials in part because prior endeavors failed due to inappropriate endpoints or measurements. Investors

³Prevent Blindness America, 2007, *The Economic Impact of Vision Problems*.

⁴Alliance for Aging Research, 2012, *The Silver Book: Vision Loss*, Volume II.

simply will not invest in trials when they have to guess what steps are necessary to achieve regulatory approval. We understand why such challenges exist within FDA as the FDA has had to move from regulatory oversight of U.S. drugs/devices/biologics to an international oversight environment with limited budget for additional staff/resources. Yet, the FDA approval process is a critical barrier to product approval, a process that European countries made more efficient. Some companies and investors now start their studies in Europe instead of the United States, with a resulting loss of U.S. jobs due to these differences in regulatory environments.

So Much Vision Progress at Stake

The very health of the vision research community is at stake with the proposed declines in NEI funding. Not only will funding for new investigators be at risk, but also that of seasoned investigators, which threatens the continuity of research and the retention of trained staff. When institutions must release staff due to lack of extramural funding, highly trained people are lost to the field. This is unfortunate. As NEI's fiscal year 2013 budget Director's overview stated, "NEI made a considerable investment in basic research that is now creating unprecedented opportunities to develop new treatments that address the root cause of vision loss". Examples of progress made with prior vision research investments include the following examples.

- Better age-related macular degeneration therapies are expected to reduce the incidence of legal blindness by 72 percent and visual impairment by 37 percent in 2 years.⁴
- Current treatments for abnormal blood vessel growth in diabetic retinopathy patients reduced the rate of legal blindness within 5 years from 50 percent to less than 5 percent.⁴ Fifty percent of treated patients experienced improved visual function within 1 year. Laser treatment and vitrectomy reduced the risk of blindness in patients with severe diabetic retinopathy by 90 percent.⁴
- Prescription eye drops delay or prevent 50 percent of glaucoma cases in African Americans.⁴
- Treatments that delay/prevent diabetic retinopathy now save the United States \$1.6 billion annually.⁴

In summary, ARVO requests NEI funding at \$730 million, reflecting biomedical inflation plus modest growth commensurate with that of NIH overall, since our Nation's investment in vision health is an investment in overall health. NEI's breakthrough research is a cost-effective investment, since it is leading to treatments and therapies that can ultimately delay, save, and prevent health expenditures, especially those associated with the Medicare and Medicaid programs. It can also increase productivity, help individuals to maintain their independence, and generally improve the quality of life, especially since vision loss is associated with increased depression and accelerated mortality.

About the Association for Research in Vision and Ophthalmology

ARVO is the world's largest international association of vision scientists (scientists who study diseases and disorders of the eye). More than 7,000 members are supported by NIH grant funding. Vision science is a multi-disciplinary field, but the NEI is the only freestanding NIH institute with a mission statement that specifically addresses vision research. ARVO supports increased fiscal year 2013 NIH funding.

ARVO is also a member of the National Alliance for Eye and Vision Research, and supports their testimony. www.eyersearch.org

PREPARED STATEMENT OF AUTISM SPEAKS

Chairman Harkin, Ranking Member Shelby, and members of the subcommittee, thank you for the opportunity to offer testimony on the importance of continued funding for autism.

My name is Peter Bell and I am executive vice president of programs and services for Autism Speaks. My responsibilities at Autism Speaks include overseeing the foundation's family services and Government relations activities. I also serve as an advisor to our science division. Autism Speaks is the world's leading autism science and advocacy organization. Since its inception in 2005, Autism Speaks has committed more than \$173 million to autism research as well as developing innovative resources for individuals with autism and their families. Our mission is to change the future for those who live with autism. We do this through funding science, raising awareness, helping families, and advocating for those who live on the spectrum.

I am also the proud father of a child with autism. His name is Tyler and he recently turned 19. In 1996 when my wife and I first heard the words "your son has

autism,” we were stunned. Our only reference to autism at the time was from the Oscar-winning movie “Rain Man.” We had never known anyone with autism, nor did we know any families who had a child with autism. I suspect this would have been true for most of you on this committee. However, today, I’m willing to wager that every one of you personally knows someone or some family who is touched by autism. Each year, nearly 50,000 families hear those same words—“your child has autism.”

Twenty years ago, the experts estimated that 1 of every 2,500 children had autism. The latest statistic, announced on March 29 by the Centers for Disease Control and Prevention (CDC), is 1 in 88, 1 in 54 for boys. Increasingly we hear the word “epidemic” associated with autism in America. But we at Autism Speaks are hearing something else from the families in our community and it is getting louder by the day.

And that is the question, “what is our Government doing to confront this public health crisis?” We are increasingly frustrated and frankly confused by what appears to be a lack of will from Washington. When the number of people on the spectrum is going up, why are the dollars for autism research and prevention going down?

When Bob and Suzanne Wright founded Autism Speaks in 2005, they were shocked that a disorder as prevalent as autism commanded so little in terms of resources devoted to research and treatment when compared to other, less common disorders. Working together with thousands of families affected by autism, we were able to enact the Combating Autism Act of 2006. Signed by President Bush, this historic act was considered to be the most comprehensive piece of single-disease legislation ever passed by the Congress. Last year, working with many of you in bipartisan fashion, the Combating Autism Act was reauthorized when President Obama signed a 3-year reauthorization into law on September 30.

Autism Speaks and the 1 million plus members of our community are of course grateful for this funding. But we also recognize it provides but a fraction of the billion dollar a year commitment that had been promised by President Obama, a commitment that better reflects the actual need for funding meaningful research, treatment, and services. That disappointment has now been compounded by fears that the funding that was authorized just last September may now be in jeopardy as a result of this year’s appropriations process.

Funding for the CDC to continue prevalence research under the President’s budget request was \$700,000 below the \$22 million authorized funding level and then inexplicably incorporated within the Prevention and Public Health Fund created under the Affordable Care Act. As you know, recent legislation reduces the fund by 20 percent in fiscal year 2013, further jeopardizing the CDC’s autism surveillance activities. Since 2000, funding for this work has always been included within the CDC’s total discretionary budget authority. It should continue there. Autism Speaks requests that you include \$22 million for autism activities within the National Birth Defects Center, within CDC’s discretionary budget authority.

Further, we urge you to fully fund the basic and clinical research initiatives for autism at the levels called for under the Combating Autism Reauthorization Act (CARA). Specifically, we ask you to support at least \$161 million for the NIH’s autism research programs and \$48 million for HRSA’s autism research, treatment, and training activities. We also urge the Subcommittee to fund CDC’s autism activities within CDC’s Discretionary Budget Authority.

As I mentioned earlier, Autism Speaks has committed more than \$173 million through private fundraising to scientific research studies, fellowships, and scientific initiatives. Other private foundations have contributed in excess of \$125 million. But we can’t do this alone. We ask that the Congress restore full funding as authorized under CARA for autism research, surveillance and treatment. And we ask that Washington treat autism as the epidemic it has become.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF HEMATOLOGY

The American Society of Hematology (ASH) thanks the subcommittee for the opportunity to submit written testimony on the fiscal year 2013 Departments of Labor, Health and Human Services, and Education appropriations bill.

ASH represents approximately 14,000 clinicians and scientists committed to the study and treatment of blood and blood-related diseases. These diseases encompass malignant disorders such as leukemia, lymphoma, and myeloma; life-threatening conditions, including thrombosis and bleeding disorders; and congenital diseases such as sickle cell anemia, thalassemia, and hemophilia. In addition, hematologists have been pioneers in the fields of bone marrow transplantation, stem cell biology

and regenerative medicine, gene therapy, and the development of many drugs for the prevention and treatment of heart attacks and strokes.

Over the past 60 years, American biomedical research has led the world in probing the nature of human disease. This research has led to new medical treatments, saved innumerable lives, reduced human suffering, and spawned entire new industries. This research would not have been possible without support from the National Institutes of Health (NIH). NIH-funded research drives medical innovation that improves health and quality of life through new and better diagnostics, improved prevention strategies, and more effective treatments. Discoveries gained through basic research yield the medical advances that improve the fiscal and physical health of the country.

Funding for hematology research has been an important component of this investment in the Nation's health. With the advances gained through an increasingly sophisticated understanding of how the blood system functions, hematologists have changed the face of medicine through their dedication to improving the lives of patients. As a result, children are routinely cured of acute lymphoblastic leukemia (ALL); more than 90 percent of patients with acute promyelocytic leukemia (APL) are cured with a drug derived from vitamin A; older patients suffering from previously lethal chronic myeloid leukemia (CML) are now effectively treated with well-tolerated pills; and patients with multiple myeloma are treated with new classes of drugs.

Hematology advances also help patients with other types of cancers, heart disease, and stroke. Blood thinners effectively treat or prevent blood clots, pulmonary embolism, and strokes. Death rates from heart attacks are reduced by new forms of anticoagulation drugs. Stem cell transplantation can cure not only blood diseases but also inherited metabolic disorders, while gene therapy holds the promise of effectively treating even more genetic diseases. Even modest investments in hematology research have yielded large dividends for other disciplines.

Fiscal Year 2013 Funding Request

ASH supports the recommendation of the Ad Hoc Group for Medical Research that the Subcommittee recognize NIH as a critical national priority by providing at least \$32 billion in funding in the fiscal year 2013 Labor-HHS-Education appropriations bill. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

It is critically important that our country continues to capitalize on the momentum of previous investments to drive research progress to develop new treatments for serious disorders, train the next generation of scientists, create jobs, and promote economic growth and innovation. Adequate funding is necessary for NIH to sustain current research capacity and encourage promising new areas of science and cures.

For Fiscal Year 2013, the American Society of Hematology Seeks Congressional Support for the Following Activities

In fiscal year 2013, ASH also urges the Subcommittee to recognize the following areas of hematology research that have shown impressive progress and offer the potential of future advances:

Stem Cells and Regenerative Medicine: Improving Current Technologies to Cure Blood Disorders

Hematologists have been at the forefront of research in stem cell biology by studying blood cell development and exploring stem cells' potential to repair damaged tissue, fight infections, and reduce autoimmune diseases. The techniques and principles used by hematologists in studying the blood system stem cells have been applied to stem cells from many other tissues with great success, spawning a huge research effort across all areas of medicine.

Researchers have made significant progress in developing re-programmed adult cells, called induced pluripotent stem (iPS) cells, which can subsequently develop into any tissue of the body. iPS cells can be generated and used in patients who have genetic blood diseases as well as other complex diseases because they will not be attacked by a patient's own immune system, they serve as a continuous source of cells, and they are amenable to genetic manipulation.

Recent research has suggested that iPS cells can be manipulated to become blood stem cells and can be used as a transplant source for patients who do not have a matched donor. This will greatly enhance bone marrow and cord blood stem cell transplantation for the treatment of blood cancers and other hematologic disorders and subsequently inform our understanding of transplantation-related morbidities for other organs. iPS-generated red blood cells from rare blood types also could be

used in blood banking as reagents to identify patients and blood units suitable for transfusion.

Future stem cell advances are highly dependent on the ability to transplant stem cells at high efficiencies and then have them perform well once transplanted. However, several barriers remain that currently prevent the clinical translation of iPS cell technology. Compared to other sources of stem cells, iPS cells have slower growth kinetics, are more genomically unstable, and have decreased efficiency for differentiation. These barriers are also important areas for future research.

ASH applauds the efforts of the National Heart, Lung, and Blood Institute (NHLBI) to conduct further research in the development of blood stem cells from iPS cells and to address the barriers to the clinical translation of iPS cell technology.

Research in Sickle Cell Trait and Exercise-Related Illness

Sickle cell disease (SCD) is an inherited blood disorder that affects 80,000–100,000 Americans, mostly but not exclusively of African ancestry. SCD causes production of abnormal hemoglobin, resulting in severe anemia, pain, other devastating disabilities, and, in some cases, premature death.

Eight to 10 percent of African-Americans have sickle cell trait. Individuals with sickle cell trait do not have SCD, but are carriers of one defective gene associated with SCD. Millions of Americans with sickle cell trait enjoy normal life spans without serious health consequences. At the same time, possible health risks have been reported for individuals with sickle cell trait including increased incidence of renal failure and malignancy, thromboembolic disorders, splenic infarction as a high altitude complication, and exertion-related sudden death.

In April 2010, the National Collegiate Athletic Association (NCAA) adopted a policy requiring Division I institutions to perform sickle cell trait testing for all incoming student athletes. This policy has been controversial because there are no high quality (well-controlled, hypothesis-driven, prospective) studies on sickle cell trait and exertional collapse or evidence to justify it.

There is a need for increased biomedical and population-based research on sickle cell trait and its relation to exertion-related illness as well as other conditions. Based on its 2010 Consensus Conference on this topic, NHLBI has identified a research agenda and ASH, the American Academy of Sports Medicine, and the NCAA have met to discuss potential studies to pursue. It is important that the research agenda is moved forward collaboratively under the direction of the NHLBI.

Conclusion

Hematology research offers enormous potential to better understand, prevent, treat, and cure a number of blood-related and other conditions. Recent investments have created dramatic new research opportunities, spurring advancements and precipitating the promise of personalized medicine that will yield far-reaching health and economic benefits. Trials to find new therapies and cures for millions of Americans with blood cancers, bleeding disorders, clotting problems, and genetic diseases are just a few of the important projects that could be delayed unless NIH continues to receive predictable and sustained funding.

ASH urges the Subcommittee to continue to be a champion for research and support at least \$32 billion in funding for NIH in fiscal year 2013. The American people are depending on you to ensure the Nation does not lose the health and economic benefits of our extraordinary commitment to medical research.

Thank you again for the opportunity to submit testimony. Please contact Tracy Roades, ASH Research Advocacy Manager, at troades@hematology.org, or Ulyana Desiderio, PhD, ASH Senior Manager for Scientific Affairs, at udesiderio@hematology.org, if you have any questions or need further information concerning hematology research or ASH's fiscal year 2013 funding request.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

The American Society for Microbiology (ASM) is pleased to submit the following statement on the fiscal year 2013 appropriation for the Centers for Disease Control and Prevention (CDC). The ASM is the largest single life science organization in the world with approximately 38,000 members. The ASM strongly supports the leadership role of CDC, in partnership with State and local health departments and global organizations, in safeguarding the public health and protecting against infectious disease threats through surveillance, laboratory diagnosis, and control and prevention strategies.

The ASM is greatly concerned that the proposed fiscal year 2013 budget for CDC of \$5.1 billion represents a decrease of \$664 million, or 11.6 percent. The CDC bud-

et may be reduced in fiscal year 2013 by an additional 8 percent as the result of an across-the-board, sequestration provision in the Budget Control Act. The fiscal year 2013 decreases accelerate declines in CDC's funding that have occurred in the past several years. Such cuts will inevitably have a severe impact on CDC's ability to protect the Nation from disease threats and public health emergencies. CDC oversees programs that are critical to addressing vaccine preventable diseases, foodborne diseases, pandemic influenza, vector-borne and zoonotic diseases, high consequence pathogens, antimicrobial resistance, healthcare acquired infections, and outbreak response activities. Because of declining funding for CDC in recent years, its core infectious disease budget has eroded and these reductions threaten core epidemiology, laboratory and surveillance capacity, as well as modern technologies and methods to ensure that CDC laboratories, researchers and outbreak response teams are able to continue critical infectious disease activities. In the past, declines in resources for prevention and control of infectious diseases have resulted in disease reemergence, leading to significantly higher costs for the healthcare system and for disease containment efforts. The ominous increase in measles cases seen in the United States in 2011 is an example of the potential for disease reemergence when public health programs are not optimized.

Although concerned about CDC's overall budget, the ASM does support those areas that have received funding increases. These include the proposed increase for the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) of \$27 million and for the National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Infections and Tuberculosis Prevention of \$35 million. The NCEZD includes CDC's antimicrobial resistance activities for surveillance, data collection and stewardship which require additional resources to address the danger of pathogens resistant to antibiotics. The ASM is pleased to see the increase of \$17 million for food safety activities to restore and improve State and local surveillance and outbreak response capacity and move toward implementation of CDC's provisions of the Food Safety Modernization Act including Centers of Excellence. The ASM also supports the increase of \$12.6 million for the National Healthcare Safety Network (NHSN). This investment is needed as the number of hospitals, long term care facilities, and hemodialysis centers that are now using NHSN has risen dramatically in the last 2 years in response to State and Federal efforts to control healthcare associated infections. The additional funds for NHSN will allow CDC to maintain and update the system to meet the increased demands and optimally target prevention and control measures.

The ASM is concerned about the proposed cut of \$15.5 million in funding to State and local preparedness and response capacity which threatens the Nation's preparedness for infectious disease outbreaks and other hazards. The strategic national stockpile is reduced by \$64 million in the administration's proposed budget. CDC is one of the few Federal agencies providing continuous surveillance, detection and response for chemical, biological, radiological and nuclear threats, as well as natural disasters, outbreaks and epidemics. CDC fulfills this critical role by supporting State and local health departments, safeguarding deadly pathogens, managing the strategic national stockpile, creating national tracking and surveillance systems and overseeing the national laboratory network. The fiscal year 2013 budget represents a decrease of \$54 million below fiscal year 2012 for these critical activities, including elimination of funding for the Academic Centers for Public Health Preparedness. We urge the Congress to reject these reductions and to restore funding for these important programs.

Centers for Disease Control and Prevention Funding Supports Strategies to Protect Public Health

CDC activities are critical to preventing disease and disability across the United States and abroad. Through partnerships with local, State, Federal, and international institutions, CDC has created disease prevention campaigns that combine scientific research, public education and training of health professionals, case surveillance systems, and prevention protocols. Only programs of wide scope and complexity like those administered by CDC can be effective against major health issues, such as drug resistant pathogens and microbial threats to the Nation's food supply.

Antimicrobial Resistance.—Both United States and global health officials list microorganisms resistant to available drugs as one of their top priorities. According to the World Health Organization (WHO), there are about 440,000 new cases of multidrug resistant tuberculosis (MDR TB) each year and at least 150,000 MDR TB deaths. Drug resistant cases of malaria and cholera are rising in number, and healthcare facilities worldwide are beset by unacceptable rates of AR infections like methicillin resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* infections (CDI). Recently CDC surveillance has collected case reports from across the

United States of bacteria, including *E. coli*, that produce *Klebsiella pneumoniae* carbapenemase (KPC), an enzyme that makes bacteria resistant to most known treatments.

In large part due to CDC partnerships and prevention initiatives, there has been a 60 percent reduction of MRSA in Veterans Administration facilities and a 2010 report demonstrated a significant MRSA decline in United States healthcare settings in general. CDC data also show that rates of MRSA bloodstream infections in hospitalized patients fell nearly 50 percent from 1997 to 2007. Last November, CDC initiated a new antibiotic tracking system within its National Healthcare Safety Network (NHSN) for monitoring in hospital antibiotic use electronically. Promotion of appropriate antimicrobial stewardship is a critical component of a comprehensive program to reverse the impact of antibiotic resistance.

Healthcare Associated Infections (HAIs).—Pathogens like MRSA that are increasingly resistant to therapeutics are particularly alarming among vulnerable patients being treated for other medical conditions. Last year CDC expanded its NHSN surveillance system from 3,400 to 5,000 hospitals, hemodialysis and long term acute care facilities, and other facilities faced with patient infections acquired in house. NHSN data are strong evidence that CDC education and surveillance programs achieve gains against these infections. For example, infections reported to NHSN that declined in 2010 included a 33 percent reduction in central line associated bloodstream infections and 35 percent among critical care patients. Such declines result in billions of dollars of cost savings to the healthcare system, although the economic and human costs of HAIs remain far too high. CDC estimates that 1 out of 20 hospitalized patients will develop an infection while receiving treatment for other conditions. Continued investments in addressing other costly healthcare associated infections such as surgical site infections and ventilator associated pneumonia should have similar impacts to those seen with bloodstream infections.

Immunization.—CDC campaigns have made impressive progress against childhood vaccine preventable diseases in the United States and, jointly with WHO and other stakeholders, worldwide. A recent CDC report listing the most significant global public health achievements in the past decade included various vaccination programs that prevent 2.5 million deaths every year among young children, that is, measles, polio, and diphtheria tetanus pertussis vaccinations. Global mortality from measles has declined from an estimated 733,000 deaths in 2000 to 164,000 in 2008. Since 1988, polio incidence has fallen by 99 percent, from more than 350,000 cases to 1,410 in 2010, with four remaining endemic countries. In December, CDC activated its Emergency Operations Center to strengthen its partnership with the Global Polio Eradication Initiative. However, more than 1 million infants and young children still die from vaccine preventable pneumococcal disease and rotavirus diarrhea every year, and multiple other diseases take lives that could be saved through immunization. However, as noted above, the increase in measles cases seen in the United States in 2011 and similar increases in pertussis in 2010–2011 demonstrates the importance of continued investment in vaccination programs to keep these diseases at bay.

The CDC continues to make progress in raising immunization coverage levels for some of the newly available vaccines. In the United States, vaccinating infants against rotavirus has shown impressive gains against a major cause of severe diarrhea in infants and young children. Before introduction of the rotavirus vaccines in 2006, the pathogen was responsible for about 200,000 emergency room visits and 55,000–70,000 hospitalizations per year. Intensive immunization campaigns resulted in high percentages of protected children, responsible for a 75 percent decline in rotavirus related hospitalizations in 2007–2008 compared with pre vaccine levels. Federal estimates indicate that for every dollar invested in immunizing Americans, we save \$10.20 in direct medical costs.

Food Safety.—Based on surveillance data, CDC believes that foodborne contaminants are responsible for about 128,000 United States hospitalizations annually. The 31 known microbial pathogens linked to foodborne illness account for an estimated 9.4 million of the roughly 47.8 million illnesses yearly, the remaining blamed on “unspecified agents.” Five pathogens targeted by CDC account for more than 90 percent of the identified agent cases: norovirus, *Salmonella*, *Clostridium perfringens*, *Campylobacter*, and *Staphylococcus aureus*. The agency’s food safety activities utilize multiple tools that include case reporting systems, public and food processor education, and product recalls. CDC will support five Food Safety Centers of Excellence at State health departments across the country. A 2011 CDC report summarizing 15 years of case surveillance showed that illnesses from *E. coli* O157 have been cut nearly in half and the overall rates of six foodborne infections have been reduced by 23 percent, but warned that *Salmonella* caused infections have risen 10 percent. However, problems like the 2011 outbreak of listeriosis associated

with cantaloupes, the deadliest foodborne outbreak in the United States in decades, demonstrates the importance of prompt recognition and response to foodborne disease, including laboratory capacity to make the diagnosis and fingerprint the strains.

Public Safety and Preparedness.—The ASM is concerned that the administration’s fiscal year 2013 budget decreases funding for some important CDC biodefense and emergency preparedness activities. Programs like the Strategic National Stockpile build our national capabilities against both intentionally released and naturally occurring infectious agent threats. The agency oversees a national laboratory network, develops science based expertise in numerous health threats, and serves as primary first responder during sporadic disease outbreaks, epidemics, and a broad spectrum of other crises. With State and local budgets strained economically, it is all the more important that CDC is able to fully support health departments across the country. The ASM also urges the Congress recognize that funding is needed to ensure CDC’s own laboratories and personnel continue to serve as national and global leaders against infectious disease and other health threats.

Centers for Disease Control and Prevention Funding Supports Research and Education to Prevent Infectious Disease

The CDC Office of Infectious Diseases (OID), which oversees the National Center for Immunization and Respiratory Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention addresses antimicrobial resistance, chronic viral hepatitis, food and water safety, healthcare associated infections, HIV/AIDS, respiratory infections, vaccine preventable diseases, and zoonotic and vectorborne diseases. The ASM strongly supports funding for OID efforts to identify, treat, and prevent a long list of infectious diseases that kill millions each year. CDC’s infectious disease programs play a critical role in protecting all Americans from the dangers of microbial threats, and we cannot allow these important functions to continue to erode.

The ASM urges the Congress to provide needed new resources in fiscal year 2013 for the CDC budget to strengthen science based programs that have so effectively investigated, controlled, and, most importantly, prevented disease and disability. This funding is critical to maintaining the CDC laboratories, expert personnel, education and prevention campaigns, and CDC supported collaborations that work together daily to protect people in this Nation and worldwide.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR NUTRITION

The American Society for Nutrition (ASN) appreciates the opportunity to submit testimony regarding fiscal year 2013 appropriations for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention’s National Center for Health Statistics (NCHS). Founded in 1928, ASN is a nonprofit scientific society with more than 4,500 members in academia, clinical practice, Government and industry. ASN respectfully requests \$32 billion for the National Institutes of Health, and we urge you to adopt the President’s request of \$162 million for the National Center for Health Statistics in fiscal year 2013.

Basic and applied nutrition research on the relationship between nutrition and chronic disease, nutrient composition, and nutrition monitoring are critical for the health of all Americans and the U.S. economy. Awareness of the growing epidemic of obesity and the contribution of chronic illness to burgeoning healthcare costs has highlighted the need for improved information on dietary components, dietary intake, strategies for dietary change and nutritional therapies. The health costs of obesity alone are estimated at \$147 billion each year. This enormous health and economic burden is largely preventable, along with the many other chronic diseases that plague the United States. It is for this reason that we urge you to consider these recommended funding levels for two agencies under the Department of Health and Human Services that have profound effects on nutrition research, nutrition monitoring, and the health of all Americans—the National Institutes of Health and the National Center for Health Statistics.

National Institutes of Health

The National Institutes of Health (NIH) is the Nation’s premier sponsor of biomedical research and is the agency responsible for conducting and supporting 86 percent (approximately \$1.4 billion) of federally funded basic and clinical nutrition research. Nutrition research, which makes up about 4 percent of the NIH budget, is truly a trans-NIH endeavor, being conducted and funded across multiple Institutes and Centers. Some of the most promising nutrition-related research discoveries have been made possible by NIH support. In order to fulfill the full potential

of biomedical research, including nutrition research, ASN recommends an fiscal year 2013 funding level of \$32 billion for the NIH, a modest increase over the current funding level of \$30.64 billion.

The modest increase we recommend is necessary to maintain both the existing and future scientific infrastructure. The discovery process—while it produces tremendous value—often takes a lengthy and unpredictable path. Economic stagnation is disruptive to training, careers, long range projects and ultimately to progress. NIH needs sustainable and predictable budget growth to achieve the full promise of medical research to improve the health and longevity of all Americans. It is imperative that we continue our commitment to biomedical research and continue our Nation's dominance in this area by making the NIH a national priority.

Over the past 50 years, NIH and its grantees have played a major role in the growth of knowledge that has transformed our understanding of human health, and how to prevent and treat human disease. Because of the unprecedented number of breakthroughs and discoveries made possible by NIH funding, scientists are helping Americans to live healthier and more productive lives. Many of these discoveries are nutrition-related and have impacted the way clinicians prevent and treat heart disease, cancer, diabetes and other chronic diseases. By 2030, the number of Americans age 65 and older is expected to grow to 72 million, and the incidence of chronic disease will also grow. Sustained support for basic and clinical research is required if we are to successfully confront the healthcare challenges associated with an older, and potentially sicker, population.

Centers for Disease Control and Prevention National Center for Health Statistics

The National Center for Health Statistics (NCHS), housed within the Centers for Disease Control and Prevention, is the Nation's principal health statistics agency. The NCHS provides critical data on all aspects of our healthcare system, and it is responsible for monitoring the Nation's health and nutrition status through surveys such as the National Health and Nutrition Examination Survey (NHANES), that serve as a gold standard for data collection around the world. Nutrition and health data, largely collected through NHANES, are essential for tracking the nutrition, health and well-being of the American population, and are especially important for observing nutritional and health trends in our Nation's children.

Nutrition monitoring conducted by the Department of Health and Human Services in partnership with the U.S. Department of Agriculture Agricultural Research Service is a unique and critically important surveillance function in which dietary intake, nutritional status, and health status are evaluated in a rigorous and standardized manner. Nutrition monitoring is an inherently governmental function and findings are essential for multiple Government agencies, as well as the public and private sector. Nutrition monitoring is essential to track what Americans are eating, inform nutrition and dietary guidance policy, evaluate the effectiveness and efficiency of nutrition assistance programs, and study nutrition-related disease outcomes. Funds are needed to ensure the continuation of this critical surveillance of the nation's nutritional status and the many benefits it provides.

Through learning both what Americans eat and how their diets directly affect their health, the NCHS is able to monitor the prevalence of obesity and other chronic diseases in the United States and track the performance of preventive interventions, as well as assess "nutrients of concern" such as calcium, which are consumed in inadequate amounts by many subsets of our population. Data such as these are critical to guide policy development in the area of health and nutrition, including food safety, food labeling, food assistance, military rations and dietary guidance. For example, NHANES data are used to determine funding levels for programs such as the Supplemental Nutrition Assistance Program (SNAP) and the Women, Infants, and Children (WIC) clinics, which provide nourishment to low-income women and children.

To continue support for the agency and its important mission, ASN recommends a fiscal year 2013 funding level of \$162 million for NCHS. Sustained funding for NCHS can help to ensure uninterrupted collection of vital health and nutrition statistics, and will help to cover the costs needed for technology and information security upgrades that are necessary to replace aging survey infrastructure.

Thank you for your support of the NIH and the NCHS, and thank you for the opportunity to submit testimony regarding fiscal year 2013 appropriations. Please contact John E. Courtney, Ph.D., Executive Officer, if ASN may provide further assistance. He can be reached at 9650 Rockville Pike, Bethesda, Maryland 20814 or jcourtney@nutrition.org.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF NEPHROLOGY

EXECUTIVE SUMMARY

The American Society of Nephrology (ASN) requests \$32 billion in funding for the National Institutes of Health (NIH) and \$2.03 billion in funding for NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in the fiscal year 2013 Labor-HHS-Education appropriations bill.

ASN is dedicated to the study, prevention, and treatment of kidney disease, and the society respects your leadership and commitment to both preventing illness and maintaining fiscal responsibility. Estimates of chronic kidney disease (CKD) in the United States suggest that it affects more than 26 million, or 1 in 9, Americans, and more than 550,000 of them have irreversible kidney failure.

Without research funded by NIH broadly and NIDDK specifically, research leading to advances in the care and treatment of adults and children afflicted with kidney disease would not be conducted.

For instance, hereditary diseases such as cystinosis—a metabolic disorder that affects the kidneys, eyes, thyroid, pancreas, and brain—can now be treated to prevent or delay its worst effects on children. Although cystinosis is a relatively rare disease, this achievement highlights that advancing understanding of the genetics of kidney diseases in children enables us to address a previously untreatable condition as well as gain significant insight into the mechanisms of other kidney conditions.

In addition, investigative studies supported by NIH and NIDDK generated a groundbreaking discovery that helps explain racial/ethnic disparities that increase risks for kidney disease, which can lead to earlier detection and treatment. The recent finding that African-Americans with variant APOL1 genes are at increased risk of kidney disease is a crucial step in understanding why this sector of our population is four times more likely to have kidney failure than non-Hispanic whites.

Funding from NIH and NIDDK also enabled research that could improve ESRD patients' heart health and physical wellness: patients receiving daily in-center dialysis had better outcomes compared to conventional thrice-weekly dialysis. The discovery of these advantages has significant implications for the future of dialysis care for patients with end-stage renal disease (ESRD).

A funding increase of 4 percent for NIH and 4.5 percent for NIDDK would continue the important work that is necessary to move the model from curative healthcare, where interventions occur late in the natural history of a disease, to a preemptive model in which the onset of disease is significantly delayed or even prevented—saving taxpayer funds and creating a better quality of life for Americans.

ESRD is covered by Medicare regardless of a patient's age or disability status. Consequently, preventing kidney disease and advancing the effectiveness of therapies for kidney failure—starting with innovative research at NIDDK—would have a greater impact at the highest level of costs within the Centers for Medicare and Medicaid Services. Perhaps most importantly, in human terms, the applied research will help prevent greater suffering among those who would otherwise progress to an even greater level of illness.

Sustained, predictable investment in research is the only way that scientific investigations can be effective and lead to new discoveries. With funding from NIH and NIDDK, scientists have been able to pursue cutting-edge basic, clinical and translational research. While ASN fully understands the difficult economic environment and the intense pressure you are under as an elected official to guide America forward during these tough times, the society firmly believes that funding NIH at \$32 billion and NIDDK at \$2.03 billion will continue to create jobs, support the next generation of investigators, and ultimately improve public health.

Several recent studies have concluded that Federal support for medical research is a major force in the economic health of communities across the Nation.

It is critically important that the Nation continue to capitalize on previous investments to drive research progress, train the next generation of scientists, create new jobs, promote economic growth, and maintain leadership in the global innovation economy—particularly as other countries increase their investments in scientific research.

Most important, a failure to maintain and strengthen NIH and NIDDK's ability to support the groundbreaking work of researchers across the country carries a palpable human toll, denying hope to the millions of patients awaiting the possibility of a healthier tomorrow.

ASN strongly recommends that the fiscal year 2013 Labor-HHS-Education appropriations bill uphold its longstanding legacy of bipartisan support for biomedical research by providing funding of no less than \$32 billion for NIH and \$2.03 billion for NIDDK.

Should you have any questions or wish to discuss NIH, NIDDK, or kidney disease research in more detail, please contact ASN Manager of Policy and Government Affairs Rachel Shaffer at rhaffer@asn-online.org.

ABOUT ASN

The American Society of Nephrology (ASN) is a 501(c)(3) nonprofit, tax-exempt organization that leads the fight against kidney disease by educating the society's 13,500 physicians, scientists, and other healthcare professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients. For more information, visit ASN's website at www.asn-online.org.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF PLANT BIOLOGISTS

On behalf of the American Society of Plant Biologists (ASPB) we would like to thank the Subcommittee for its support of the National Institutes of Health (NIH). ASPB and its members recognize the difficult fiscal environment our Nation faces, but believe investments in scientific research will be a critical step toward economic recovery. ASPB asks that the Subcommittee Members encourage increased support for plant biology research within NIH; such research has contributed in innumerable ways to improving the lives of people throughout the world.

ASPB is an organization of approximately 5,000 professional plant biology researchers, educators, graduate students, and postdoctoral scientists with members in all 50 States and throughout the world. A strong voice for the global plant science community, our mission—achieved through work in the realms of research, education, and public policy—is to promote the growth and development of plant biology, to encourage and communicate research in plant biology, and to promote the interests and growth of plant scientists in general.

Plant Biology Research and America's Future

Plants are vital to our very existence. They harvest sunlight, converting it to chemical energy for food and feed; they take up carbon dioxide and produce oxygen; and they are the primary producers on which all life depends. Indeed, plant biology research is making many fundamental contributions in the areas of domestic fuel security and environmental stewardship; the continued and sustainable development of better foods, fabrics, pharmaceuticals, and building materials; and in the understanding of basic biological principles that underpin improvements in the health and nutrition of all Americans.

Despite the fact that foundational plant biology research underpins vital advances in practical applications in health, agriculture, energy, and the environment, the amount of money invested in understanding the basic function and mechanisms of plants is relatively small. This is especially true when considering the significant positive impact plants have on the Nation's economy and in addressing some of our most urgent challenges in health and nutrition.

Understanding the importance of these areas and in order to address future challenges, ASPB organized the Plant Science Research Summit held in September 2011. With funding from the National Science Foundation, U.S. Department of Agriculture (USDA), Department of Energy, and the Howard Hughes Medical Institute, the Summit brought together representatives from across the full spectrum of plant science research to identify critical gaps in our understanding of plant biology that must be filled over the next 10 years or more in order to address the grand challenges facing our Nation and our planet. The grand challenges identified at the Summit include:

- To feed everyone well, now and in the future, advances in plant science research will be needed for higher yielding, more nutritious crop varieties able to withstand a variable climate.
- Innovations leading to improvements in water use, nutrient use, and disease and pest resistance that reduce the burden on the environment are needed and will allow for improved ecosystem services, such as clean air, clean water, fertile soil, and biodiversity benefits, such as pest suppression and pollination.
- To fuel the future with clean energy—and to ensure that our Nation meets its fuel requirements—improvements are needed in current biofuels technologies, including breeding, crop production methods, and processing.
- For all the benefits that advances in plant science bestow, to have lasting, permanent benefit they must be economically, socially, and environmentally sustainable.

In spring 2012, a report from the Plant Science Research Summit will be published. This report will further detail priorities and needs to address the grand challenges.

Plant Biology and the National Institutes of Health

The mission of the NIH is to pursue “fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.” Plant biology research is highly relevant to this mission.

Plants are often the ideal model systems to advance our “fundamental knowledge about the nature and behavior of living systems,” as they provide the context of multi-cellularity while affording ease of genetic manipulation, a lesser regulatory burden, and inexpensive maintenance requirements than the use of animal systems. Many basic biological components and mechanisms are shared by both plants and animals. For example, a property known as RNA interference, which has potential application in the treatment of human disease, was first noted in plants. Upon further elucidation in other plants and animals, this research earned two American scientists, Andrew Fire and Craig Mello, the 2006 Nobel Prize in Physiology or Medicine.

Health and Nutrition.—Plant biology research is also central to the application of basic knowledge to “extend healthy life and reduce the burdens of illness and disability.” Without good nutrition, there cannot be good health. Indeed, a World Health Organization study on childhood nutrition in developing countries concluded that more than 50 percent of the deaths of children less than 5 years of age could be attributed to malnutrition’s effects in exacerbating common illnesses such as respiratory infections and diarrhea. Strikingly, most of these deaths were not linked to severe malnutrition but only to mild or moderate nutritional deficiencies. Plant biology researchers are working today to improve the nutritional content of crop plants by increasing the availability of nutrients and vitamins such as iron, vitamin E, and vitamin A.

By contrast, obesity, cardiac disease, and cancer take a striking toll in the developed world. Research to improve the lipid composition of plant fats and efforts to optimize concentrations of plant compounds that are known to have anti-carcinogenic properties, such as the glucosinolates found in broccoli and cabbage, and the lycopenes found in tomato will help in addressing these concerns. Ongoing development of crop varieties with tailored nutraceutical content is an important contribution that plant biologists are making toward realizing the goal of personalized medicine, especially personalized preventative medicine.

Drug Discovery.—Plants are also fundamentally important as sources of both extant drugs and drug discovery leads. In fact, more than 10 percent of the drugs considered by the World Health Organization to be “basic and essential” are still exclusively obtained from flowering plants. A recent example of the importance of plant-based pharmaceuticals is the anti-cancer drug taxol, which was discovered as an anti-carcinogenic compound from the bark of the Pacific yew tree through collaborative work involving scientists at the NIH National Cancer Institute and plant biologists at the USDA. Originally, taxol could only be obtained from the tree bark itself, but additional research led to the elucidation of its molecular structure and eventually to its chemical synthesis in the laboratory. Taxol is just one example of the estimated 200,000 secondary plant compounds that will continue to provide a fruitful source of new drug leads, particularly if collaborations such as the one described above can be fostered and funded. With additional research support from NIH, plant biologists can lead the way to developing new medicines and biomedical applications to enhance the treatment of devastating diseases.

Conclusion

The NIH does recognize that plants help serve its mission. However, because the boundaries of plant biology research are permeable and because information about plants integrates with many different disciplines that are highly relevant to NIH, ASPB asks the Subcommittee to provide direction to NIH to support additional plant biology research in order to help pioneer new discoveries and new methods in biomedical research.

Thank you for your consideration of our testimony on behalf of the American Society of Plant Biologists. For more information about ASPB, please see www.aspb.org.

PREPARED STATEMENT OF THE AMERICAN SOCIETY FOR PHARMACOLOGY &
EXPERIMENTAL THERAPEUTICS

The American Society for Pharmacology and Experimental Therapeutics (ASPET) is pleased to submit written testimony in support of the National Institutes of Health (NIH) fiscal year 2013 budget. ASPET is a 5,100 member scientific society whose members conduct basic, translational, and clinical pharmacological research within the academic, industrial and government sectors. Our members discover and develop new medicines and therapeutic agents that fight existing and emerging diseases, as well as increase our knowledge regarding how therapeutics affects humans.

ASPET recommends a budget of at least \$32 billion for the NIH in fiscal year 2013. Research funded by the NIH improves public health, stimulates our economy and improves global competitiveness. Sustained growth for the NIH should be an urgent national priority. Flat funding or cuts to the NIH budget will delay advances in medical research, jeopardizing potential cures, eliminate jobs, and threaten American leadership and innovation in biomedical research.

A \$32 billion budget for the NIH in fiscal year 2013 will provide a modest 4 percent increase to the agency and help restore NIH to more sustainable growth. Currently, the NIH cannot begin to fund all the high quality research that needs to be accomplished. After several years of flat funding and spending cuts enacted in 2011, the NIH's funding environment has reached a critical point:

- Adjusted for inflation, the fiscal year 2012 budget and the President's fiscal year 2013 budget proposal are \$4 billion lower than the peak year of fiscal year 2003;
- The number of research project grants funded by NIH has declined every year since 2004, and NIH is projected to fund 3,100 fewer grants in fiscal year 2012–2013 than in fiscal year 2004; and
- Success rates have fallen more than 14 percent in a decade and are projected to decline further in fiscal year 2012 and fiscal year 2013.

If flat funding continues or if additional cuts are mandated to the NIH budget for fiscal year 2013 and beyond, research that improves the quality of life will be delayed or stopped, and fewer clinical trials will be conducted. International competitors will continue to gain on this highly innovative U.S. enterprise, and we will lose a generation of young scientists who see no prospects for careers in biomedical research. Flat or reduced funding for NIH will mean that the agency would have to dramatically reduce new awards and many research projects in progress would not receive sufficient funding to complete ongoing work, thus representing a waste of valuable research resources.

An fiscal year 2013 NIH budget of \$32 billion would help to begin to restore momentum to NIH funding. A \$32 billion fiscal year 2013 NIH budget will help the agency manage its research portfolio effectively without too much disruption of existing grants to researchers throughout the country. The NIH, and the entire scientific enterprise, cannot rationally manage boom or bust funding cycles. Scientific research takes time. Only through steady, sustainable and predictable funding increases can NIH continue to fund the highest quality biomedical research to help improve the health of all Americans and continue to make significant economic impact in many communities across the country. An fiscal year 2013 NIH budget of \$32 billion will help NIH move to more fully exploit promising areas of biomedical research and translate the resulting findings into improved healthcare.

Diminished Support for National Institutes of Health Will Negatively Impact Human Health

Diminished funding for NIH will mean a loss of scientific opportunities to discover new therapeutic targets and will create disincentives to young scientists to commit to careers in biomedical science. A difficult Federal funding environment becomes more problematic as economic difficulties have led to less investment by the pharmaceutical industry and diminished venture capital needed by the biotech industry. Previous investments in NIH research have been instrumental in improving human health. However, a greater investment in research is needed to help improve the lives of many afflicted by chronic diseases:

- Parkinson's disease is estimated to afflict more than 1 million Americans at an annual cost of \$26 billion. The discovery of Levodopa was a breakthrough in treating the disease and allows patients to lead relatively normal, productive lives. It is estimated that treatments slowing the progress of disease by 10 percent could save the United States \$327 million a year. Current treatments slow progression of the disease, but more research is needed to identify the causes of the disease and help to develop better therapies.

- More than 38 million Americans are blind or visually impaired, and that number will grow with an aging population. Eye disease and vision loss cost the United States \$68 billion annually. NIH funded research has developed new treatments that delay or prevent diabetic retinopathy, saving \$1.6 billion a year. Discovery of gene variations in age-related macular degeneration could result in new screening tests and preventive therapies.
- One in eight older Americans suffer from Alzheimer's disease at annual costs of more than \$200 billion. It is estimated that by 2050 more than 14 million Americans will live with the disease with projected costs of \$1.1 trillion (in 2012 dollars). Although there are new clinical candidates for Alzheimer's disease in development, more basic research is needed to focus on new molecular targets and potential cures for this disease. Inadequate funding will delay and prevent improved treatment of the disease.
- Heart disease and stroke are the number one and three killers of Americans, respectively. Cardiovascular disease costs the United States more than \$350 billion annually. Death rates from cardiovascular disease have fallen by 50 percent since 1970. Statin drugs that reduce cholesterol help to prevent heart disease and stroke, decrease recurrence of heart attacks and improve survival rates for heart transplant patients.
- Cancer is the second leading cause of death in the United States. The NIH estimates that the annual cost of the disease is more than \$228 billion. NIH research has shown that human papillomavirus (HPV) vaccines protect against persistent infection by the two types of HPV that cause approximately 70 percent of cervical cancers. NIH funded researchers are using nanotechnology to develop probes that could pinpoint the location of tumors and deliver drugs directly to cancer cells. NIH funded basic research built the foundation for one of the most revolutionary FDA approved new treatments for melanoma and helped launch the era of modern personalized medicine.
- NIH-funded investigators discovered an enzyme that may act as a tumor suppressor, therapeutic target, and clinical biomarker in patients with colorectal cancer. Clinical trials are now underway to study its role as a possible novel chemoprevention approach to prevent colorectal cancer and determine the utility of the enzyme as a prognostic and predictive marker for staging patients with disease. The enzyme is also being used as a vaccine target to prevent recurrent disease. Studies are underway evaluating this enzyme's role in regulating appetite and as a possible novel therapeutic target to prevent obesity, diabetes, and metabolic syndrome.
- Finding new uses for existing drugs is difficult but could be life saving and cost effective. NIH-funded researchers using new bioinformatic approaches have discovered that a drug designed to treat heartburn also inhibited the growth of human lung tumors in laboratory mice. Without adequate support for NIH funding, this type of discovery may become impossible and potential clinical benefits will not be realized.
- There are almost 7,000 rare diseases, each afflicting fewer than 200,000 individuals. More than 350 drugs have been approved for rare diseases since passage of the Orphan Drug Act in 1983. The number of new drugs in development is increasing rapidly as researchers gain a better understanding of the underlying molecular and genetic causes of disease. Diminished support for NIH will prevent new and ongoing investigations into rare diseases that FDA estimates almost 90 percent are serious or life-threatening.

NIH-funded studies have also indicated that adopting intensive lifestyle changes delayed onset of type-2 diabetes by 58 percent, and that progesterone therapy can reduce premature births by 30 percent in at-risk women. Historically, our past investment in basic biological research has led to many innovative medicines. The National Research Council reported that of the 21 drugs with the highest therapeutic impact, only 5 were developed without input from the public sector. The significant past investment in the NIH has provided major gains in our knowledge of the human genome, resulting in the promise of pharmacogenomics and a reduction in adverse drug reactions that currently represent a major worldwide health concern. Already, there are several examples where complete human genome sequence analysis has pinpointed disease-causing variants that have led to improved therapy and cures. Although the costs for such analyses have been reduced dramatically by technology improvements, widespread use of this approach will require further improvements in technology that will be delayed or obstructed with inadequate NIH funding.

Investing in National Institutes of Health Helps America Compete Economically

A \$32 billion budget in fiscal year 2013 will also help the NIH train the next generation of scientists. This investment will help to create jobs and promote economic growth. Limiting or cutting the NIH budget will mean forfeiting future discoveries to other countries.

Worldwide, other nations continue to invest aggressively in science. China has grown its science portfolio with annual increases to the research and development budget averaging more than 23 percent annually since 2000. And while Great Britain has imposed strict austerity measures to address that Nation's debt problems, the British conservative party had the foresight to keep its strategic investments in science at current levels. The European Union, despite austerity measures and the severe debt problems of its member nations, has proposed to increase spending on research and innovation by 45 percent between 2014 and 2020.

NIH research funding catalyzes private sector growth. More than 83 percent of NIH funding is awarded to more than 3,000 universities, medical schools, teaching hospitals and other research institutions in every State. One national study by an economic consulting firm found that Federal (and State) funded research at the Nation's medical schools and hospitals supported almost 300,000 jobs and added nearly \$45 billion to the U.S. economy. NIH funding also provides the most significant scientific innovations of the pharmaceutical and biotechnology industries.

Inadequate funding for NIH means more than a loss of scientific potential and discovery. As we have noted, failing to help meet the NIH's scientific potential has led to a significant reduction in research grants and the resulting phasing-out of high quality research programs and jobs lost.

Conclusion

ASPET appreciates the many competing and important spending decisions the Subcommittee must make. The Nation's deficit and debt problems are great. However, NIH and the biomedical research enterprise face a critical moment. The agency's contribution to the Nation's economic and physical well-being should make it one of the Nation's top priorities. With enhanced and sustained funding, NIH has the potential to address many of the more promising scientific opportunities that currently challenge medicine. A \$32 billion fiscal year 2013 NIH budget will allow the agency to begin moving forward to full program capacity, exploiting more scientific opportunities for investigation, and increasing investigator's chances of discoveries that prevent, diagnose and treat disease. NIH should be restored to its role as a national treasure, one that attracts and retains the best and brightest to biomedical research and provides hope to millions of individuals afflicted with illness and disease.

PREPARED STATEMENT OF THE AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE

The American Society of Tropical Medicine and Hygiene (ASTMH)—the principal professional membership organization representing, educating, and supporting scientists, physicians, clinicians, researchers, epidemiologists, and other health professionals dedicated to the prevention and control of tropical diseases—appreciates the opportunity to submit testimony to the Senate Labor, Health and Human Services, and Education Appropriations Subcommittee.

The benefits of U.S. investment in tropical diseases are both humanitarian and diplomatic. With this in mind, we respectfully request that the Subcommittee provide at least \$32 billion for the NIH, and fully fund CDC in the fiscal year 2013 LHHS appropriations bill to allow them to maintain their current activities and research priorities to ensure a continued U.S. Government investment in global health and tropical medicine research and development:

National Institutes of Health

Malaria and neglected tropical disease treatment, control, and research and development efforts within the National Institute of Allergy and Infectious Diseases;

An expanded focus on the treatment, control, and research and development for new tools for diarrheal disease within the NIH; specifically the inclusion of enteric infections on the Research, Condition, and Disease Categorization (RCDC) process on the Research Portfolio Online Reporting Tools (RePORT) website; and

Research capacity development in countries where populations are at heightened risk for malaria, neglected tropical diseases (NTDs), and diarrheal diseases through the Fogarty International Center.

The Centers for Disease Control and Prevention

The Center for Global Health, which includes CDC's work in malaria and NTDs; and

The National Center for Emerging & Zoonotic Infectious Diseases, which houses the Emerging and Zoonotic Infectious Disease Program and the Vector-Borne Disease Program that are responsible for protecting the United States from new and emerging infections.

RETURN ON INVESTMENT OF U.S.-FUNDED RESEARCH

CDC and NIH play essential roles in research and development for tropical medicine and global health. Both agencies are at the forefront of the new science that leads to tools to combat malaria and NTDs. This research provides jobs for American researchers and an opportunity for the United States to be a leader in the fight against global disease, in addition to creating lifesaving new drugs and diagnostics to some of the poorest, most at-risk people in the world.

TROPICAL DISEASE

Most tropical diseases are prevalent in either sub-Saharan Africa, parts of Asia (including the Indian subcontinent), or Central and South America. Many of the world's developing nations are located in these areas; thus, tropical medicine tends to focus on diseases that impact the world's most impoverished individuals.

Malaria and Parasitic Disease.—Malaria remains a global emergency affecting mostly poor women and children; it is an acute, sometimes fatal disease. Despite being treatable and preventable, malaria is one of the leading causes of death and disease worldwide. Approximately every 30 seconds, a child dies of malaria—a total of about 800,000 under the age of 5 every year. The World Health Organization estimates that one-half of the world's people are at risk for malaria and that there are 108 malaria-endemic countries. Additionally, WHO has estimated that malaria reduces sub-Saharan Africa's economic growth by up to 1.3 percent per year.

Neglected Tropical Diseases, Also Known as Diseases of Poverty.—NTDs are a group of chronic parasitic diseases, such as hookworm, elephantiasis, schistosomiasis, and river blindness, which represent the most common infections of the world's poorest people. These infections have been revealed as the stealth reason why the "bottom billion"—the 1.4 billion poorest people living below the poverty line—cannot escape poverty, because of the effects of these diseases on reducing child growth, cognition and intellect, and worker productivity.

Diarrheal Disease.—The child death toll due to diarrheal illnesses exceeds that of AIDS, tuberculosis, and malaria combined. In poor countries, diarrheal disease is second only to pneumonia as the cause of death among children under 5 years old. Every week, 31,000 children in low-income countries die from diarrheal diseases.

The United States has a long history of leading the fight against tropical diseases that cause human suffering and pose financial burden that can negatively impact a country's economic and political stability. Tropical diseases, many of them neglected for decades, impact U.S. citizens working or traveling overseas, as well as our military personnel. Furthermore, some of the agents responsible for these diseases can be introduced and become established in the United States (like West Nile virus), or might even be weaponized.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases.—A long-term investment is critical to achieve the drugs, diagnostics, and research capacity needed to control malaria and NTDs. NIAID is the lead institute for malaria and NTD research.

ASTMH encourages the subcommittee to:

- Increase funding for NIH to expand the agency's investment in malaria, NTDs, and diarrheal disease research and to coordinate that work with other Government agencies to maximize resources and ensure development of basic discoveries into usable solutions;
- Specifically invest in NIAID to support its role at the forefront of these efforts to developing the next generation of drugs, vaccines, and other interventions; and
- Urge NIH to include enteric infections and neglected diseases in its RCDC process on the RePORT website to outline the work that is being done in these important research areas.

Fogarty International Center (FIC).—Biomedical research has provided major advances in the treatment and prevention of malaria, NTDs, and other infectious diseases. These benefits, however, are often slow to reach the people who need them

most. FIC plays a critical role in strengthening science and public health research institutions in low-income countries. FIC works to strengthen research capacity in countries where populations are particularly vulnerable to threats posed by malaria, NTDs, and other infectious disease. This maximizes the impact of U.S. investments and is critical to fighting malaria and other tropical diseases.

ASTMH encourages the subcommittee to:

- Allocate sufficient resources to FIC in fiscal year 2013 to increase these efforts, particularly as they address the control and treatment of malaria, NTDs, and diarrheal disease.

THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Malaria and Parasitic Disease.—Malaria has been eliminated as an endemic threat in the United States for over 50 years, and CDC remains on the cutting edge of global efforts to reduce the toll of this deadly disease. CDC efforts on malaria and parasitic disease fall into three broad categories: prevention, treatment, and monitoring/evaluation of efforts. The agency performs a wide range of basic research within these categories, such as:

- Conducting research on antimalarial drug resistance to inform new strategies and prevention approaches;
- Assessing new monitoring, evaluation, and surveillance strategies;
- Conducting additional research on malaria vaccines, including field evaluations; and
- Developing innovative public health strategies for improving access to antimalarial treatment and delaying the appearance of antimalarial drug resistance.

ASTMH encourages the subcommittee to:

- Fund a comprehensive approach to effective and efficient malaria and parasitic disease, including adequately funding the important contributions of CDC in malaria and parasitic disease at no less than \$18 million.

Neglected Tropical Diseases.—CDC currently receives zero dollars directly for NTD work outside of parasitic diseases; however, this should be changed to allow for more comprehensive work to be done on NTDs at the CDC. CDC has a long history of working on NTDs and has provided much of the science that underlies the global policies and programs in existence today. This work is important to any global health initiative, as individuals are often infected with multiple NTDs simultaneously.

ASTMH encourages the subcommittee to:

- Provide direct funding to CDC to continue its work on NTDs, including but not limited to parasitic diseases; and
- Urge CDC to continue its monitoring, evaluation, and technical assistance in these areas as an underpinning of efforts to control and eliminate these diseases.

Vector-Borne Disease Program (VBDP).—Through the VBDP, researchers are able to practice essential surveillance and monitoring activities that protect the United States from deadly infections before they reach our borders. The world is becoming increasingly smaller as international travel increases and new pathogens are introduced quickly into new environments. We have seen this with SARS, avian influenza, and now, dengue fever, in the United States. Arboviruses like dengue, and others, such as chikungunya, are a constant threat to travelers, and to Americans generally.

Dengue fever, a disease with increased risk for Americans as the weather warms and dengue cases increase, is an example of why it is imperative that CDC be able to continue its disease monitoring and surveillance activities to protect the country from new and emerging threats like dengue and other arboviruses. Dengue fever, a viral disease transmitted by the Aedes mosquito, recently reemerged as a threat to Americans, with documented cases in the Florida Keys. Dengue usually results in fever, headache, and chills, but hemorrhagic dengue fever can cause severe internal bleeding, loss of blood, and even death. Because the Aedes mosquito is urban dwelling and often breeds in areas of poor sanitation, dengue is a serious concern for poor residents of coastal, urban areas in Texas, Louisiana, Mississippi, Alabama, and Florida.

ASTMH encourages the subcommittee to:

- Ensure that CDC maintain these important activities by continuing CDC funding for VBDP activities through the National Center for Emerging and Infectious Zoonotic Diseases.

CONCLUSION

Thank you for your attention to these important United States and global health matters. We know the Congress and the American people face many challenges in choosing funding priorities, and we hope you will provide the requested fiscal year 2013 resources to those programs identified above that meet critical needs for Americans and people around the world. ASTMH appreciates the opportunity to share its expertise, and we thank you for your consideration of these requests that will help improve the lives of Americans and the global poor.

PREPARED STATEMENT OF THE AMERICAN THORACIC SOCIETY

SUMMARY: FUNDING RECOMMENDATIONS

[In millions of dollars]

	Amount
National Institutes of Health	32,000
National Heart, Lung and Blood Institute	3,214
National Institute of Allergy and Infectious Disease	4,701
National Institute of Environmental Health Sciences	717.7
Fogarty International Center	72.7
National Institute of Nursing Research	151
Centers for Disease Control and Prevention	7,800
National Institute for Occupational Safety and Health	293.6
Asthma Programs	25.3
Div. of Tuberculosis Elimination	243
Office on Smoking and Health	197.1
National Sleep Awareness Roundtable (NSART)	1

The American Thoracic Society (ATS) is pleased to submit our recommendations for programs in the Labor Health and Human Services and Education Appropriations Subcommittee purview. Founded in 1905, the ATS is an international education and scientific society of 15,000 members that focuses on respiratory and critical care medicine. The ATS's 15,000 members help prevent and fight respiratory disease through research, education, patient care and advocacy.

Lung Disease in America

Diseases of breathing constitute the third leading cause of death in the United States, responsible for 1 of every 7 deaths. Diseases affecting the respiratory (breathing) system include chronic obstructive pulmonary disease (COPD), lung cancer, tuberculosis, influenza, sleep disordered breathing, pediatric lung disorders, occupational lung disease, sarcoidosis, asthma, and critical illness. The death rate due to COPD has doubled within the last 30 years and is still increasing, while the rates for the other three top causes of death (heart disease, cancer and stroke) have decreased by more than 50 percent. The number of people with asthma in the United States has surged more than 150 percent since 1980 and the root causes of the disease are still not fully known.

National Institutes of Health

The NIH is the world's leader in groundbreaking biomedical health research into the prevention, treatment and cure of diseases such as lung cancer, COPD and tuberculosis. Due to the combination of funding that has not kept pace with biomedical research and inflation and the rising costs of doing research, the number of research project grants supported by the NIH is now at the lowest level since 2001. The success rate for NIH grants has plummeted to below 13 percent, meaning that more than 87 percent of meritorious research is not being funded. Without a funding increase to sustain the research pipeline, the NIH will be forced to reduce the number of research grants funded, which will result in the halting of vital research into diseases affecting millions around the world. We ask the subcommittee to provide \$32 billion for the NIH in fiscal year 2013.

Despite the rising lung disease burden, lung disease research is underfunded. In fiscal year 2011, lung disease research represented just 23.4 percent of the National Heart, Lung, and Blood Institute's (NHLBI) budget. Although COPD is the third leading cause of death in the United States, research funding for the disease is a fraction of the money invested for the other leading causes of death.

Centers for Disease Control and Prevention

In order to ensure that health promotion and chronic disease prevention are given top priority in Federal funding, the ATS supports a funding level for the Centers for Disease Control and Prevention (CDC) that enables it to carry out its prevention mission, and ensure a translation of new research into effective State and local public health programs. We ask that the CDC budget be adjusted to reflect increased needs in chronic disease prevention, infectious disease control, including TB control and occupational safety and health research and training. The ATS recommends a funding level of \$7.8 billion for the CDC in fiscal year 2013.

Chronic Obstructive Pulmonary Disease

COPD is the third leading cause of death in the United States and the third leading cause of death worldwide. CDC estimates that 12 million patients have COPD; an additional 12 million Americans are unaware that they have this life threatening disease. In 2010, the estimated economic cost of lung disease in the United States was \$186 billion, including \$117 billion in direct health expenditures and \$69 billion in indirect morbidity and mortality costs.

Despite the growing burden of COPD, the United States does not have a public health action plan on the disease. The ATS urges the Congress to direct the NHLBI to develop a national action plan on COPD, in coordination with the Centers for Disease Control and Prevention (CDC) to expand COPD surveillance, development of public health interventions and research on the disease and increase public awareness of the disease. The NHLBI has shown successful leadership in educating the public about COPD through the COPD Education and Prevention Program.

CDC has an additional role to play in this work. We urge CDC to include COPD-based questions to future CDC health surveys, including the National Health and Nutrition Evaluation Survey (NHANES) and the National Health Information Survey (NHIS).

Tobacco Control

Cigarette smoking is the leading preventable cause of death in the United States, responsible for 1 in 5 deaths annually. The ATS is pleased that the Department of Health and Human Services has made tobacco use prevention a key priority. The CDC's Office of Smoking and Health coordinates public health efforts to reduce tobacco use. In order to significantly reduce tobacco use within 5 years, as recommended by the subcommittee in fiscal year 2010, the ATS recommends a total funding level of \$197 million for the Office of Smoking and Health in fiscal year 2013.

Pediatric Lung Disease

The ATS is pleased to report that infant death rates for various lung diseases have declined for the past 10 years. In 2007, of the 10 leading causes of infant mortality, 4 were lung diseases or had a lung disease component. Many of the precursors of adult respiratory disease start in childhood. Many children with respiratory illness grow into adults with COPD. It is estimated that 7.1 million children suffer from asthma. While some children appear to outgrow their asthma when they reach adulthood, 75 percent will require life-long treatment and monitoring of their condition. The ATS encourages the NHLBI to continue with its research efforts to study lung development and pediatric lung diseases.

Asthma

Asthma is a significant public health problem in the United States. Approximately 25 million Americans currently have asthma. In 2009, 3,445 Americans in 2009 died as a result of asthma exacerbations. Asthma is the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences from chronic disease. The disease costs our healthcare system more than \$50.1 billion per year. African-Americans have the highest asthma prevalence of any racial/ethnic group and the age-adjusted death rate for asthma in this population is three times the rate in whites.

The President's fiscal year 2013 budget request proposes to merge the CDC's National Asthma Control Program with the Healthy Homes/Lead Poisoning Prevention Program and recommends funding cuts to the combined programs of more than 50 percent. The ATS is deeply concerned that this proposal would drastically reduce States' capacity to implement a proven public health response to this disease. Asthma public health interventions are cost effective. A study published in the American Journal of Respiratory Critical Care recently found that for every dollar invested in asthma interventions, there was a \$36 benefit. We ask that in your appropriations request for fiscal year 2013 that funding for CDC's National Asthma Control Pro-

gram be maintained at a funding level of at least \$25.3 million and that the National Asthma Control Program remain as a distinct, stand-alone program.

Sleep

Several research studies demonstrate that sleep-disordered breathing and sleep-related illnesses affect an estimated 50–70 million Americans. The public health impact of sleep illnesses and sleep disordered breathing is still being determined, but is known to include increased mortality, traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other sleep-related comorbidities. Despite the increased need for study in this area, research on sleep and sleep-related disorders has been underfunded. The ATS recommends a funding level of \$1 million in fiscal year 2013 to support activities related to sleep and sleep disorders at the CDC, including for the National Sleep Awareness Roundtable (NSART), surveillance activities, and public educational activities. The ATS also recommends an increase of funding for research on sleep disorders at the National Center for Sleep Disordered Research (NCSDR) at the NHLBI.

Tuberculosis

Tuberculosis (TB) is the second leading global infectious disease killer, claiming 1.4 million lives each year. It is estimated that 9–12 million Americans have latent tuberculosis. Drug-resistant TB poses a particular challenge to domestic TB control due to the high costs of treatment and intensive healthcare resources required. Treatment costs for multidrug-resistant (MDR) TB range from \$100,000 to \$300,000. The global TB pandemic and spread of drug resistant TB present a persistent public health threat to the United States.

Despite declining rates, persistent challenges to TB control in the United States remain. Specifically: (1) racial and ethnic minorities continue to suffer from TB more than majority populations; (2) foreign-born persons are adversely impacted; (3) sporadic outbreaks occur, outstripping local capacity; (4) continued emergence of drug resistance; and (5) there are critical needs for new diagnostics, treatment and prevention tools.

The Comprehensive Tuberculosis Elimination Act (CTEA, Public Law 110–392), enacted in 2008, reauthorized programs at CDC with the goal of putting the United States back on the path to eliminating TB. The ATS, recommends a funding level of \$243 million in fiscal year 2013 for CDC's Division of TB Elimination, as authorized under the CTEA, and encourages the NIH to expand efforts to develop new tools to reduce the rising global TB burden.

Critical Illness

The burden associated with the provision of care to critically ill patients is enormous, and is anticipated to increase significantly as the population ages. Approximately 200,000 people in the United States require hospitalization in an intensive care unit because they develop a form of pulmonary disease called Acute Lung Injury. Despite the best available treatments, 75,000 of these individuals die each year from this disease. To put that in context, that is the approximately the number of deaths each year due to breast cancer, colon cancer, and prostate cancer combined. This disease can be triggered by a variety of causes, including infections, drowning, traumatic accidents, burn injuries, blood transfusions and inhalation of toxic substances. Investigation into diagnosis, treatment and outcomes in critically ill patients should be a high priority, and the NIH should be encouraged and funded to coordinate investigation related to critical illness in order to meet this growing national imperative.

Fogarty International Center

The Fogarty International Center (FIC) at NIH provides training grants to U.S. universities to teach AIDS treatment and research techniques to international physicians and researchers. FIC has created supplemental TB training grants for these institutions to train international health professionals in TB treatment and research. The ATS recommends the Congress provide \$72.8 million for FIC in fiscal year 2013, to allow expansion of the TB training grant program from a supplemental grant to an open competition grant.

Researching and Preventing Occupational Lung Disease

The ATS urges the subcommittee to provide at least level funding for the National Institute for Occupational Safety and Health (NIOSH). NIOSH, within the Centers for Disease Control and Prevention (CDC), is the primary Federal agency responsible for conducting research and making recommendations for the prevention of work-related illness and injury. NIOSH provides national and world leadership to avert workplace illness, injury, disability, and death by gathering information, con-

ducting scientific research, and translating this knowledge into products and services. NIOSH supports programs in every State to improve the health and safety of workers.

The ATS appreciates the opportunity to submit this statement to the subcommittee.

PREPARED STATEMENT OF THE AMERICAN UROGYNECOLOGIC SOCIETY

Founded in 1979, the American Urogynecologic Society (AUGS) is a professional organization of 1,400 physicians and allied health professionals who are dedicated to caring for women with pelvic floor disorders (PFD) that include pelvic organ prolapse, stress urinary incontinence, and defecatory disorders such as constipation and fecal incontinence.

As the largest U.S. professional organization dedicated to caring for women with PFDs, AUGS is committed to advancing this vastly understudied field as a means to improve the quality of life of women worldwide. We are pleased to submit testimony to the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies requesting a greater commitment to biomedical research focused on female pelvic floor disorders, including incontinence.

Impact of Pelvic Floor Disorders

Female pelvic floor disorders (PFD) represent an under-appreciated, but major public health burden with high prevalence, impairment of quality of life, and substantial economic costs. These disorders, which include urinary and fecal incontinence as well as pelvic organ prolapse (POP) (pelvic organs protruding outside of the body), affect 25 percent of women aged 40–59. Women with PFDs suffer from pressure, pain, embarrassment, and frequently social isolation. However, because PFDs are rarely fatal and are underreported by those affected, public attention is sparse. While many of us take bladder and bowel control for granted, for those that suffer, day-to-day life is not routine. Prevalence dramatically increases with age; 50 percent of women over 80 suffer from uncontrollable leakage of urine or stool and/or POP. As the United States population ages, PFDs will become an even greater public health issue that cannot be ignored.

List of research priorities for PFDs:

- Expand research into understanding what causes some women to suffer from PFDs, while other women are spared.
- Foster collaborations between clinician scientists, basic researchers, and translational scientists.
- Facilitate clinical effectiveness studies through the development of large practice-based networks, registries, or multi-institutional databases.

Amount requested: \$25 million in fiscal year 2013.

Since fiscal year 1999 (14 fiscal years), the National Institute of Child Health and Human Development (NICHD), National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK) and the National Institute on Aging (NIA) have provided \$150 million (or \$10.7 million per annum) to PFD research (NIH Reporter query 4/21/12 [search criteria = “pelvic floor”). This funding has resulted in several important discoveries and programs, briefly summarized here:

- The prevalence of the most common PFDs is better understood. (Nygaard, Brown, Bharucha, Guise)
- Using increasingly well-characterized knockout mouse models, the role of modeling and remodeling of connective tissue constituents for pelvic floor support has been better elucidated. (Moalli, Word, Chen, Clark)
- Utilizing magnetic resonance imaging and 3D ultrasound, the functional (and dysfunctional) anatomy of pelvic floor organ support by deep pelvic floor muscles is being explored. (Delancey, Ashton-Miller, Dietz)
- The role of peripheral nerve injury in the function of sphincteric muscles has been evaluated in rodents, in some nonhuman primates, and in humans. (Damaser, Wai, Pierce, Kuehl, Weidner)
- Genetic determination of disease expression is currently being explored in populations of families. (Norton)
- Major NIH-funded networks (the Pelvic Floor Disorders Network and the Urinary Incontinence Treatment Network) have provided new insights from well-conceived clinical trials that are being incorporated into routine practice.

Although these studies have led to important advances in PFD research, they have also unveiled a wealth of unanswered questions that only can be addressed with ongoing funded research. Given the potential for further critical research in this area and the large proportion of the population affected by these disorders, we

respectfully request a significant increase in funding to \$25 million in fiscal year 2013 in order to build on the work already done. By providing at least \$32 billion in funding to the National Institutes of Health in the fiscal year 2013 Labor-HHS-Education appropriations bill, there would be enough of an increase to also allow NICHD and NIDDK to appropriately provide for this requested increase in PFD research, as well.

Further Detail Regarding Research Priorities for Pelvic Floor Disorders

NICHD, NIDDK and NIA need to expand research into understanding what causes some women to suffer from PFDs, while other women are spared.

Rationale.—Unlike many other disease processes, the underlying causes of PFDs are poorly understood, and thus, our ability to accurately determine which woman will be affected is rudimentary. Because of these significant knowledge gaps, efforts to develop effective preventive strategies and long-term treatment options remain empiric, rather than based on understanding of the underlying mechanisms of disease. This, in turn, likely contributes to the lack of long-term success of existing therapies. For example, women who suffer from urinary incontinence due to a condition called “overactive bladder” only achieve moderate improvements with currently approved medications. Furthermore, those that do get relief frequently discontinue medication because of equally bothersome side effects. An accurate understanding of disease mechanisms and varied expression of the disease is critical for advancing prevention strategies and developing new treatments. Better understanding of treatment failures will additionally serve to achieve our ultimate goal of improving the lives of millions of women who suffer from these highly prevalent disorders.

Research Goal.—Encourage diverse research methodologies such as biomechanics, bioinformatics, genomics and proteomics, cellular biology and epidemiology. Below two research initiatives aimed at expanding research in the pathophysiology and phenotypes of PFDs are briefly outlined. To achieve this goal AUGS recommends the following:

Pathophysiology.—Scientific understanding of tissue-specific abnormalities that underlie female PFDs is in its infancy with many competing concepts and hypotheses that do not have unifying themes. It is unclear whether the abnormalities presently associated with pelvic floor dysfunction are due to acute or repeated injury, deterioration, or inherent abnormalities of the structures studied. Investigations are urgently needed into the mechanisms underlying observed changes in the skeletal and smooth muscles of the pelvic floor; autonomic, peripheral and central nervous systems; and the connective tissues of the pelvic floor.

—Create a multi-center discovery network of expert centers focused on the pathophysiology of PFD to develop coordinated research.

—Publish RFAs to fund the required mechanistic research into the basic causes of the occurrence and progression of PFD.

Phenotyping.—Accurate disease/disorder categorization is uniformly critical to high-quality research; however, current knowledge of various forms of urinary and fecal incontinence and POP is limited. The process of developing definitions of “disease/disorder” requires the use of epidemiologic, biologic, molecular and computational methodologies for complex processes such as PFDs. Therefore AUGS recommends:

—Publish a specific RFA to fund multidisciplinary research on how to phenotype PFD.

—Once the process has been defined, fund a consortium of centers focused on multidisciplinary approaches to accurately phenotype pelvic floor disorders.

NIH Institutes need to foster collaborations between clinician scientists, basic researchers, and translational scientists.

Rationale.—The Inaugural AUGS Research Summit 2010 recommended a variety of complex research topics to advance understanding in PFDs, all of which require multidisciplinary expertise. It is critical to prioritize enhancing partnerships between clinician scientists and basic/translational scientists to maximize the bi-directional flow of research.

Research Goals.—We propose the following near-term action items to achieve this priority.

—Using the RFA and PA mechanisms, include basic science research in ongoing and new large collaborative/network trials. This would allow basic scientists to create a tissue bank and access data and tissues collected from diverse yet well-characterized populations. Additionally, research grant requirements could be redefined so that large clinical studies are required to include a basic science component. This would encourage clinicians to think about the mechanisms

leading to their observations and outcomes, and basic scientists to base their investigations on clinical perspective in their areas of expertise.

- Develop seed funding mechanisms focused on bringing multidisciplinary experts together to plan and design studies in Female Pelvic Medicine and Reconstructive Surgery. Primary barriers preventing collaborative groups from receiving funding are the protected time necessary for investigators to plan and funds for them to generate pilot data together to produce meaningful proposals.
- Increase ongoing communications between NICHD, NIDDK, NIA and Office of Research on Women's Health (ORWH) to align their goals and strategies in Female Pelvic Medicine and Reconstructive Surgery research. This also includes identifying scientific officers within these NIH Institutes and ORWH with specific responsibilities of advocacy for basic science/multidisciplinary research projects in Female Pelvic Medicine and Reconstructive Surgery. This organization at the level of the NIH would better focus research priorities and reduce redundancy, translating into better use of resources.

NICHD, NIDDK and the Agency for Healthcare Research and Quality should work together and facilitate clinical effectiveness studies through the development of large practice-based networks, registries, or multi-institutional databases.

Rationale.—Finding safe and cost-effective treatments for PFDs is of the utmost importance; however, the pipeline from bench to bedside is laborious. Women, in the meantime, continue to suffer from and seek treatment for PFDs. Research focused on comparative effectiveness, health behavior, cost-effectiveness and implementation science are crucial to provide safe, effective care to the many women who suffer from pelvic floor dysfunction in the immediate term. In order to make such research possible, it is imperative to develop an infrastructure that allows the study of treatment effectiveness or how treatments perform in a more “real world” setting. Broader participation in such efforts would be facilitated by the development of a system to encourage non-NIH funded investigators to contribute patients to ongoing multi-center trials or cohort studies. To achieve these goals, we recommend the following immediate actions:

Establish Evidence-Based Outcome Measures.—Currently, clinical research is limited by the variability (across studies) in techniques for measurement of clinically relevant outcomes. Therefore, uniform evidence-based outcome measures should be selected or developed to allow cross-study comparisons and meta-analyses.

- To select and develop this “bank” of measures, an interdisciplinary team should be convened and should include representatives from traditional Federal funding and oversight entities, as well as broad representation of other stakeholders including professional societies, and patients. The minimum data set proposed by the NIH Standardization of Terminology for Researchers in Female Pelvic Floor Disorders (2001) should be revised. The concept of a clinical outcome measure that balances improvement in pre-existing symptoms with the development of new symptoms and complications should be explored.

- A library for clinical measurements in research should be established, including those that apply to both affected and unaffected individuals and including minority populations; such measures must be available in Spanish. Uniform measures across centers would promote comparisons of treatment outcomes in various settings and populations. In addition, this would facilitate the identification of quality indicators that assess the balance between benefits and harms.

Practice-Based Networks.—The past 10 years has seen substantial progress with respect to high-quality clinical trials in the evaluation and treatment of PFDs. This will be crucial to ensure high quality as well as cost-effective care for our aging population.

- Develop practice-based networks for clinical research for short and long-term (5 years or more) outcomes. The challenges are to engage practicing physicians in research, to encourage patients to participate in clinical trials, and to ensure best research practices in this context.
- Develop a web-based comprehensive database for data collection. Ideally, this database would interface not only with the central repository, but also with the local medical record.

Support a National Registry for Permanent Surgical Implants Used in POP Surgery.—The past decade has seen an unprecedented increase in the development of new surgical implants, many with uncertain long-term effects. Indeed, in 2008 the FDA issued a Public Health Notification and in 2011 a Safety Update regarding “serious complications associated with transvaginal placement of surgical mesh”. Such a registry would allow the tracking and study of long-term

efficacy and safety outcomes as well as the improved identification of rare adverse events associated with the use of these implants.

We thank you, Mr. Chairman, and the Subcommittee, for your support of research regarding Pelvic Floor Disorders and thank you for the opportunity to share these comments.

PREPARED STATEMENT OF THE ANIMAL WELFARE INSTITUTE

We are grateful to the Animal Welfare Institute (AWI) subcommittee for this opportunity to offer testimony as you consider budget priorities for fiscal year 2013. This testimony addresses the National Institutes of Health (NIH), but does not make any funding requests.

Thanks to the 2009 National Academy of Sciences (NAS) report “Scientific and Humane Issues in the Use of Random Source Dogs and Cats in Research”, and to ongoing concern on the part of the Congress, the NIH has begun the process of prohibiting its extramural researchers from acquiring dogs and cats from random source Class B dealers. The ban on the acquisition of cats from these dealers will take effect on October 1, and the ban on the acquisition of dogs is scheduled to take effect in 2015.

It should be clarified that the NAS report addressed extramural research funded by NIH, not NIH’s internal research endeavors. There was no need—NIH had ceased using Class B dog and cat dealers in its own research over 20 years ago, recognizing the problems—both ethical and scientific—caused by acquiring animals from sources that treat dogs and cats inhumanely; fail to provide proper veterinary care and the basic necessities of life such as clean water, food, and shelter; acquire animals through fraud and deception; and are constantly under investigation for apparent violations of the Animal Welfare Act. In fact, in a 2010 article in *Science* (David Grimm, “Dog Dealers’ Days May Be Numbered,” Vol. 327, 26 February 2010, p. 1076–1077), Dr. Robert Whitney, director of NIH’s animal resources program for 20 years, is quoted as saying, “By using these animals, we risk losing our credibility with the public. It’s an Achilles’ heel for research.” Even so, and even in the face of congressional concern, NIH had steadfastly refused to hold its outside grant recipients to the same high standards it was requiring of its intramural researchers. We commend NIH for taking the NAS report recommendations and the Congress’ concerns to heart and moving forward to end its support for the Class B dealer system.

As a result of the NAS report, ongoing congressional interest, intensive (and overly expensive) oversight, and evaporating demand for their dogs and cats, very few of these dealers remain. Of the eight remaining random source Class B dog and cat dealers, one is still under a license suspension, one has received an Official Warning/Violation of Federal Regulations, and three others remain under investigation. Cases are still pending against two dealers who have given up their licenses; one of them was indicted on a number of Federal charges, including conspiracy, aggravated identity theft, mail fraud, and making false statements to a Federal agency.

However, even with positive steps toward ending the Class B dealer system as a source of dogs and cats for research, it is too early for the Congress to take its eye off the ball. Until the Pet Safety and Protection Act is enacted, thus putting a permanent end to the supply of animals to research through Class B dealers, the potential will exist for the system to reconstitute itself. In light of this, it is vital that the Congress take every opportunity to underscore its continuing vigilance on this issue. We therefore respectfully ask the subcommittee to include the following language in its report:

“The Committee wishes to acknowledge that NIH has made progress in moving to end the use of Class B random source dealers as suppliers of dogs and cats to its grant recipients by recently announcing a ban, effective October 1, 2012, on the acquisition of cats from Class B random source dealers. The Committee urges NIH to move as expeditiously as possible to implement the ban on the acquisition of dogs from Class B random source dealers, preferably before, but certainly no later than, 2015, and to ensure that the ban covers not only future grant awards but also those in place at the time the ban goes into effect. Finally, the Committee requests that NIH provide regular reports to the Committee on the status of this process.”

Thank you for your consideration of this request.

PREPARED STATEMENT OF THE BRAIN INJURY ASSOCIATION OF AMERICA

Chairman Harkin and Ranking Member Shelby, thank you for the opportunity to submit this written testimony with regard to the fiscal year 2013 Labor-HHS-Education appropriations bill. This testimony is on behalf of the Brain Injury Association of America (BIAA), our national network of State affiliates, and hundreds of local chapters and support groups from across the country.

In the civilian population alone every year, more than 1.7 million people sustain brain injuries from falls, car crashes, assaults and contact sports. Males are more likely than females to sustain brain injuries. Children, teens and seniors are at greatest risk.

Recently, we are seeing an increasing number of service members returning from the conflicts in Iraq and Afghanistan with TBI, which has been termed one of the signature injuries of the war. Many of these returning service members are undiagnosed or misdiagnosed and subsequently they and their families will look to community and local resources for information to better understand TBI and to obtain vital support services to facilitate successful reintegration into the community.

For the past 13 years the Congress has provided minimal funding through the HRSA Federal TBI Program to assist States in developing services and systems to help individuals with a range of service and family support needs following their loved one's brain injury. Similarly, the grants to State Protection and Advocacy Systems to assist individuals with traumatic brain injuries in accessing services through education, legal and advocacy remedies are woefully underfunded. Rehabilitation, community support and long-term care systems are still developing in many States, while stretched to capacity in others. Additional numbers of individuals with TBI as the result of war-related injuries only adds more stress to these inadequately funded systems.

BIAA respectfully urges you to provide States with the resources they need to address both the civilian and military populations who look to them for much needed support in order to live and work in their communities.

With broader regard to all of the programs authorized through the TBI Act, BIAA specifically requests:

- \$10 million (+\$4 million) for the Centers for Disease Control and Prevention TBI Registries and Surveillance, Brain Injury Acute Care Guidelines, Prevention and National Public Education/Awareness;
- \$8 million (+\$1 million) for the Health Resources and Services Administration (HRSA) Federal TBI State Grant Program; and
- \$4 million (+\$1 million) for the HRSA Federal TBI Protection & Advocacy (P&A) Systems Grant Program.

CDC—National Injury Center.—The Centers for Disease Control and Prevention's National Injury Center is responsible for assessing the incidence and prevalence of TBI in the United States. The CDC estimates that 1.7 million TBIs occur each year and 3.4 million Americans live with a life-long disability as a result of TBI. In addition, the TBI Act as amended in 2008 requires the CDC to coordinate with the Departments of Defense and Veterans Affairs to include the number of TBIs occurring in the military. This coordination will likely increase CDC's estimate of the number of Americans sustaining TBI and living with the consequences.

CDC also funds States for TBI registries, creates and disseminates public and professional educational materials, for families, caregivers and medical personnel, and has recently collaborated with the National Football League and National Hockey League to improve awareness of the incidence of concussion in sports. CDC plays a leading role in helping standardize evidence based guidelines for the management of TBI and \$1 million of this request would go to fund CDC's work in this area.

HRSA TBI State Grant Program.—The TBI Act authorizes the HHS, Health Resources and Service Administration (HRSA) to award grants to (1) States, American Indian Consortia and territories to improve access to service delivery and to (2) State Protection and Advocacy (P&A) Systems to expand advocacy services to include individuals with traumatic brain injury. For the past 13 years the HRSA Federal TBI State Grant Program has supported State efforts to address the needs of persons with brain injury and their families and to expand and improve services to underserved and unserved populations including children and youth; veterans and returning troops; and individuals with co-occurring conditions

In fiscal year 2009, HRSA reduced the number of State grant awards to 15, in order to increase each monetary award from \$118,000 to \$250,000. This means that many States that had participated in the program in past years have now been forced to close down their operations, leaving many unable to access brain injury care.

Increasing the program to \$8 million will provide funding necessary to sustain the grants for the 21 States currently receiving funding along with the 3 additional States added this year and to ensure funding for 4 additional States. Steady increases over 5 years for this program will provide for each State including the District of Columbia and the American Indian Consortium and territories to sustain and expand State service delivery; and to expand the use of the grant funds to pay for such services as Information & Referral (I&R), systems coordination and other necessary services and supports identified by the State.

HRSA TBI P&A Program.—Similarly, the HRSA TBI P&A Program currently provides funding to all State P&A systems for purposes of protecting the legal and human rights of individuals with TBI. State P&As provide a wide range of activities including training in self-advocacy, outreach, information and referral and legal assistance to people residing in nursing homes, to returning military seeking veterans benefits, and students who need educational services.

Effective Protection and Advocacy services for people with traumatic brain injury is needed to help reduce Government expenditures and increase productivity, independence and community integration. However, advocates must possess specialized skills, and their work is often time-intensive. A \$4 million appropriation would ensure that each P&A can move toward providing a significant PATBI program with appropriate staff time and expertise.

NIDRR TBI Model Systems of Care.—Funding for the TBI Model Systems in the Department of Education is urgently needed to ensure that the Nation's valuable TBI research capacity is not diminished, and to maintain and build upon the 16 TBI Model Systems research centers around the country.

The TBI Model Systems of Care program represents an already existing vital national network of expertise and research in the field of TBI, and weakening this program would have resounding effects on both military and civilian populations. The TBI Model Systems are the only source of non-proprietary longitudinal data on what happens to people with brain injury. They are a key source of evidence-based medicine, and serve as a "proving ground" for future researchers.

In order to make this program more comprehensive, the Congress should provide \$11 million (+\$1.5 million) in fiscal year 2012 for NIDRR's TBI Model Systems of Care program, in order to add one new Collaborative Research Project. In addition, given the national importance of this research program, the TBI Model Systems of Care should receive "line-item" status within the broader NIDRR budget.

We ask that you consider favorably these requests for the CDC, the HRSA Federal TBI Program, and the NIDRR TBI Model Systems Program to further data collection, increase public awareness, improve medical care, assist states in coordinating services, protect the rights of persons with TBI, and bolster vital research.

PREPARED STATEMENT OF THE COMMUNITIES ADVOCATING EMERGENCY AIDS RELIEF COALITION

On behalf of the tens of thousands of individuals living with HIV/AIDS to whom members of the Communities Advocating Emergency AIDS Relief (CAEAR) Coalition provide care, I thank Chairman Harkin and Ranking Member Shelby for affording us the opportunity to submit testimony regarding increased funding for the Ryan White HIV/AIDS Program.

The Communities Advocating Emergency AIDS Relief (CAEAR) Coalition is a national membership organization which advocates for sound Federal policy, program regulations, and sufficient appropriations to meet the care, treatment, support service and prevention/wellness needs of people living with HIV/AIDS and the organizations that serve them, focusing on ensuring access to high quality healthcare and the evolving role of the Ryan White Program.

A Wise Investment in a Program That Works

The Ryan White Program works. In its Program Assessment Rating Tool (PART), the White House Office of Management and Budget (OMB) gave the Ryan White Program its highest possible rating of "effective"—a distinction shared by only 18 percent of all programs rated. According to OMB, effective programs "set ambitious goals, achieve results, are well-managed and improve efficiency." Even more impressively, OMB's assessment of the Ryan White Program found it to be in the top 1 percent of all Federal programs in the area of "Program Results and Accountability." Out of the 1,016 Federal programs rated—98 percent of all Federal programs—the Ryan White Program was 1 of 7 that received a score of 100 percent in "Program Results and Accountability."

The Ryan White Program serves as the indispensable safety net for thousands of low-income, uninsured or underinsured people living with HIV/AIDS.

- Part A provides much-needed funding to the 52 major metropolitan areas hardest hit by the HIV/AIDS epidemic with severe needs for additional resources to serve those living with HIV disease in their communities.
- Part B assists States and territories in improving the quality, availability, and organization of healthcare and support services for individuals and families with HIV.
- The AIDS Drug Assistance Program (ADAP) in Part B provides life-saving, urgently needed medications to people living with HIV/AIDS in all 50 States and the territories.
- Part C provides grants to 345 faith- and community-based primary care health clinics and public health providers in 49 States, Puerto Rico and the District of Columbia. These clinics play a central role in the delivery of HIV-related medical services to underserved communities, people of color, and rural areas where Part C funded clinics provide the only HIV specific medical services available in the region.
- Part F AETC supports training for healthcare providers to identify, counsel, diagnose, treat, and manage individuals with HIV infection and to help prevent high-risk behaviors that lead to infection. It has 130 program sites with coverage in all 50 States.

CAEAR Coalition's fiscal year 2013 funding requests for Part A, Part B base and ADAP, and Part C reflect the amounts authorized by the Congress in the most recent authorization of the program.

There continues to be an increasing gap between the number of people living with HIV/AIDS in the United States in need of care and the Federal resources available to serve them. Between 2001 and 2009 the number of people living with AIDS grew 44 percent and yet funding for medical care and support services in communities with the greatest burden of HIV disease grew less than 12 percent between 2001 and 2011. Similarly, funding for Part C—funded, faith and community-based primary care clinics, which provide medical care for people living with HIV/AIDS in remote, rural and geographically isolated, urban communities nationwide, grew by only 11 percent between 2001 and 2012 as the number of people they care for grew by 52 percent. The authorized amounts we request would not fully address these funding deficiencies, but would begin to reduce the still growing gaps in funding.

We thank you in advance for your consideration of our comments and our request for:

- \$789.5 million for Part A to support grants to the cities where most people with HIV/AIDS live and receive their care and treatment.
- \$502.9 million for Part B base to provide additional needed resources to the States to bolster the public health response statewide regardless of location.
- \$1,123.3 million in funding for the ADAP line item in Part B so uninsured and underinsured people with HIV/AIDS can access the anti-HIV and other prescribed medications they need to survive.
- \$285.8 million for Part C to support grants to faith- and community-based organizations, healthcare agencies, and clinics.
- \$42.2 million to fund the 11 regional centers funded under by Part F AETC to offer specialized clinical education and consultation to frontline providers.

Sufficient Funding for Ryan White Programs Saves Money and Saves Lives

Increased funding for Ryan White Programs will reap a significant health return for minimal investment. Data show that Part A and Part C programs have reduced HIV-related hospital admissions by 30 percent nationally and by up to 75 percent in some locations. The programs supported by the Ryan White HIV/AIDS Program also have been critical in reducing AIDS mortality by 70 percent. The Ryan White Program works, resulting in both economic stimulus and social savings by helping keep people, stable, healthy and productive.

Growing Needs as More Tested and Entering Care

The Centers for Disease Control and Prevention (CDC) estimates that as of 2008 there were 1,178,350 persons living with HIV/AIDS in the United States. This represents an increase of approximately 7 percent from the previous estimate in 2006. Among persons initially diagnosed with HIV infection during 2008, one-third (33 percent) received an AIDS diagnosis within 12 months. These late diagnoses represent missed opportunities for treatment and prevention.

The fiscal year 2013 appropriation presents a crucial opportunity to provide the Ryan White Program with the levels of funding needed to address a growing epi-

demic in young men, as the CDC continues to increase efforts to expand HIV testing so people living with HIV know their status, control their health, and protect others.

CAEAR Coalition supports efforts to help individuals infected with HIV learn their status at the earliest possible time. However, CAEAR Coalition is concerned about the unmet demand for services created by insufficient resources at the Federal level. Researchers estimate that CDC's expanded HIV testing guidelines will bring an additional 46,000 people into care over 5 years and significantly reduce the 20 percent of people living with HIV who do not know they are infected and therefore are not in care. Bringing these individuals into care will save large sums of money in the long run, but requires an initial investment now. Research clearly shows that averting a single HIV infection saves \$221,365 in lifetime healthcare costs¹, and getting people on anti-HIV treatment early lowers levels of HIV circulating in the body and reduces potential transmissions²—saving lives and money in the long term—but we must invest now in care and treatment to reap those rewards. Caring for individuals early in their disease will increase the cost of care by \$2.7 billion over 5 years and the majority of those costs will fall to Federal discretionary programs like the Ryan White Program and will not be offset by entitlement programs.³

Community-based providers are stretched to provide high-quality care with the scarce resources available. CAEAR Coalition is concerned that many HIV expert medical staff are scheduled to retire and the persistent financial pressures may accelerate the loss of trained professionals in the field. This additional pressure on an already overburdened system will leave many of the more than 200,000 HIV-infected individuals who do not know their HIV status without access to the care they need.

State budget cuts have created a continuing and growing ADAP funding crisis as a record number of people are in need of ADAP services due to the economic downturn. As of April 2012, there are 3,079 people on ADAP waiting lists in 10 States. Additionally, ADAP waiting lists and other cost-containment measures, including limited formularies, reducing eligibility, or removing already enrolled people from the program, are clear evidence that the need for HIV-related medications continues to outstrip availability. ADAPs are forced to make difficult trade-offs between serving a greater number of people living with HIV/AIDS with fewer services or serving fewer people with more services. Additional resources are needed to reduce and prevent further use of cost-containment measures to limit access to ADAPs and to allow all State ADAPs to provide a full range of HIV antiretrovirals and treatment for opportunistic infections.

The number of clients entering the 349 Part C community health centers and outpatient clinics has consistently increased over the last 5 years. More than 255,000 unduplicated persons living with HIV/AIDS receive medical care in Part C-funded community health centers and clinics each year. These faith- and community-based HIV/AIDS providers are staggering under the burden of treatment and care after years of funding cuts prior to the modest increase in recent years. The success of the CDC's routine HIV testing recommendations has generated new clients for Part C-funded health centers and clinics too, but unfortunately with no increase in funding to provide the high quality healthcare services and treatment access people with HIV/AIDS require.

Ryan White-Funded Programs are Economic Engines in their Communities

Ryan White-funded programs, including many community health centers, are small businesses providing jobs, vendor contracts and other types of economic development to low-income, urban and rural communities, frequently serving as anchors for existing and new businesses and investments. These organizations employ people in their communities, providing critical entry-level jobs, community-based training and career building.

For example, a large, urban community health center brings an estimated economic impact of \$21.6 million, employing 281 people, and a small, rural health center has an estimated economic impact of \$3.9 million, employing 52 people. Invest-

¹Holtgrave DR, Briddell K, Little E, Bendixen AV, Hooper M, Kidder DP, et al. Cost and threshold analysis of housing as an HIV prevention intervention. *AIDS & Behavior*.(2007)11(Suppl 2), S162–S166.

²Montaner J, Lima VD, Barrios R, et al. Association of highly active antiretroviral therapy coverage, population viral load, and yearly new HIV diagnoses in British Columbia, Canada: a population-based study. *The Lancet* (2010) 376(9740): 532–539.

³Martin EG, Paltiel AD, Walensky, RP, Schackman BR, Expanded HIV Screening in the United States: What Will It Cost Government Discretionary and Entitlement Programs? *A Budget Impact Analysis. Value in Health* (2010) 13: 893–902.

ing in AIDS care and treatment is an investment in jobs and community development in communities that need it most.

Ryan White Program Key to Meeting the Goals of the National HIV/AIDS Strategy

CAEAR Coalition is eager to work with the Congress to meet the challenges posed by the HIV/AIDS epidemic. In 2013, we have the collective chance to implement the community-embraced healthcare goals and policies in the National HIV/AIDS Strategy (NHAS). The National Strategy is an opportunity to reinvigorate the Nation's response to the HIV/AIDS epidemic and stop its relentless movement into our communities. The Ryan White HIV/AIDS Program is key to reaching the NHAS goals of reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV/AIDS, and reducing HIV-related health disparities. Ryan White provides HIV/AIDS care and treatment services to a significantly higher proportion of racial/ethnic minorities and women than their representation among reported AIDS cases—suggesting the programs and resources are targeted to underserved and marginalized populations. Early care and treatment are more critical than ever because we can help those infected learn their status and get into care and treatment in order to improve their own health and the health of their communities.

The Ryan White Program's history of accomplishments for public health and people living with HIV/AIDS is a wonderful legacy for the U.S. Congress. There continues to be a vast need for additional resources to address the healthcare and treatment needs of people living with HIV across the country. In recognition of its high level of effectiveness and validation over time from credible Federal Government institutions, CAEAR urges the committee to provide the Ryan White HIV/AIDS Program with the funding levels authorized by the Congress for fiscal year 2013.

PREPARED STATEMENT OF THE COUNCIL OF ACADEMIC FAMILY MEDICINE

FISCAL YEAR 2013 FUNDING REQUESTS

Concerning.—Health Resources and Services Administration (HRSA), Title VII Primary Care Training and Enhancement (Section 747 of Public Health Service Act (PHS)), Title VII, Sections 749A and B, the Teaching Health Center Development Grants and the Rural Physician Training Grants, the Agency for Healthcare Research and Quality (AHRQ) and its Primary Care Extension Program, and the National Health Workforce Commission.

The member organizations of the Council of Academic Family Medicine (CAFM) are pleased to submit testimony on behalf of programs under the jurisdiction of the Health Resources and Services Administration (HRSA) and the Agency for Healthcare Research and Quality (AHRQ). The programs we support in our testimony are ones that deliver an investment in our Nation's workforce and health infrastructure. They are a down payment on a U.S. healthcare system with a foundation of primary care that will produce better health outcomes and reduce the ever rising costs of healthcare. We understand that hard decisions must be made in these difficult fiscal times, but even in this climate we hope the Committee will recognize that the production of a robust primary care workforce for the future is a necessary investment that cannot wait.

Members of both parties agree there is much that must be done to support primary care provider production and to nourish the development of a high quality, highly effective primary care workforce to serve as a foundation for our healthcare system. Providing strong funding for these programs is essential to the development of a robust workforce needed to provide this foundation.

We urge the Committee to appropriate at least \$71 million for the health professions program, Primary Care Training and Enhancement, authorized under Title VII, Section 747 of the Public Health Service Act in order to allow for a new competitive cycle for physician primary care training grants.

Primary Care Training and Enhancement

The Primary Care Training and Enhancement Program (Title VII, Section 747 of the Public Health Service Act) has a long history of providing indispensable funding for the training of primary care physicians. With each successive reauthorization, the Congress has modified the Title VII health professions programs to address relevant workforce needs. The most recent authorization directs the Health Resources and Services Administration (HRSA) to prioritize training in the new competencies relevant to providing care in the patient-centered medical home model. It also calls for the development of infrastructure within primary care departments for the improvement of clinical care and research critical to primary care delivery, as well as

innovations in team management of chronic disease, integrated models of care, and transitioning between healthcare settings.

We urge you to support at least a \$71 million appropriation for the Primary Care Training and Enhancement program funded through the Labor-HHS-Education appropriations bill. This funding level is necessary to permit a competitive grant cycle for physician primary care training grants. Without additional funding, this will be the second year in a row there are insufficient funds to conduct a grant cycle. In a time of increasing primary care need, we urge you to recognize the importance of maintaining and expanding the pipeline of primary care production and training. Funding for primary care training is an investment in the future restraint of healthcare spending, as well as in improved health outcomes.

Level funding for primary care training is not enough. With the allocation of 15 percent of the appropriations of the Primary Care Training and Enhancement program line for physician assistant training, the Congress has taken steps to alleviate the shortfall in physician assistant training. However, not funding a competitive cycle for physicians stifles opportunities for inter-professional, team-based training. The Nation needs new initiatives relating to increased training in inter-professional care, the patient-centered medical home, and other new competencies required in our developing health system. Such initiatives will be impossible to implement without a competitive grant cycle. Now is the time to ensure that critical funding for the Primary Care Training and Enhancement program takes place. We cannot allow the primary care pipeline to dry up.

Key advisory bodies such as the Institute of Medicine (IOM) and the Congressional Research Service (CRS) have also called for increased funding. The IOM (December 2008) pointed to the drastic decline in Title VII funding and described these health professions workforce training programs as “an undervalued asset.” The CRS found that reduced funding to the primary care cluster has negatively affected the programs during a time when more primary care is needed (February 2008).

According to the Robert Graham Center, (Title VII’s decline: Shrinking investment in the primary care training pipeline, Oct. 2009), “the number of graduating U.S. allopathic medical students choosing primary care declined steadily over the past decade, and the proportion of minorities within this workforce remains low.” Unfortunately, this decline coincides with a decline in primary care training funding—funding that we know is associated with increased primary care physician production and practice in underserved areas. The report goes on to say that “the Nation needs renewed or enhanced investment in programs like Title VII that support the production of primary care physicians and their placement in underserved areas.”

A recent study in the *Annals of Family Medicine* (Phillips and Turner, March/April 2012) stated that “Meeting this increased demand [for primary care physician production] requires a major investment in primary care training.” The study continues, “Expansion of Title VII, Section 747 with the goal of improving access to primary care would be an important part of a needed, broader effort to counter the decline of primary care. Failure to launch such a national primary care workforce revitalization program will put the health and economic viability of our Nation at risk.”

Title VII has a profound impact on States across the country and is vital to the continued development of a workforce designed to care for the most vulnerable populations and meet the needs of the 21st century.

The evidence is clear:

- Demonstration projects and international experiences that preferentially invest in primary care can reduce spending, particularly for inpatient and emergency department care (Health Affairs, March-April 2009).
- “There is compelling evidence that healthcare outcomes and costs in the United States are strongly linked to the availability of primary care physicians. For each incremental primary care physician (PCP), there is 1.44 fewer deaths per 10,000 persons. Patients with a regular primary care physician have lower overall healthcare costs than those without one.” (Council on Graduate Medical Education (COGME) December, 2010)
- Hospital readmission after discharge is often a costly failing of the U.S. healthcare system to adequately manage patients who are ill. Increasing the number of family physicians (FPs) is associated with significant reductions in hospital readmissions and substantial cost savings. (Robert Graham Center, 2011)

Agency for Health Care Research and Quality

As mentioned above, the overall health of a population is directly linked to the strength of its primary healthcare system. Primary care research includes: trans-

lating science into the practice of medicine and caring for patients, understanding how to better organize healthcare to meet patient and population needs, evaluating innovations to provide the best healthcare to patients, and engaging patients, communities, and practices to improve health.

Research related to the most common acute, chronic, and comorbid conditions that primary care clinicians care for on a daily basis is lacking. AHRQ supports research to improve healthcare quality, reduce costs, advance patient safety, decrease medical errors, and broaden access to essential services. This research is key to helping create a robust primary care system for our Nation—one that delivers higher quality of care and better health while reducing the rising cost of care. Despite this need, little is known about how patients can best decide how and when to seek care, introduce and disseminate new discoveries into real life practice, and how to maximize appropriate care. And yet, the majority of research funding supports research of one specific disease, organ system, cellular, or chemical process—not for primary care.

One cogent example of how AHRQ funded research is making a difference in primary care practices is a study on “Care Coordination Accountability Measures for Primary Care Practice,” published in January, 2012. This report builds on earlier work and presents measures “that are well suited for use by health plans and insurers to assess the quality of coordination in primary care practices and by primary care practices themselves to assess their own performance.” This type of research requires sufficient funding for AHRQ so it can help researchers address the problems confronting our health system today.

We recommend the Committee fund AHRQ at a base, discretionary level of at least \$400 million for fiscal year 2013.

Primary Care Extension Program

The Primary Care Extension Program was modeled after the successful United States Agriculture Extension Service. This program, under Title III of the Public Health Service Act, is designed to support and assist primary care providers with the adoption and incorporation of techniques to improve community health. As the authors of an article describing this concept (JAMA, June 24, 2009) have stated, “To successfully redesign practices requires knowledge transfer, performance feedback, facilitation, and HIT support provided by individuals with whom practices have established relationships over time. The farming community learned these principles a century ago. Primary care practices are like small farms of that era, which were geographically dispersed, poorly resourced for change, and inefficient in adopting new techniques or technology, but vital to the Nation’s well-being.”

Congress agreed with the authors that “practicing physicians need something similar to the agricultural extension agent who was so transformative for farming,” and authorized this program at \$120 million for fiscal year 2011 and 2012.

We recommend the Committee fund the Primary Care Extension program at the authorized level of \$120 million for fiscal year 2013.

Rural Physician Training Grants

“Rural Physician Training Grants,” Title VII Section 749B of the Public Health Service Act, were developed to increase the supply of rural physicians by authorizing grants to medical schools which establish or expand rural training. The program would provide grants to produce rural physicians of all specialties. It would help medical schools recruit students most likely to practice medicine in underserved rural communities, provide rural-focused training and experience, and increase the number of medical graduates who practice in underserved rural communities.

According to a July 2007 report of the Robert Graham Center (Medical school expansion: An immediate opportunity to meet rural healthcare needs), data show that although 21 percent of the U.S. population lives in rural areas, only 10 percent of physicians practice there. The Graham Center study describes the educational pipeline to rural medical practice as “long and complex.” There are multiple tactics needed to reverse this situation, and this grant program includes several of them. Strategies to increase the number of physicians practicing in rural areas include “increasing the number of rural-background students in medical school, selecting the “right” students and giving them the “right” content and experiences to train them for rural practice.” This is exactly what this grant program is designed to do.

We request the Committee provide the fully authorized amount of \$4 million in fiscal year 2013 for Title VII Section 749B Rural Physician Training Grants.

Teaching Health Centers

Teaching Health Centers (THC) are community health centers or other similar venues that sponsor residency programs and provide residents with their ambula-

tory training experiences in the health center. This training in the community, rather than solely at the hospital bedside is one of the hallmarks of family medicine training. However, payment issues have always caused a tension and struggle between the hospital, which currently receives reimbursement for residents it sponsors when they train in the hospital, and programs that require training in non-hospital settings.

We are pleased that THC's operations are currently funded through a mandatory appropriations trust fund of \$230 million over 5 years, and it is essential that these important centers continue to be funded through this mandatory appropriation.

Teaching Health Center Development Grants

This program is designed to provide residency programs and community health centers grant funding to plan for a transition in sponsorship, or the establishment of new programs. In the first year of the program there were already 11 community-based entities from States across the country that committed to train 44 additional primary care residents: the second year of the program brought 11 additional grantees into the program, expanding both the scope of specialties trained and increasing the number of full-time equivalent residents trained to 143. This demonstration of early success of the program should not go unnoticed or unsupported. The limiting factor to the program is not the operating funds, but the ability of residencies to plan for the change in their sponsorship. Funding Teaching Health Center Development Grants will help fulfill the promise of these innovative programs.

We recommend the Committee appropriate the full authorized amount for the Title VII Teaching Health Centers development grants of at least \$10 million for fiscal year 2013.

Workforce Commission

We have recognized the need, and called for a national commission on health workforce issues for many years. We appreciate the work of this Committee in funding the National Workforce Commission at \$3 million for fiscal year 2012 and were disappointed the final bill didn't contain funding for the Commission.

We ask the Committee to continue to recommend \$3 million for the National Workforce Commission at \$3 million for fiscal year 2013.

PREPARED STATEMENT OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION
COALITION

The CDC Coalition (c/o American Public Health Association) is a nonpartisan coalition of more than 140 organizations committed to strengthening our Nation's prevention programs. Our mission is to ensure that health promotion and disease prevention are given top priority in Federal funding, to support a funding level for the Centers for Disease Control and Prevention (CDC) that enables it to carry out its critical mission, and to assure an adequate translation of new research into effective State and local programs. Coalition member groups represent millions of public health workers, clinicians, researchers, educators, and citizens served by CDC programs.

The CDC Coalition believes that the Congress should support CDC as an agency—not just the individual programs that it funds. In the best judgment of the CDC Coalition—given the challenges and burdens of chronic disease, a potential influenza pandemic, terrorism, disaster preparedness, new and reemerging infectious diseases and our many unmet public health needs and missed prevention opportunities—we believe the agency will require funding of at least \$7.8 billion for CDC's programs in fiscal year 2013. We are deeply disappointed with the proposed \$664 million cut to CDC's budget authority contained in the President's fiscal year 2013 budget proposal. In fact, when including the President's fiscal year 2013 request, CDC's budget authority would have been decreased by a staggering \$1.4 billion since fiscal year 2010. While CDC has received and the President's fiscal year 2013 budget proposal directs significant funding from the Prevention and Public Health Fund to CDC, we believe this funding is essentially supplanting cuts made to CDC's budget authority. As you know, the Prevention and Public Health Fund was intended to supplement and not supplant the base funding of our public health agencies and programs. We urge you to restore this cut to CDC's budget authority and to support the \$1 billion available through Prevention and Public Health Fund in fiscal year 2013.

By translating research findings into effective intervention efforts, CDC has been a key source of funding for many of our State and local programs that aim to improve the health of communities. Perhaps more importantly, Federal funding through CDC provides the foundation for our State and local public health depart-

ments, supporting a trained workforce, laboratory capacity and public health education communications systems.

CDC serves as the command center for our Nation's public health defense system, conducting surveillance and detection of emerging and reemerging infectious diseases. With the potential onset of a worldwide influenza pandemic, in addition to the many other natural and man-made threats that exist in the modern world, the CDC has become the Nation's—and the world's—expert resource and response center, coordinating communications and action and serving as the laboratory reference center.

CDC serves as the lead agency for bioterrorism and other public health emergency preparedness and must receive sustained support for its preparedness programs in order for our Nation to meet future challenges. Given the challenges of terrorism and disaster preparedness, and our many unmet public health needs and missed prevention opportunities we urge you to provide adequate funding for State and local capacity grants.

Heart disease remains the Nation's No. 1 killer. In 2009, more than 599,000 people in the United States died from heart disease, accounting for nearly 25 percent of all U.S. deaths. More women than men die of heart disease and stroke each year, and in 2009, females had higher rates of stroke mortality than males. Stroke is the fourth leading cause of death and is a leading cause of disability. In 2009, stroke killed almost 129,000 people (60 percent of them women), accounting for about 1 of every 19 deaths.

Cancer is the second most common cause of death in the United States. There are 1,638,910 new cancer cases and 577,190 deaths from cancer expected in 2012. The financial cost of cancer is also significant. According to the National Institutes of Health, in 2007 the overall cost for cancer in the United States was more than \$226.8 billion: \$103.8 billion for direct medical costs, \$123 billion for indirect mortality costs (cost of lost productivity due to premature death). Among the ways CDC is fighting cancer, is through funding the National Breast and Cervical Cancer Early Detection Program that helps low-income, uninsured and medically underserved women gain access to lifesaving breast and cervical cancer screenings and provides a gateway to treatment upon diagnosis. CDC also funds grants to all 50 States to develop Comprehensive Cancer Control plans, bringing together a broad partnership of public and private stakeholders to set joint priorities and implement specific cancer prevention and control activities customized to address each State's particular needs.

Although more than 25.8 million Americans have diabetes, nearly 7 million cases are undiagnosed. In 2010, about 1.9 million people aged 20 years or older were newly diagnosed with diabetes. Diabetes is the leading cause of kidney failure, non-traumatic lower-limb amputations, and new cases of blindness among adults in the United States. The total direct and indirect costs associated with diabetes were \$178 billion in 2007. Preventive care such as routine eye and foot examinations, self-monitoring of blood glucose, and glycemic control could reduce these numbers.

Arthritis is the most common cause of disability in the United States, striking 50 million Americans of all ages, races and ethnicities. CDC's Arthritis Program plays a critical role in addressing this growing public health crisis.

Over the last 25 years, obesity rates have doubled among adults and children, and tripled in teens. Obesity, diet and inactivity are cross-cutting risk factors that contribute significantly to heart disease, cancer, stroke and diabetes. CDC funds programs to encourage the consumption of fruits and vegetables, encourage sufficient exercise, and to develop other habits of healthy nutrition and activity. An estimated 443,000 people die prematurely every year due to tobacco use. CDC's tobacco control efforts seek to prevent tobacco addiction in the first place, as well as help those who want to quit. We must continue to support these vital programs and reduce tobacco use in the United States.

Each day more than 3,800 young people initiate cigarette smoking. At the same time, according to CDC, only 1 out of 3 high school students participate in daily physical education classes. Seventy-eight percent of high school students do not eat the recommended number of servings of fruits and vegetables, while 1 in 3 children and adolescents are overweight or obese. And every year, more than 400,000 teen girls give birth and nearly half of all sexually transmitted diseases occur in young people between the ages of 15 and 24. CDC plays a critical role in ensuring good public health and health promotion in our schools.

CDC provides national leadership in helping control the HIV epidemic by working with community, State, national, and international partners in surveillance, research, prevention and evaluation activities. CDC estimates that about 1.1 million Americans are living with HIV, 21 percent of who are undiagnosed. Also, the number of people living with HIV is increasing, as new drug therapies are keeping HIV-

infected persons healthy longer and dramatically reducing the death rate. Prevention of HIV transmission is the best defense against the AIDS epidemic that has already killed more than 619,400 in the United States and is devastating populations around the globe.

The United States has the highest rates of sexually transmitted diseases (STDs) in the industrialized world. More than 19 million new infections occur each year, almost half of them among young people. CDC estimates that STDs, including HIV, cost the U.S. healthcare system as much as \$17 billion annually. An adequate investment in STD prevention could save millions in annual healthcare costs in the future.

CDC and its National Center for Health Statistics collect data on chronic disease prevalence, health disparities, emergency room use, teen pregnancy, infant mortality and causes of death. The health data collected through the Behavioral Risk Factor Surveillance System, Youth Risk Behavior Survey, Youth Tobacco Survey, National Vital Statistics System, and National Health and Nutrition Examination Survey are an essential part of the Nation's statistical and public health infrastructure.

We must address the growing disparity in the health of racial and ethnic minorities. CDC is helping States address serious disparities in infant mortality, breast and cervical cancer, cardiovascular disease, diabetes, HIV/AIDS and immunizations. Our members are committed to ending the disparities and we encourage the Subcommittee to provide adequate funds for these efforts.

CDC oversees immunization programs for children, adolescents and adults, and is a global partner in the ongoing effort to eradicate polio worldwide. The value of adult immunization programs to improve length and quality of life, and to save healthcare costs, is realized through a number of CDC programs, but there is much work to be done and a need for sound funding to achieve our goals. Influenza vaccination levels remain low for adults. Levels are substantially lower for pneumococcal vaccination and significant racial and ethnic disparities in vaccination levels persist among the elderly. In addition, developing functional immunization registries in all States will be less costly in the long run than maintaining the incomplete systems currently in place. Childhood immunizations provide one of the best returns on investment of any public health program. For every dollar spent on seven vaccines recommended in the childhood series, \$16.50 is saved in direct and indirect costs. An estimated 14 million cases of childhood disease and 33,000 deaths are prevented each year through timely immunization. Despite the incredible success of the program, it faces serious financial challenges.

Injuries are the leading causes of death for persons aged 1–44 years. Unintentional injuries and violence such as older adult falls, unintentional drug poisonings, child maltreatment and sexual violence accounts for more than 35 percent of emergency department visits annually. Annually, injury and violence cost the United States approximately \$406 billion in direct and indirect medical costs including lost productivity. Unintentional injury consistently remains the leading cause of death among young Americans ages 1–34 with the majority of unintentional fatal injuries caused by motor vehicle traffic fatalities. CDC's Injury Center works to prevent unintentional and violence-related injuries to minimize the consequences of injuries when they occur by researching the problem; identifying the risk and protective factors; developing and testing interventions and ensuring widespread adoption of proven strategies.

One in every 33 babies born each year in the United States is born with one or more birth defects. Birth defects are the leading cause of infant mortality. Children with birth defects who survive often experience lifelong physical and mental disabilities. More than 50 million people in the United States currently live with a disability, and 17 percent of children under the age of 18 have a developmental disability. The National Center on Birth Defects and Developmental Disabilities at CDC conducts programs to protect and improve the health of children and adults by preventing birth defects and developmental disabilities; promoting optimal child development and health and wellness among children and adults with disabilities.

CDC's National Center for Environmental Health is essential to protecting the health and well-being of the American public from threats associated with West Nile virus, climate change, terrorism, E. coli, lead-based paint and other hazards. NCEH funds programs to reduce the burden of asthma in our States and communities and to track the impact of environmental exposures on our health. We ask you to support adequate funding for these vital programs which has been significantly reduced over the past several years.

We thank you for your past support and urge you to adopt our fiscal year 2013 request of \$7.8 billion for CDC's programs.

PREPARED STATEMENT OF THE CHRISTOPHER & DANA REEVE FOUNDATION

Senator Harkin, Ranking Member Shelby and Members of the Subcommittee, thank you for the opportunity to submit testimony in support of funding for the National Center on Birth Defects and Developmental Disabilities (NCBDDD) within the Centers for Disease Control and Prevention, as well as on the importance of a strong Federal investment in medical research at the National Institutes of Health (NIH).

I am Matthew Reeve, the eldest son of Christopher Reeve, and I have served on the Board of the Christopher & Dana Reeve Foundation since 2006. I also serve on the Foundation's Quality of Life Committee, which funds programs across all 50 States and around the globe to help people living with paralysis become more fully integrated members of society.

The Foundation is dedicated to both curing spinal cord injury by funding innovative research and to improving the quality of life for nearly 6 million people currently living with paralysis and those that care for them. Since its inception, the Foundation has provided \$100 million in research grants to more than 750 researchers, and has provided more than \$15 million to almost 2,000 organizations across the country through our Quality of Life grants program.

It is a priority of the Reeve Foundation to ensure that individuals living with spinal cord injury and paralysis have access to the resources and tools necessary to live life to their fullest abilities. When my father suffered his injury in 1995, the world was a different place for those living with a spinal cord injury. I was 15 years old at the time of his accident, and I remember those first few weeks after his injury very clearly. I will never forget the sense of helplessness that we all felt, coupled with the knowledge that in an instant my father's life, as well as that of our entire family, had changed forever. Being active one day, and immobile the next, thrusts you and your family into an entirely new existence. Every day we found that there were more questions to be answered yet information and services were limited and difficult to locate. The unanswered issues we faced were outside the expertise of the doctors, nurses and staff at the Intensive Care Unit. We felt that we had nowhere to turn. Following our family's experience, my stepmother Dana was determined to do whatever she could to ensure that other families did not encounter the same problem.

Led by her charge, over the past 10 years the Reeve Foundation has created a national resource center to help individuals and their families navigate a complicated healthcare system and to provide them with the tools and information they need to lead a productive and fulfilling life. The Paralysis Resource Center (PRC) funded through the NCBDDD, partners with organizations across the country to offer programs that promote independent and healthy living for all individuals living with paralysis. Currently, the PRC provides services to more than 500,000 individuals annually, and is indispensable in providing vital information and services that the paralysis community depends upon each day. The PRC provides patients with access to state-of-the-art therapies focused on improving health and mobility; guidance for evaluating rehab facilities and redesigning a home to make it wheelchair accessible; referrals to community support programs; and information and resources on a full range of topics related to paralysis and issues that arise from secondary complications.

The Foundation is extremely proud of the infrastructure that has been built through support from NCBDDD, as well as the programs that serve the disability community beyond spinal cord injury and paralysis. NCBDDD was established by the Congress in 2000, and is the only entity within the Federal Government that focuses on the specific needs of many of our Nation's most fragile populations. The Foundation is very concerned about both the funding and structure of the Center in the President's budget. The President's fiscal year 2013 budget recommends a funding level of \$126 million, a decrease of \$11 million, for NCBDDD. To achieve these reductions, CDC has indicated that they plan to focus on cutting research, resource, surveillance programs, and information centers. These programs are a critical component of our Nation's public health infrastructure, and cutting them puts the infrastructure we have worked so hard to create at great risk. Second, in an effort to create efficiencies and cost savings, the President's budget proposes consolidation of funding for Federal agencies, including the CDC. Within the CDC is a proposal to consolidate the ten disability programs' funding lines that fall under the NCBDDD Division of Human Development and Disability into one.

Last year, a similar consolidation of NCBDDD was proposed in the President's budget. In response, and under your leadership Chairman Harkin, the Congress included report language in the fiscal year 2012 LHHS Appropriations Subcommittee conference report rejecting the proposed consolidation and directing the CDC to con-

duct a needs assessment before moving forward with future consolidation proposals. Members of the disability community came together to work with the Congress to stop consolidation from moving forward because we knew that consolidation of disability programs funded through NCBDDD would be devastating not only for the spinal cord injury and paralysis population, but for the entire disabled community. We are grateful for the support shown by you, Chairman Harkin, and your Subcommittee. However, despite the congressional direction, consolidation is back in this year's budget and is not accompanied by the conference committee's requests.

On behalf of the Christopher & Dana Reeve Foundation, and the nearly 6 million individuals affected by spinal cord injury and paralysis, I ask that this Subcommittee once again reject the proposed NCBDDD consolidation included in the President's budget and direct CDC to conduct a needs assessment which reflects the impact of consolidation on the disability groups represented by NCBDDD.

Programs funded through the NCBDDD are making an active difference in the lives of millions of individuals living with a disability. For the paralysis community, funding for the PRC is essential in the day-to-day lives of thousands of individuals living with paralysis. I am incredibly grateful for the ongoing support this committee has shown the disability community and for the relationships we have built on behalf of the Foundation.

A core mission of the Reeve Foundation is to invest in research to develop effective treatments for acute and chronic spinal cord injury. But we cannot do it alone. A strong Federal investment in medical research at the NIH is critical in the quest for better cures and treatments for the paralysis community. The Foundation supports an appropriation of \$32 billion for NIH in fiscal year 2013. The NIH funds some of the most groundbreaking research in the areas of spinal cord injury and paralysis and a strong Federal investment is critical so we can achieve our shared goal.

NIH grants have supported the basic science of locomotor training and advanced the current research being conducted in epidural stimulation. NIH has also funded the Tongue Drive System, which is a wireless device that enables people with high-level spinal cord injuries to operate a computer and maneuver an electrically powered wheelchair simply by moving their tongues. These are examples of how NIH is turning research into reality and changing the lives of those living with paralysis. We need the support of this Subcommittee to ensure that NIH receives the necessary funding to continue to advance this critical research.

As you move forward with the budget process we look forward to working with this Subcommittee to stop consolidation of the NCBDDD until the impact of the consolidation on the communities served by NCBDDD is addressed, as well as ensuring a strong Federal investment in medical research at the NIH.

Thank you again, Mr. Chairman, for the opportunity to submit my testimony on behalf of the Foundation.

PREPARED STATEMENT OF THE CHILDREN'S ENVIRONMENTAL HEALTH NETWORK

The Children's Environmental Health Network (CEHN or the Network) providing testimony on fiscal year 2013 appropriations, especially appropriations for the Centers for Disease Control and Prevention (CDC) and the National Institute of Environmental Health Sciences (NIEHS), an institute within the National Institutes of Health (NIH).

This year, the Children's Environmental Health Network is celebrating its 20th anniversary as a national nonprofit organization whose mission is to protect the developing child from environmental hazards and promote a healthier environment. The Network's Board and committee members include internationally recognized experts in children's environmental health science and policy who serve on key Federal advisory panels and scientific boards. We recognize that children, in our society, have unique moral standing.

The Network is deeply concerned about the health of the Nation's children and urges the Subcommittee to help all children grow up in healthy environments by embracing its role in protecting our environment and our health.

American competitiveness depends on having healthy educated children who grow up to be healthy productive adults. Yet, growing numbers of our children are diagnosed with chronic and developmental illnesses and disabilities. The National Academy of Sciences estimates that toxic environmental exposures play a role in 28 percent of neurobehavioral disorders in children and this does not include other conditions such as asthma or cancers. Thus, it is vital that the Federal programs and activities that protect children from environmental hazards receive adequate resources.

CEHN urges the Subcommittee to provide funding at or above the requested levels for the following CDC and NIEHS activities: National Center for Environmental Health; National Asthma Control Program and the Healthy Homes/Lead Poisoning Prevention Program; National Environmental Public Health Tracking Program; National Institute of Environmental Health Sciences; Children's Environmental Health Research Centers of Excellence; and National Children's Study.

Centers for Disease Control and Prevention

The CDC is the Nation's leader in public health promotion and disease prevention, and should receive top priority in Federal funding. CDC continues to be faced with unprecedented challenges and responsibilities. CEHN urges you to support a funding level of \$7.8 billion for CDC's core programs in fiscal year 2013.

Within CDC, the National Center for Environmental Health (NCEH) is particularly important to protect the environmental health of young children. NCEH programs, such as its efforts to continue and expand biomonitoring and its national report card on exposure information, are key national assets. CEHN is thus deeply concerned about the proposed severe cuts to CDC's environmental public health programs in the President's fiscal year 2013 budget. NCEH has absorbed a disproportionately large share of the imposed cuts. Since fiscal year 2009, NCEH funding has been cut approximately 25 percent.

We strongly recommend that the National Asthma Control Program and the Healthy Homes/Lead Poisoning Prevention Program remain separate and distinct programs. The National Asthma Control Program works to reduce the burden of asthma, which affects 25 million Americans including 7 million children. The 36 State and territorial programs funded by the National Asthma Control Program include surveillance, environmental measures to reduce exposure to indoor and outdoor air pollutants, awareness and self-management education, and appropriate healthcare services.

The Healthy Homes and Lead Poisoning Prevention Program, serves the 12.3 million children with harmful lead levels. The 35 State programs funded by the program screen children for lead poisoning, track the incidence of the disease, inspect homes for environmental hazards, and conduct community lead poisoning prevention initiatives.

The goals of the two programs as well as their target patient groups and methods of delivering services are markedly different. We strongly support maintaining the separation of these two programs to enable them to continue to fulfill their distinct missions.

We support reinstatement of CDC's Healthy Homes and Lead Poisoning Prevention Program at \$29 million (the same as fiscal year 2011 and support an additional valuable targeted increase (8.6 percent) to certain NCEH programs.

CDC's National Environmental Public Health Tracking Program tracks environmental hazards and the diseases they may cause and coordinates and integrates local, State and Federal health agencies' collection of critical health and environmental data. Public health officials need integrated health and environmental data so that they can protect the public's health. We urge you to reverse the CDC operating plan for fiscal year 2011 and 2012, which eliminated all budget authority for this vital program. We urge you to support additional funding for the program in fiscal year 2013. Its biomonitoring activities allow the measurement of the actual levels of more than 450 chemicals and nutritional indicators in people's bodies. This information helps public health officials to determine which population groups are at high risk for exposure and adverse health effects, assess public health interventions, and monitor exposure trends over time.

National Institutes of Health

The National Institute of Environmental Health Sciences (NIEHS) is the leading institute conducting research to understand how the environment influences the development and progression of human disease. Children are uniquely vulnerable to harmful substances in their environment, and the NIEHS plays a critical role in uncovering the connections between environmental exposures and children's health. Thus, it plays a vital role in our efforts to understand how to protect children, whether it is identifying and understanding the impact of substances that are endocrine disruptors or understanding childhood exposures that may not affect health until decades later.

NIEHS' fiscal year 2013 President's budget is at \$684 million (exclusive of Superfund amounts under Subcommittee on the Interior, Environment, and Related Agencies appropriations). This represents a reduction of \$725,000 from NIEHS' fiscal year 2012 budget, which will have an impact on their program and research on chil-

children's environmental health. CEHN, therefore, urges you to set NIEHS' fiscal year 2013 budget at least to its fiscal year 2012 level.

Children's Environmental Health Research Centers of Excellence

The Children's Environmental Health Research Centers, jointly funded by the NIEHS and the U.S. Environmental Protection Agency (EPA), play a key role in providing the scientific basis for protecting children from environmental hazards. With their modest budgets, which have been unchanged for more than 10 years, these Centers generate valuable research. A unique aspect of these Centers is the requirement that each Center actively involves its local community in a collaborative partnership, leading both to community-based participatory research projects and to the translation of research findings into child-protective programs and policies. The scientific output of these centers has been outstanding. For example, findings from four Centers clearly showed that prenatal exposure to a widely used pesticide affected developmental outcomes at birth and early childhood. This was important information to EPA's decisionmakers in their regulation of this pesticide.

Several Centers have established longitudinal cohorts, which have resulted in valuable research results. The Network is concerned that as a Center's multi-year grant ends and the Center is shuttered, these cohorts and the invaluable information they can provide are being lost. The Network urges the Subcommittee to assure that NIEHS has the funding and the direction to support Centers in continuing these cohorts.

The work of these Centers has also shown us that, in addition to research regarding a specific pollutant or health outcome, research is desperately needed in understanding the totality of the child's environment—for example, all of the exposures the child experiences in the home, school, and child care environment—and how to evaluate those multiple factors. CEHN urges you to support these Centers, to assure they receive full funding and are extended and expanded as described above.

National Children's Study

The National Children's Study (NCS) is examining the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. This landmark longitudinal cohort study—involving a consortium of agencies including NIEHS and CDC—will be one of the richest research efforts ever geared toward studying children's health and development and will form the basis of child health guidance, interventions, and policy for generations to come. We urge the Subcommittee to assure that the NCS retains on its original focus on environmental chemicals and assure that the communities most at risk are well represented in the cohort. While the NCS is housed at NICHD, it must be a multi-agency study and it must be responsive to its mission and to its partner agencies.

Investments in programs that protect and promote children's health will be repaid by healthier children with brighter futures. Protecting our children—those born as well as those yet to be born—from environmental hazards is truly a national security issue. Cutting or weakening programs that protect children from harmful chemicals in their environment is not only very costly to our Nation (for example, the Clean Air Act Amendments of 1990 have saved \$1 trillion in healthcare costs). Such cuts will reduce the number of exceptionally bright children.

We understand that our Federal budget faces many long-term challenges, but we also believe strongly that a commitment to and strong investment in environmental public health activities will be critical to our Nation's long-term fiscal and physical health. We thank you for considering these recommendations.

In conclusion, investments in programs that protect and promote children's health will be repaid by healthier children with brighter futures, an outcome we can all support. That is why CEHN asks you to give priority to these programs. Thank you for the opportunity to comment.

PREPARED STATEMENT OF THE COALITION OF EPSCoR/IDEA STATES AND THE MISSISSIPPI RESEARCH CONSORTIUM

Mr. Chairman and Members of the Subcommittee; thank you for the opportunity to submit this statement regarding fiscal year 2013 funding for the National Institutes of Health's Institutional Development Award or "IDeA" Program. My name is Dr. David Shaw and I am the Vice President for Research and Economic Development at Mississippi State University. I submit this testimony on behalf of the Coalition of EPSCoR/IDEA States and the Mississippi Research Consortium (MRC) to include the following research institutions in our State: University of Southern Mississippi (USM), University of Mississippi (UM)/University of Mississippi Medical

Center (UMMC), Mississippi State University (MSU), and Jackson State University (JSU).

Impact of the IDeA Program on Mississippi

Please allow me to describe how the INBRE and COBRE programs have dramatically impacted the biomedical landscape across the State of Mississippi.

INBRE

Mississippi's INBRE is located on the campus of the USM in Hattiesburg, Mississippi. A statewide network, the INBRE includes all five research-intensive institutions, six Partner Undergraduate Institutions (PUIs) and eight Outreach Institutions. The MS-INBRE represents the largest network of institutions in Mississippi with the mission to promote biomedical research and training in the State. The instrumentation core of the project includes the Genomics Facility located at the UMMC, the Imaging Facility located at the USM, and the Proteomics Core located at MSU. These facilities are available to all Mississippi scientists and students at no cost thus providing access to high cost equipment that promotes biomedical research in the State. The Bioinformatics Core is a new initiative through the INBRE that has brought together bioinformatics faculty from across Mississippi who serves as the backbone providing support and resources in research, training and education, and infrastructure.

MS-INBRE continues to build on existing interdisciplinary collaborations, create new collaborative efforts, address the serious cyberinfrastructure needs in Mississippi, and train students in bioinformatics at the Partner Undergraduate Institutions. Particularly, many students would not have the opportunity to participate in biomedical research training without this funding which in turn means that we lose a lot of brain power and disenfranchise a lot of bright students in Mississippi.

The established research labs at PUIs have made a great impact on the number of undergraduate students trained in biomedical research. The "success rate" is defined as the percentage successfully pursuing biomedical career via graduate school, professional school, teaching or working in research.

—Undergraduates trained via 12-week intensive summer internships = 313 (success rate = 90 percent).

—Undergraduates trained via working in MS-INBRE PUI labs = 127 (success rate 94 percent).

—Total Mississippi undergraduate students trained = 440.

Please note the importance of the opportunity that this funding has provided for these students who otherwise would have not had the research training. These students are the future researchers, clinicians, scientists, teachers, policymakers, etc. If we do not continue to provide these opportunities, Mississippi, and our Nation, will fall even farther behind other countries in STEM areas.

—Training our students to work with faculty and help write grant proposals has been successful: 54 funded projects with 14 more currently pending.

Examples from NIH: 3 R01; 1 R21; 12 R15; 5 Publications: 119 peer-reviewed pubs; 6—Presentations at scientific meetings: 386.

COBRE in Mississippi

University of Mississippi (UM).—UM's first COBRE project, the Center for Psychiatric Neuroscience (CPN), was initiated 9 years ago at the University of Mississippi Medical Center in Jackson. The CPN is dedicated to generating knowledge about the relationships between neurobiology and clinical psychiatry. Over the past 9 years, CPN has made major strides toward its goal of becoming a depression research center that is innovative, multidisciplinary and increasingly independently funded; COBRE funding in the past 9 years has supported CPN-affiliated faculty in successfully competing for \$9,082,910 in Federal grants and \$923,702 in foundation grants. COBRE's support has been instrumental in achieving this—and continues to be instrumental.

CPN has developed focuses in the areas of depression and alcohol dependence; both of these are recognized as highly prevalent, serious concerns in the United States. Of all mental illnesses, depression is the most common; it is a serious, persistent and potentially life-threatening medical illness affecting nearly 10 million American adults in any year (Healthy People 2010). It is estimated that lost productivity due to depression costs \$44 billion per year in the United States (Stewart et al., 2003). Although antidepressant medications and psychotherapy provide some benefit to many people, depression continues to be a chronic and potentially life-threatening illness. New treatment strategies remain a high priority for many reasons: depression is a complex syndrome of variable symptoms; the sites of pathology in the brain appear to be multiple; and, most significantly, only about 50 percent of individuals with depression show full remission in response to currently available

therapies (Berton and Nestler, 2006). Alcohol use disorders are also very common in the United States, with approximately 7 percent of adults being alcohol dependent. There is a high correlation between alcohol use disorders and other psychiatric problems. Shrinkage of the brain is significantly present in alcohol-dependent subjects, and the development of new therapies is impeded by a lack of understanding of the precise mechanism leading to this pathological shrinkage.

Projects funded by the CPN have been unique in describing the monoamine and excitatory amino acid neurotransmitter systems, and the contributions of vascular, gender-specific and aging-related risk factors to the pathophysiology of depression and alcohol dependence. Groundbreaking observations on the roles of neurons and glia, cerebral vasculature, aging, gender, transcription factors, serotonin and glutamate in depression as well as alcohol dependence have been reported by a critical mass of faculty of the CPN and its academic home, UMMC's Department of Psychiatry and Human Behavior. The CPN has provided an excellent environment for junior, mid-level and senior investigators working in close collaboration with leading national centers and scientists to carry out the projects building on these novel insights into the pathophysiology of depression and alcoholism.

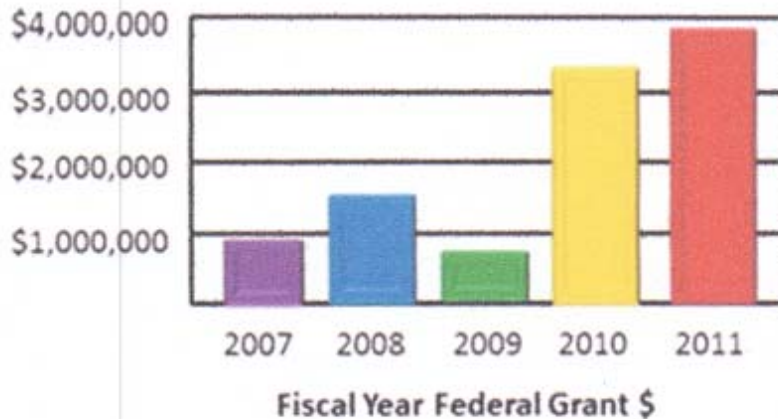
The University of Mississippi's second COBRE project, Center of Research Excellence in Natural Products Neuroscience (CORE-NPN), was initiated 5 years ago at the university's main campus in Oxford to evaluate the effects of natural products on the central nervous system (CNS). CORE-NPN has developed a multidisciplinary team committed to studying the neuroscientific properties of natural products and identifying potential new targets for the treatment of various disorders. CORE-NPN builds on UM's existing strengths at the National Center for Natural Products Research (NCNPR), the Nation's only university-affiliated research center devoted to improving human health and agricultural productivity through the discovery, development, and commercialization of pharmaceuticals and agrochemicals derived from natural products. With the development of the NIGMS COBRE CORE-NPN, the research capacity of NCNPR to discover new drugs for unmet therapeutic needs has skyrocketed. CORE-NPN has allowed UM's investigators to synergize their efforts with the resources provided through the existing NCNPR to develop an unmatched program in natural products neuroscience.

CORE-NPN has allowed faculty in the NCNPR (and other UM departments) to develop expertise in a previously unavailable area. Expertise exists among the CORE-NPN faculty to extract and purify the chemical constituents of plants, microbes, and marine organisms; to perform bioassay-guided fractionation to rapidly identify active natural products from complex mixtures of metabolites; to elucidate the chemical structures of isolated natural products; to scale up these quantities for research; to perform *in vitro* characterization of their actions; and to perform *in vivo* behavioral studies to further evaluate their properties, therapeutic potential, and liabilities. Additional expertise exists to further modify promising leads into even better therapeutic compounds, perform limited toxicity tests, formulate drug delivery systems, and to conduct small-scale clinical trials in collaboration with UMMC. CORE-NPN participating faculty continue to increase their funding success rate. The growing number of faculty awards in natural product neuroscience has a strongly beneficial impact on UM (home of the State's only School of Pharmacy) and in turn on the reputations of the center's faculty and staff. Further, the CORE-NPN's research-intensive programs provide quality research and interdisciplinary training for students, enhance recruitment efforts, and further the development of novel natural products as potential therapeutic agents.

A solid core of natural product researchers developed during Phase 1 of the COBRE at UM are making cutting-edge discoveries on the endocannabinoid, opioid and sigma systems. The endocannabinoid system is regarded as a major regulatory system in the central and peripheral nervous systems and is involved in the modulation of a variety of physiological processes; among them is control of emotional behavior, suggesting the involvement of this system in the pathogenesis of mental disorders. The endocannabinoid system is also linked to appetite, emesis, pain, hypertension, and cardiac remodeling. CORE-NPN researchers have made novel observations of natural products from Cannabis on appetite in rodents; are evaluating the potential usefulness in treating depression with several novel phytocannabinoids; are developing computational models that can be used to predict a compound's ability to have affinity for the cannabinoid receptors; and have developed novel agents that attenuate the effects of cocaine and methamphetamine. The COBRE program funding has allowed UM to develop several pre-clinical candidates that might have utility in managing obesity, wasting syndrome, depression, anxiety, and drug addiction, and more. The critical mass of scientists working in the CNS area has increased from 5 to 23 scientists as a result of COBRE Phase 1 funding, and the significant rise in endocannabinoid-related publications reveals strong development by

the CORE-NPN that is innovative, multidisciplinary, and moving toward the goal of independent funding for its programs.

As part of the COBRE program, investigators are mentored to foster and facilitate their development as young scientists. The ability to secure external funding is the major index of success showing the transition from “young investigator” to “independent scientist.” The graph below, of fiscal year Federal grant funding, outlines the year-to-year progression in external funding awards obtained since the inception of CORE-NPN. This effort resulted in a total of 38 grant awards and included: 13-R-type NIH grants, 1-ARRA Supplement, 5-NSF, 1-F32, 2-HRSA, 2-NOAA, 1-DOD, and 1-P50, among others.



The developmental program began in 2006. A base-line of \$0 was set for that year and subsequent years represent new grant awards.

This increase in funding dollars is directly related to the number of applications the young faculty members made while enrolled in the COBRE Mentoring Plan. The 38 grant awards have been a result of 113 Federal grant applications and 24 grant foundation applications submitted by the enrolled faculty. Overall, the mentorship has resulted in a success rate of 34 percent for NIH grant awards, which is much greater than the national average.

Mississippi State University.—Mississippi State University was awarded a COBRE in 2002–2008 and the benefits of that center are still obvious. The funding supported research on the susceptibility of the dopamine neurons in the Nurr1-null heterozygous mice to neurotoxin exposure. The best lab space in the College of Veterinary Medicine is the Wise Center which was designed and renovated using COBRE funds. Frequently used equipment was obtained. Most importantly, the three faculty members who were involved by the end of the previous COBRE as junior investigators have received NIH funding, and one of them has been consistently averaging more than 5 peer reviewed publications per year.

MSU currently has a pending COBRE application which involves an area of research that is already one of our strongest—infectious diseases. With the mentoring, research, and infrastructure funding from the COBRE, we expect to develop teams that will be competitive for center grants and individuals competitive for research grants from major funding agencies.

The COBRE program is even more important to MSU and similar institutions in recent years than it was when the first one was awarded at MSU. Because the success rate for NIH grant applications is so low nationally, it is difficult for anyone to compete for this funding, and it is particularly difficult when the applicant is located at an institution that is not well known for its biomedical research. The COBRE will give five of MSU’s most promising junior investigators an opportunity to build their scientific reputation by supporting their research, and it will give them formalized internal and external mentoring needed to teach them the skills and to help them build their professional networks needed for success. This will make our investigators better collaborators for other researchers in Mississippi and will enhance collaborations that already exist. It will also provide research support

for investigators who have already shown interest and skill in commercializing their research ideas (two of our COBRE application leaders and one junior investigator have taken steps toward development of intellectual property, up to and including formation of a company).

Despite these successes, our task is far from complete. Funding disparities between the States remain and may have a detrimental impact on our national self-interest. And that is why the IDeA program is so important. It is helping to ensure that all regions of the country participate in biomedical research and education. Citizens from all States should have the opportunity to benefit from the latest innovations in healthcare, which are most readily available in centers of biomedical research excellence.

On behalf of the MRC, I express gratitude to this Subcommittee for the efforts it has made over the years to provide increased funding for IDeA, in particular this committee's work to ensure a funding increase in fiscal year 2012. I hope that you will continue to invest in this program, which is so important to almost half of the States in the Union. The importance of this program, especially to junior investigators who are starting to become competitive for NIH funding, should not be underestimated. They should not receive the wrong message by cutting or even possibly eliminating funding for their research after encouraging them to pursue a career in biomedical research.

On behalf of the EPSCoR/IDeA Coalition, the MRC, and our partner institutions across Mississippi, I thank the Subcommittee for the opportunity to submit this testimony.

PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation and the approximately 30,000 people with cystic fibrosis (CF) in the United States, we are pleased to submit the following testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies requesting \$32 billion for the National Institutes of Health (NIH) in fiscal year 2013. Particularly, the CF Foundation urges the Committee to support NIH's National Center for Advancing Translational Sciences (NCATS), programs under the NCATS umbrella including the Therapeutics for Rare and Neglected Diseases (TRND) program, and collaborative efforts by NIH and the Food and Drug Administration (FDA) such as the Regulatory Science Initiative and the FDA-NIH Joint Leadership Council.

ABOUT CYSTIC FIBROSIS

Cystic fibrosis is a life-threatening genetic disease for which there is no cure. People with CF have two copies of a defective CFTR gene, which causes the body to produce abnormally thick, sticky mucus that clogs the lungs and results in life-threatening lung infections. This mucus also obstructs the pancreas, preventing pancreatic enzymes from assisting in the breakdown of food and the absorption of nutrients.

The mission of the Cystic Fibrosis Foundation is to find a cure for cystic fibrosis and improve the quality of life for people living with the disease. This is accomplished by funding life-saving research and working to provide access to quality care and effective therapies for people with CF. Through the Foundation's efforts, the life expectancy of a child with CF has doubled in the last 30 years. Although real progress toward a cure has been made, the lives of young people with CF are still cut far too short.

SUSTAINING THE FEDERAL INVESTMENT IN BIOMEDICAL RESEARCH

This Committee and the Congress are to be commended for their support for biomedical research through the years, particularly for increasing funding for the NIH and establishing the National Center for Advancing Translational Sciences (NCATS) in fiscal year 2012. It is vital that we continue to provide robust funding for the NIH, so that it can allow patients to benefit from scientific advances like the mapping of the human genome, and continue to train the next generation of scientists, create new jobs, and promote economic growth.

We support the recommendation of the Ad Hoc Group for Medical Research that the Subcommittee recognize the National Institutes of Health (NIH) as a critical national priority by providing at least \$32 billion in funding in the fiscal year 2013 Labor-HHS-Education appropriations bill. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

A report from United for Medical Research indicates that funding from the National Institutes of Health supported more than 432,000 jobs and generated more than \$62.1 billion in economic activity in 2011. Cutting funding for NIH would not only curb this economic growth, but would impede the fight against many of the most serious diseases and stifle the scientific progress that makes the United States the worldwide leader in biomedical research.

We urge this Committee and the Congress to maintain robust investment in biomedical research at the NIH so it can fund critical research today that will provide the cures of tomorrow.

STRENGTHENING CLINICAL RESEARCH AND DRUG DEVELOPMENT

In the past two decades the Cystic Fibrosis Foundation has pioneered an innovative research approach resulting in a robust pipeline of potential therapies that target cystic fibrosis from every angle.

As part of this approach the Foundation created a “venture philanthropy” model, through which CFF has raised and invested hundreds of millions of dollars to help fund cystic fibrosis drugs and therapies. Nearly every CF drug and therapy available today was supported by the CF Foundation. By providing upfront funding and reducing financial risk for drug companies like Vertex Pharmaceuticals, CFF has made sure that this rare disease has not been ignored.

The Foundation has also created a Therapeutics Development Network (TDN) to achieve greater efficiency in clinical investigation. Challenges inherent in small patient populations, like the availability of participants for clinical trials, prompted the Foundation to create a network of academic centers and CF care centers that collaborate across sectors and share best practices, speeding clinical research on promising potential treatments.

One such treatment developed through this approach is Kalydeco™, a groundbreaking new drug created by Vertex Pharmaceuticals in collaboration with the Cystic Fibrosis Foundation. Kalydeco is a breakthrough as it is the first treatment to address the underlying cause of cystic fibrosis in 1,200 patients with a particular genetic mutation. It has led to tremendous health gains for those who take the drug and has opened exciting new doors to research and development that may eventually lead to a cure for all people living with CF.

While the CF Foundation has made great progress, still more needs to be done for cystic fibrosis and other rare diseases, many of which have no treatments available. We are hopeful that the Committee will bolster programs that support translating basic scientific research into therapies that can make a real difference to vulnerable patient populations.

Advancing Translational Science at the National Institutes of Health

The CF Foundation strongly urges this Committee to increase funding for NIH’s newly established National Center for Advancing Translational Sciences (NCATS), which will catalyze innovation by improving the process by which diagnostics and therapeutics are developed, thereby diminishing obstacles to translating basic scientific research into treatments. This will make translational science more efficient, less expensive, and less risky.

The specific programs housed in NCATS are integral to this mission, including the Clinical and Translational Science Awards (CTSA), the Cures Acceleration Network (CAN), and the Therapeutics for Rare and Neglected Diseases (TRND) program. They are designed to transform the way in which clinical and translational research is conducted and funded. NIH Director Dr. Francis Collins has cited the Cystic Fibrosis Foundation’s successful Therapeutics Development Network as a model for TRND’s innovative therapeutics development model.

NCATS is already advancing a number of initiatives. For example, NCATS is working with the Defense Advanced Research Projects Agency (DARPA) and the FDA to design a tissue chip for drug screening. This chip, composed of diverse human cells and tissues, mimics how drugs interact in humans. If successful, this chip could make drug safety and efficacy assessments more accurate and even make them possible earlier in the development process—enabling investigators to concentrate on the most promising new drugs.

Robust funding for NCATS will give industry, academia, and other stakeholders the tools and resources needed to speed the development of diagnostics and treatments.

Increasing Collaboration

The CF Foundation urges the Committee to support collaborative efforts by the Food and Drug Administration and the National Institutes of Health, such as the Regulatory Science Initiative and the FDA–NIH Joint Leadership Council. Collabo-

ration between the NIH and FDA has the potential to help move innovative new drugs more quickly through the development process and into the hands of patients by ensuring that the FDA has the resources, strategies, and tools it needs to efficiently review and regulate drugs in this ever changing scientific landscape. As treatments like Kalydeco are being developed to target specific genetic mutations and smaller and smaller populations, it is important that the FDA has the expertise it needs to quickly move these drugs through the review process.

Support should also be directed toward the continuation and expansion of research networks, such as NIH's pediatric liver disease consortium at the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK). This successful collaboration is helping researchers discover treatments not only for CF liver disease but for other diseases that affect thousands of children each year.

SUPPORTING DRUG DISCOVERY

The Cystic Fibrosis Foundation's clinical research is fueled by a drug discovery effort comprised of early stage translational research into successful treatments for this disease. Several research projects at the NIH could eventually be the key to controlling or curing cystic fibrosis.

For example, the CF Foundation commends NIH for issuing two Requests for Applications (RFAs) that specifically target cystic fibrosis—one on early lung disease and the other on cystic fibrosis related diabetes. The Cystic Fibrosis Foundation also encourages NIH to continue its investment in a research program at the University of Iowa to study the effects of CF in a pig model. The program, funded through research awards from the National Heart, Lung, and Blood Institute (NHLBI) and the CF Foundation, bears great promise to help make significant developments in the search for a cure.

Understanding CFTR Folding and Trafficking

The data that emerged from Kalydeco Phase 2 and 3 clinical trials is proof that the way in which this drug targets the physiological defect that causes CF, called CFTR protein function modulation, is a viable therapeutic approach. However, this exciting data was obtained from patients with a specific CF mutation which affects only 4 percent of the CF population. More research is needed to understand other genetic mutations, the most common of which causes multiple negative effects, including misfolding and poor activation properties of the CFTR protein. We encourage the Committee to increase investment in genetic research that can help scientists to better understand this more common mutation.

Personalized Medicine

Strong Federal and private investment in research is bringing personalized medicine to the forefront of drug research and development. Kalydeco, discussed above, is an outstanding example of the power of personalized medicine. If the 4 percent of the CF population for which Kalydeco is effective had not been properly identified and targeted for this therapy, the studies would have concluded that Kalydeco was not effective, because 95 percent of patients would not have responded.

While exciting and promising for patients, the advancement of personalized medicine is also expensive, complex, and scientifically challenging. For instance, CF doctors are facing difficulties in delivering appropriate care to CF patients, as insurance providers will not cover certain combinations of medicines that clinicians have found to be effective for cystic fibrosis when there is no formal clinical data to support it. This puts patients in a difficult position, as these clinical trials are unlikely to be performed by pharmaceutical companies because they are expensive and treat a very small, targeted population. As such, we urge the Committee to provide sustained Federal investment in personalized medicine, to help move this burgeoning field forward and support the advancement of exciting scientific discoveries.

The Cystic Fibrosis Foundation has devoted our own resources to developing treatments through drug discovery, clinical development, and clinical care. Several of the drugs in our pipeline show remarkable promise in clinical trials and we are increasingly hopeful that these discoveries will bring us even closer to a cure. However, sufficient investment in basic science, translational science, clinical research, and drug development programs at NIH are vital to continuing these successes not only for CF but for all rare diseases.

We urge the Committee to consider these factors as you craft the fiscal year 2013 Labor, Health and Human Services, and Education appropriations legislation. We stand ready to work with NIH and congressional leaders on the challenging issues ahead. Thank you for your consideration.

PREPARED STATEMENT OF THE COALITION FOR HEALTH FUNDING

The Coalition for Health Funding is pleased to provide the Senate Labor, Health and Human Services, Education and Related Agencies (LHHS) appropriations subcommittee with a statement for the record on fiscal year 2013 funding levels for health agencies and programs. Since 1970, the Coalition has advocated for sufficient and sustained discretionary funding for the public health continuum to meet the mounting and evolving health challenges confronting the American people.

Every day, in important ways most Americans don't even realize, the Federal Government supports public health programs that keep them safe and secure. The agencies and programs of the LHHS: conduct health research and discover cures; prevent disease, disability, and injury; assure food, water, and drug safety; protect and respond in times of crisis; educate the next generation of scientists, healthcare providers, and public health professionals; and care for our Nation's most vulnerable.

The Coalition's 76 national, member organizations—representing the interests of more than 100 million patients, healthcare providers, public health professionals, and scientists—support the belief that the Federal Government is an essential partner with State and local governments and the nonprofit and private sectors in improving health. In this regard, we are very concerned that deficit reduction efforts to date—both actual and those under consideration—have relied almost exclusively on cuts to public health and other discretionary programs to balance the budget. Public health programs have experienced 2 straight years of funding cuts, and are facing a looming sequester that will cut even deeper—as much as \$5.7 billion from health programs within the subcommittee's jurisdiction.

These programs make up only a fraction of all Federal spending. They are not the root cause of our fiscal crisis, and cutting them further will not bring the budget into balance. On the contrary, with greater investment, public health programs are an integral part of the solution. Evidence abounds—from the Department of Defense to the U.S. Chamber of Commerce—that healthy Americans are stronger on the battlefield, have higher academic achievement, and are more productive in school and on the job. Healthy Americans drive our economic engine, and ultimately cost our Nation less in healthcare spending.

The Coalition realizes the pressure the Congress and the administration face to balance the Nation's budget. However, our Nation's health has already borne more than its fair share of the responsibility for deficit reduction. A few weeks ago, the Coalition was joined by more than 900 national, State, and local organizations urging the Appropriations Committees to increase investments in public health and other programs within the subcommittee's jurisdiction. The following list summarizes the Coalition's fiscal year 2013 specific funding recommendations for these public health agencies.

NATIONAL INSTITUTES OF HEALTH (NIH)

The Coalition joins the Ad Hoc Group for Medical Research in seeking at least \$32 billion for NIH in fiscal year 2013. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation. As the primary Federal agency responsible for conducting and supporting medical research, NIH drives scientific innovation and develops new and better diagnostics, improved prevention strategies, and more effective treatments.

NIH also contributes to the Nation's economic strength by creating skilled, high-paying jobs; new products and industries; and improved technologies. More than 83 percent of NIH research funding is awarded to more than 3,000 universities, medical schools, teaching hospitals, and other research institutions, located in every State. The Nation's longstanding, bipartisan commitment to NIH has established the United States as the world leader in medical research and innovation.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The Coalition joins the CDC Coalition in seeking \$7.8 billion for CDC in fiscal year 2013. This amount is representative of what CDC needs to fulfill its core mission in fiscal year 2013; activities and programs that are essential to protect the health of the American people. CDC continues to be faced with unprecedented challenges and responsibilities, ranging from chronic disease prevention, eliminating health disparities, bioterrorism preparedness, to combating the obesity epidemic. In addition, CDC funds community programs in injury control; health promotion efforts in schools and workplaces; initiatives to prevent diabetes, heart disease, cancer, stroke, and other chronic diseases; improvements in nutrition and immunization;

programs to monitor and combat environmental effects on health; prevention programs to improve oral health; prevention of birth defects; public health research; strategies to prevent antimicrobial resistance and infectious diseases; and data collection and analysis on a host of vital statistics and other health indicators. It is notable that more than 70 percent of CDC's budget flows out to States and local health organizations and academic institutions, many of which are currently struggling to meet growing needs with fewer resources.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

The Coalition joins the Friends of HRSA in seeking \$7 billion for HRSA in fiscal year 2013. HRSA operates programs in every State and thousands of communities across the country. It is a national leader in providing health services for individuals and families, serving as a health safety net for the medically underserved. The requested level of funding for fiscal year 2013 is critical to allow the agency to carry out critical public health programs and services that reach millions of Americans, including developing the public health and healthcare workforce; delivering primary care services through community health centers; improving access to care for rural communities; supporting maternal and child healthcare programs; providing healthcare to people living with HIV/AIDS; and many more. In the long term, much more is needed for the agency to achieve its ultimate mission of ensuring access to culturally competent, quality health services; eliminating health disparities; and rebuilding the public health and healthcare infrastructure.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

The Coalition joins the Mental Health Liaison Group and the addictions community in recommending an overall funding level of \$3.5 billion for SAMHSA in fiscal year 2013. According to results from a national survey conducted by SAMHSA, 45.1 million American adults in the United States experienced mental illness last year. However, only two-thirds of adults in the United States with mental illness received mental health services. In fact, suicide claims more than 36,000 lives annually, the equivalent of 94 suicides per day; 1 suicide every 15 minutes. Last year, 8.7 million adults aged 18 or older thought seriously about committing suicide, 2.5 million made a suicide plan, and 1.1 million attempted suicide. The funding for community mental health services from SAMHSA has never been more critical, especially in light of the \$3.6 billion reduction in State mental health funding for programs serving this vulnerable population.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The Coalition joins the Friends of AHRQ in recommending an overall funding level of \$400 million in base discretionary funding for AHRQ in fiscal year 2013. AHRQ funds research and programs at local universities, hospitals, and health departments that improve healthcare quality, enhance consumer choice, advance patient safety, improve efficiency, reduce medical errors, and broaden access to essential services—transforming people's health in communities in every State around the Nation. Specifically, the science funded by AHRQ provides consumers and their healthcare professionals with valuable evidence to make the right healthcare decisions for themselves and their families. AHRQ's research also provides the basis for protocols that reduce hospital-acquired infections, and improve patient confidence, experiences, and outcomes.

The Coalition appreciates this opportunity to provide its fiscal year 2013 funding recommendations. During the coming months, our member organizations stand ready to work with Members of Congress in developing a balanced approach to deficit reduction that will prevent the harmful, indiscriminant cuts that will occur under sequestration.

PREPARED STATEMENT OF THE COALITION OF NORTHEASTERN GOVERNORS

As the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies begins to develop the fiscal year 2013 Labor, HHS, Education, and Related Agencies appropriations bill, the Coalition of Northeastern Governors (CONEG) urges you to fund the Low Income Home Energy Assistance Program (LIHEAP) at the most current authorized level of \$5.1 billion, with at least \$4.5 billion in the core block grant program and additional contingency funding for unforeseen emergencies. We urge you to provide these funds in a manner consistent with the 1994 LIHEAP statute—"to assist low-income households, particularly those with

the lowest incomes that pay a high proportion of household income for home energy, primarily in meeting their immediate home energy needs.”

The Governors appreciate the Subcommittee’s continued support for the Low Income Home Energy Assistance Program, and recognize the difficult fiscal challenges facing the Congress this year. However, the need that the LIHEAP program meets—immediate assistance that allows the most the vulnerable low-income households to pay their home energy bills—is great and continues to grow.

LIHEAP is targeted to households whose income hovers near the Federal poverty level, which for a two-person household is less than \$15,000 per year. More than 90 percent of LIHEAP households have at least one member defined as “vulnerable”—elderly, disabled or a small child. In addition, a recent National Energy Assistance Directors’ Association survey found that the number of households with veterans receiving LIHEAP assistance has increased by more than 150 percent from 695,760 in fiscal year 2008 to 1.78 million in fiscal year 2011.

In the face of recent reductions in LIHEAP funding, the northeast States’ LIHEAP programs faced a reduction of 20 to 25 percent in their fiscal year 2012 allocation compared to fiscal year 2011. This reduction creates considerable pressures and challenges in stretching the scarce LIHEAP dollars while still providing a meaningful benefit. States have responded to the reduced LIHEAP funds in a number of ways. For example, eligibility for LIHEAP assistance has been tightened. The application season has been reduced. The number of households served this season will be lower. Most critically, a number of States have had to reduce benefits. Many northeast States have also stretched their own limited budgets to provide millions of dollars in supplemental LIHEAP funds. Few northeast States will have carry-forward funds at the end of the current season. If the fiscal year 2013 appropriations are delayed, the lack of carry-forward funds creates an additional challenge for cold-weather States, where early winters create the need for benefits in the fall. A funding level of \$4.5 billion in the block grant program provides the certainty that States need to plan and implement a cost-effective program.

The threat of reduced LIHEAP funding comes as home heating oil prices continue their steady year-to-year rise. According to the most recent weekly price reports of the Energy Information Administration (March 19, 2012), residential heating oil prices now exceed \$4 per gallon, and have risen steadily over the past month, even as winter temperatures moderate. These rising energy prices continue to erode the purchasing power of each LIHEAP dollar received by low-income households, particularly in the Northeast, which is more dependent on home heating fuel than any other region of the country. Almost 82 percent of the 8 million U.S. households that use heating oil to heat their homes are located in this region, and they have limited options to switch to lower-cost residential fuels.

At current prices, a typical LIHEAP benefit would pay for less than 30 percent of the total heating expenditure for a household using 800 gallons of heating oil during the season. Unlike most households that heat with natural gas or electricity, households that rely upon delivered fuels do not have the protection of a shut-off moratorium. If a household cannot afford to purchase home heating fuel, the delivery truck simply does not come, and the household is left in the cold. Adequate, predictable and timely Federal funding is vital for LIHEAP to assist these vulnerable, low-income households faced with increasing home energy bills.

The CONEG Governors appreciate the Subcommittee’s continuing support for LIHEAP, and urge that it fund the program at \$5.1 billion, with a \$4.5 billion funding level for the core LIHEAP block grant program and additional contingency funds provided to address unforeseen energy emergencies. An adequate and certain level of funding will help States to provide meaningful assistance to some of the Nation’s most vulnerable low-income households as they attempt to pay their home energy bills.

PREPARED STATEMENT OF THE COMMISSIONED OFFICERS ASSOCIATION OF THE U.S.
PUBLIC HEALTH SERVICE

The Commissioned Officers Association of the U.S. Public Health Service, Inc. (COA), wishes to submit this statement for the record. The Association speaks for its members, all of whom are active-duty or retired officers of the Commissioned Corps of the U.S. Public Health Service (USPHS).

The Association respectfully makes one request: support for a congressionally authorized (but unfunded) workforce program to recruit and train public health physicians, dentists, nurses, physician assistants, and mental health experts for public service careers in the USPHS Commissioned Corps. The program is called the

United States Public Health Sciences Track. Its annual cost is estimated at \$160 million.

Background and Rationale

This program was authorized in Section 5315 of the Affordable Care Act (Public Law 111–148), which is now before the U.S. Supreme Court. Despite the intense controversy surrounding other aspects of this law, there has never been, to the Association’s knowledge, any opposition expressed by any Member of Congress to the Public Health Sciences Track. Regardless of the Court’s decision, our Nation will still need a way to replenish and grow the USPHS Commissioned Corps and its active-duty force of 6,500 health professionals.

The Public Health Sciences Track means guaranteed jobs for all graduates. This is because there are thousands of unfilled positions, i.e., potential billets, for qualified clinicians who are willing to serve as uniformed public health professionals in Indian Country (especially Alaska and the American southwest) and in underserved urban and rural areas in nearly every State.

USPHS health professionals serve side-by-side with Armed Forces personnel at home and abroad, on joint training missions, and even in forward operating bases in combat zones. USPHS psychiatric nurses have treated injured soldiers and Marines under fire in Afghanistan. At home, USPHS psychologists and other mental health specialists are detailed to the Department of Defense to treat returning soldiers and Marines suffering from traumatic brain injury and post-traumatic stress disorder. The USPHS Commissioned Corps is a public health and national security force multiplier.

The Public Health Sciences Track, as set forth in Section 5315 of the ACA, would provide for 850 annual scholarships for medical, dental, nursing, and public health students who commit to public service in the USPHS. Such a program would be the first dedicated pipeline into the USPHS Commissioned Corps. The law would reserve ten slots at the Uniformed Services University of the Health Sciences (USUHS), which is the medical school and research institute for uniformed services personnel (Army, Navy, Air Force, Public Health Service). All the rest would be distributed among interested schools of medicine, dentistry, nursing, etc., based on recommendations of the U.S. Surgeon General.

Funding

The ACA provision authorizing the Public Health Sciences Track identified an existing source of funds. Full support was to come from the Public Health and Social Services Emergency Fund. The law directed the DHHS Secretary to “transfer from the Public Health and Social Services Emergency Fund such sums as may be necessary” (Sec. 274). That transfer of funds transfer never occurred, and we understand it is now precluded by language in the Continuing Resolution (CR). That is why an appropriation is necessary to keep this program alive.

As the Association’s Executive Director, I would be pleased to expand on these points or to answer any questions.

PREPARED STATEMENT OF THE COUNCIL FOR OPPORTUNITY IN EDUCATION

Over the last several years, our Nation has struggled to overcome the greatest economic crisis since the Great Depression. More and more Americans are turning to education as a means to lift their families out of poverty and empower their local communities. The Federal TRIO Programs, which serve approximately 800,000 low-income, potential first-generation college graduates, presents a unique, yet ideal mechanism to achieve our mutual goals of increased college access and completion, enhanced employment prospects for veterans and adults returning to the workforce and strengthened status within the global marketplace. To that end, I am pleased to submit the following recommendations for increases in TRIO funding.

Send Our Returning Veterans Back to the Classroom

With the winddown of overseas military conflicts, several thousand servicemen and -women are returning home and need help to re-enter the classroom and re-engage in civilian life and their local communities. Yet, there are only 47 of TRIO’s Veterans Upward Bound (VUB) programs. Through an increase of \$13.5 million, the Congress could double the program’s capacity and allow 12,000 veterans (total) to receive TRIO services. This is a more than worthwhile investment in those who have sacrificed so much for our Nation.

Help More Out-of-Work Adults and Low-Wage Earners Boost Their Employability

TRIO's Educational Opportunity Centers (EOC) target displaced and underemployed workers and guide these prospective students through the challenges of obtaining secondary education credentials, selecting and enrolling in appropriate postsecondary programs and/or navigating through the complex financial aid process. Currently, there are only 128 EOC programs supporting approximately 192,000 adult learners across the country. By infusing just \$14.9 million into the EOC program, the Congress could fund 38 additional programs—increasing the program's reach by 30 percent to serve an additional 58,000 students—and provide much needed relief to existing programs, which have sustained significant funding cuts in recent years.

Increase Retention and Graduation Rates Among Low-Income College Students

TRIO's Student Support Services (SSS) program helps low-income and first-generation students, including students with disabilities, to successfully begin and stay in college. Participants receive tutoring, counseling, and remedial instruction in order to achieve their goals of college completion. Serving nearly 203,000 students through just more than 1,000 programs on college campuses across the country, SSS is ripe for investment. By pouring \$46.8 million into current programs, the Congress would allow the host colleges and universities to serve an additional 32,000 students within a matter of weeks. This would represent a 15 percent increase in the number of low-income college students served by SSS.

Preserve Opportunity for Low-Income and Underrepresented Students to Pursue Graduate Education

TRIO's Ronald E. McNair Postbaccalaureate Achievement program encourages and prepares low-income, first-generation and other underrepresented students to achieve doctoral degrees. The McNair program provides research opportunities, faculty mentoring and other supports necessary for such students to enter into and complete challenging degree fields. Recently, the Department of Education (DOE) cut funding for this program by \$10 million (21 percent) and announced an intention to fund one-third fewer programs in the pending grant competition. By restoring this funding in fiscal year 2013, the Congress could restore services to approximately 2,000 students and allow these programs to build upon their track record of success in producing academics and other thought leaders in disciplines vital to our national interest, such as engineering and mathematics.

Restore Services to Students in the Pipeline

Due to funding cuts, several thousand low-income, potential first-generation college graduates have missed out on the opportunity to participate in TRIO. By infusing \$71.4 million into the programs, the Congress could allow 55,000 middle and high school students to receive services through Talent Search, Upward Bound and Upward Bound Math-Science.

With a longstanding history of helping low-income youth and adults become the first in their families to earn college degrees, the Federal TRIO programs are a ready resource to meet the needs of our veterans, adult learners, students with disabilities and other low-income students. Even during this time of austerity, it is critically important to make sound investments that put our Nation on a sound economic path and strengthen communities and families. This strategy proposes to do just that.

In addition to these funding concerns, I would request that your subcommittee take particular action to remedy the Department of Education's mishandling of these programs.

Imposing a Competitive Preference Priority that Moves Upward Bound grants from many States into Illinois—and particularly into Chicago. By adding “competitive priorities”—and giving extra points to institutions and agencies that addressed those priorities—in the Upward Bound competition (and also, it is expected, in the Upward Bound Math/Science competition), the Department intends to reward institutions and agencies that address those priorities. The first of three competitive priorities awards applicants an extra 5 points out of a total possible of 125 by serving “Persistently Lowest Achieving Schools” (PLAS) as defined by the Department (and not the applicant's State). Because Upward Bound does not serve elementary school students, and since many States labeled more elementary schools than secondary schools as PLAS, applicants from certain States have a five point advantage over most applications from States that concentrated on elementary schools as PLAS. As a consequence, for example, institutions and agencies serving almost 60 schools in Chicago qualify for the extra five points. Meanwhile NO institutions and agencies

serving schools in Idaho qualify and only a handful of institutions in Montana and Connecticut qualify.

The Upward Bound competition closed Friday, March 16, but it is estimated that only about 25 percent of applications qualified for extra points under the first competitive priority, serving PLAS. Other applicants simply could not earn these points because there were no nearby PLAS. It is possible that this issue also raises civil rights concerns because among the applicants disadvantaged are those serving schools on Indian reservations and applicants serving schools in Southern States such as Alabama and West Virginia that have very low numbers of qualifying PLAS.

Despite the fact that the Congress provided the Department of Education an extra year to prepare for and conduct TRIO competitions, and despite the fact that the Appropriations Committee gave specific direction to the Department to avoid delays in TRIO competitions in the fiscal year 2011 Omnibus, ED remains unable to announce grants in a timely fashion. In one (of two) TRIO competitions in fiscal year 2011, grants were so late that many expired before announcements were made. Those programs, Educational Opportunity Centers—which help unemployed and underemployed workers and other low-income adults get the education and training they need to prepare for good jobs—were forced to close down. Many educators were laid off, and many more left their employment given the uncertainty surrounding funding continuation. It is anticipated that this same problem will again occur all throughout the summer. The last time an Upward Bound competition was held, 5 years ago, applications had to be submitted in November and grant announcements were not made until May. This year, through a series of missteps, the Department closed and then re-opened the competition for Upward Bound with applications not being finally due until March 16. Although current grants to more than 300 institutions and agencies will have expired by June 1, the Department can provide no assurance that grant notifications will be made by that time. Upward Bound staff are already receiving termination notices, and very few colleges can plan summer programs with no assurance that funds will be available. The situation is compounded because—with the end of an infusion of mandatory monies—it is known that at least 150 previously funded Upward Bound programs will be discontinued.

These acts demonstrate a lack of due care with the Federal funds with which your Subcommittee has entrusted the Department in the administration of the TRIO programs. Therefore, in addition to addressing the ever-pressing funding needs of TRIO, I respectfully request your leadership in remedying the administrative ills noted above.

On behalf of the low-income, first-generation students served by TRIO, I thank you for your consideration of this testimony.

PREPARED STATEMENT OF THE COPD FOUNDATION

SUMMARY OF RECOMMENDATIONS

The Foundation requests that the National Institutes of Health, National Heart, Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases and National Institute on Aging, increase the investment in Chronic Obstructive Pulmonary Disease and that the Centers for Disease Control and Prevention initiate a Federal partnership with the COPD community to achieve the following goals:

- \$32 billion for the NIH for fiscal year 2013—that is a 4.5 percent increase for the NIH over its fiscal year 2012 funding level;
- Promotion of basic science and clinical research related to COPD;
- Programs to attract and train the best young clinicians for the care of individuals with COPD;
- Support for outstanding established scientists to work on problems within the field of COPD research;
- Development of effective new therapies to prevent progression of the disease and control symptoms of COPD; and
- Expansion of public awareness and targeted detection to promote early diagnosis and treatment.

Mr. Chairman and members of the subcommittee thank you for the opportunity to submit testimony for the record on behalf of the COPD Foundation.

The COPD Foundation has a clear mission: to develop and support programs, which improve the quality of life through research, education, early diagnosis, and enhanced therapy for persons whose lives are impacted by Chronic Obstructive Pulmonary Disease (COPD). The COPD Foundation was established to speed innovations which will make treatments more effective and affordable. It also undertakes

initiatives that result in expanded services for COPD patients and improves the lives of patients with COPD through research and education that will lead to prevention and someday a cure for this disease.

COPD: THIRD LEADING CAUSE OF DEATH AND RISING

COPD is an umbrella term used to describe progressive lung diseases including emphysema, chronic bronchitis, refractory (non-reversible) asthma, and some forms of bronchiectasis. This disease is characterized by increasing breathlessness. The NIH, National Heart, Lung and Blood Institute estimates that 12 million adults have COPD and another 12 million are undiagnosed. Smoking is not the only cause of COPD; second-hand smoke, occupational dust and chemicals, air pollution and genetic factors such as Alpha-1 Antitrypsin Deficiency also cause COPD. Dr. Susan Shurin, Acting Director, of NHLBI responsible for the Learn More Breathe Better® COPD education and awareness program notes that, "Half of the people living with COPD don't know it even though it is relatively simple to diagnose with spirometry."

COPD while chronic is often characterized by exacerbations that can cause considerable lung deterioration that possibly could be avoided with medication compliance and education. There are 500,000 to 1 million hospitalizations for COPD each year, and because of these high rates of hospitalizations and readmissions the Affordable Care Act targeted COPD as an area of improvement in readmissions. Costs related to COPD are rising and estimated to be about \$50 billion per year.

A majority of patients with COPD also have at least one other chronic condition and receive care from more than one healthcare provider (primary care physicians, pulmonologists, nurses, or respiratory therapists). In 2006, the COPD Foundation presented the results of its study on co-morbidities at the American Thoracic Society International Conference. The COPD and Co-Morbidities Survey identified other chronic conditions and the extent of these illnesses, and also determine use of medications for these additional illnesses. 81 percent of the household sample with COPD described having over six co-morbid conditions. Thus it is critical that not only do individuals with COPD receive proper diagnosis and treatment but that it is also recognized that they will need proper diagnosis and treatment for co-morbid conditions that may also be chronic in nature.

Utilization of Healthcare Services.—Individuals diagnosed with COPD and those with COPD who are undiagnosed seek treatment from Emergency Services when they find themselves in an episode of severe respiratory distress. (Survey: "Confronting COPD in America" found that in those age 45–54, 27 percent had at least one emergency room visit within the past year for their condition.) Common in emergency services is to treat the patient by relieving the present distress and discharging them with the directive to follow up with their personal physician. Relieved that the episode is past, individuals are eager to resume their usual schedule and are often unable to afford an office visit or don't even have a personal physician. Thus there is no medical follow up, leading them to repeat this scenario, requiring expensive emergency services again, within months, weeks, or even days. Improvement needs to be made in understanding transitions through the healthcare delivery system while continuing to meet the immediate clinical needs of the COPD patient.

COPD Foundation Infrastructure Is Built for Research.—The COPD Foundation has worked with the FDA to establish biomarkers that will facilitate expedited drug development. The COPD Foundation has worked with the National Institutes of Health to encourage funding of research that looks at the relationship of COPD and genetics while exceeding its goal of recruiting 10,000 research subjects the largest COPD cohort ever organized. COPDGene has enrolled more than 10,000 smokers with and without COPD across the GOLD stages that includes traditionally underserved populations of both Non-Hispanic whites and African-Americans. The COPD Foundation Research Registry is a confidential database of individuals diagnosed with COPD or at risk of developing COPD. The Registry was established in 2007 by the COPD Foundation to help researchers learn more about COPD and to help people interested in COPD research find opportunities to participate. The Registry operates under the direction of the COPD Foundation's Board of Directors and is guided by an Oversight Committee comprised of leaders in the medical, ethical, scientific and COPD communities and ensures the strictest confidentiality of participant information.

THE MEDICAL NEEDS OF THE COPD COMMUNITY HAVE GONE UNMET

While smoking is a predominant cause of COPD it is not the only cause. Other significant factors are second hand smoke, occupational dusts and chemicals, air pollution, and a genetic cause called alpha-1 antitrypsin deficiency. The other leading

causes of death have seen great improvements over the past several decades. While the mortality of COPD rose by 163 percent from 1965–1998, the mortality of coronary heart disease decreased by 59 percent and the mortality of stroke decreased by 64 percent.

And yet this third leading cause of death is a hidden, silent killer. There is a lack of awareness among the public that coughing and breathlessness is not a normal sign of aging. Those diagnosed with this disease are quick to blame themselves and are ashamed of their disease because of the current societal stigma. Many lack the information for proper disease self-management, which could easily prevent exacerbations and thusly, many hospital and emergency room visits.

Currently, the only therapy shown to improve survival is supplemental oxygen. There are other therapies that can improve symptoms but they do not alter the natural history of the disease.

COPD is Fairly Easy to Detect.—In addition to symptoms of breathlessness, cough and sputum production, spirometry is a quantitative test that measures air volume and air flow in the lung and is relatively easy and inexpensive to administer.

The COPD Foundation believes that significant Federal investment in medical research is critical to improving the health of the American people and specifically those affected with COPD. The support of this Subcommittee has made a substantial difference in improving the public's health and well-being. While this is by no means an exhaustive list, the Foundation wishes to recognize and appreciate the efforts of the National Institutes of Health in creating the COPD Clinical Research Network, for conducting a COPD state of the science conference, and launching a national education campaign.

Chronic disease have a profound human and economic toll on our Nation. Nearly 125 million Americans today are living with some form of chronic condition. The Foundation recognizes that the Centers for Disease Control and Prevention understands that COPD is one of the only top 10 causes of death that is on the increase, however, COPD has not been designated the resources to be a major focus of the CDC. The Foundation urges the Subcommittee to encourage the CDC to expand its data collection efforts and to expand programs aimed at education and prevention of the general public and healthcare providers.

COPD is a condition that has a high probability of improvability via research with the potential for new evidence to improve patient health, well being, and the quality of care.

SPECIFIC AREAS OF CONCERN AND RECOMMENDATIONS

The Foundation requests that the National Institutes of Health, National Heart Lung, and Blood Institute, National Institute of Allergy and Infectious Diseases and National Institute on Aging, increase the investment in Chronic Obstructive Pulmonary Disease and that the Centers for Disease Control and Prevention initiate a Federal partnership with the COPD community to achieve the following goals:

- Promotion of basic science and clinical research related to COPD;
- Programs to attract and train the best young clinicians for the care of individuals with COPD;
- Support for outstanding established scientists to work on problems within the field of COPD research;
- Development of effective new therapies to prevent progression of the disease and control symptoms of COPD; and
- Expansion of public awareness and targeted detection to promote early diagnosis and treatment.

PREPARED STATEMENT OF THE COLLEGE ON PROBLEMS OF DRUG DEPENDENCE

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit testimony to the Subcommittee in support of the National Institute on Drug Abuse. The College on Problems of Drug Dependence (CPDD), a membership organization with more than 800 members, has been in existence since 1929. It is the longest standing group in the United States addressing problems of drug dependence and abuse. The organization serves as an interface among governmental, industrial and academic communities maintaining liaisons with regulatory and research agencies as well as educational, treatment, and prevention facilities in the drug abuse field. CPDD also often works in collaboration with the World Health Organization.

Drug abuse is costly to Americans; it ruins lives, while tearing at the fabric of our society and taking a huge financial toll on our resources. Beyond the unacceptably high rates of morbidity and mortality, drug abuse is often implicated in family

disintegration, loss of employment, failure in school, domestic violence, child abuse, and other crimes. Placing dollar figures on the problem; smoking, alcohol and illegal drug use results in an exorbitant economic cost on our nation, estimated at more than \$600 billion annually. We know that many of these problems can be prevented entirely, and that the longer we can delay initiation of any use, the more successfully we mitigate future morbidity, mortality and economic burdens.

Over the past three decades, NIDA-supported research has revolutionized our understanding of addiction as a chronic, often-relapsing brain disease—this new knowledge has helped to correctly situate drug addiction as a serious public health issue that demands strategic solutions. By supporting research that reveals how drugs affect the brain and behavior and how multiple factors influence drug abuse and its consequences scholars supported by NIDA continue to advance effective strategies to prevent people from ever using drugs and to treat them when they cannot stop.

NIDA supports a comprehensive research portfolio that spans the continuum of basic neuroscience, behavior and genetics research through medications development and applied health services research and epidemiology. While supporting research on the positive effects of evidence-based prevention and treatment approaches, NIDA also recognizes the need to keep pace with emerging problems. We have seen encouraging trends—significant declines in a wide array of youth drug use—over the past several years that we think are due, at least in part, to NIDA's public education and awareness efforts. However, areas of significant concern, such as prescription drug abuse, remain and we support NIDA in its efforts to find successful approaches to these difficult problems.

Recognizing that so many health research issues are inter-related, CPDD requests that the subcommittee provide at least \$32 billion for the National Institutes of Health, which is a \$1.3 billion or 4.3 percent increase over fiscal year 2012. This will allow NIH to keep up with inflation. Because of the critical importance of drug abuse research for the health and economy of our Nation, we also request that you provide a proportionate increase for the National Institute on Drug Abuse.

In addition, to highlight certain priority research areas within NIDA's portfolio, we respectfully request that you include the following language in the Committee report accompanying the fiscal year 2013 funding recommendation for the National Institute on Drug Abuse:

“Medications Development.—With the recent reduction in the efforts of the pharmaceutical industry to develop new medications to treat diseases of the brain, the Committee encourages NIDA to continue to increase their efforts to develop medications to treat diseases of addiction. Reasonable success has occurred in the past and recent advances in knowledge support this effort.

“Translational Research.—The Committee encourages NIDA to continue its efforts to increase our knowledge of how genetics, age, environment and other factors affect the use of experimental drugs and the development of addiction.

“Education.—The educational efforts of NIDA to inform the public of the deleterious effects of abused substances and the life-threatening dangers of drug addiction are recognized and encouraged. Progress in this area has contributed to the decreased abuse of nicotine and its long term medical consequences, including death. Adolescents and returning veterans and their families are at a high risk for drug abuse and therefore should be areas of concentration for these educational efforts.

“Prevention and Treatment.—The Committee recognizes the reported increase in abuse of marijuana and prescription drugs and encourages NIDA to support innovative approaches to prevent and treat this abuse and the resulting harmful effects. The concentration in these areas should compliment efforts to prevent and treat addiction of all abused substances.

“Prescription Drug Abuse.—Prescription drug abuse has been the focus of much work by NIDA and its grantees and although significant progress has been made, the Committee encourages NIDA to maintain its comprehensive leadership role in the effort to halt this epidemic.

“Military Personnel, Veterans, and Their Families.—The Committee commends NIDA for its successful efforts to coordinate and support research with the Department of Veterans Affairs and other NIH institutes on substance abuse and associated problems among U.S. military personnel, veterans and their families. Many military personnel need help confronting war-related problems including traumatic brain injury, post-traumatic stress disorder, depression, anxiety, sleep disturbances, and substance abuse, including tobacco, alcohol and other drugs. Many of these problems are interconnected and contribute to individual health and family relationship crises, yet there has been little research on how to prevent and treat the

unique characteristics of wartime-related substance abuse issues. The Committee encourages NIDA to continue work in this area.”

The Nation’s previous investment in scientific research to further understand the effects of abused drugs on the body has increased our ability to prevent and treat addiction. As with other diseases, much more needs to be done to improve prevention and treatment of these dangerous and costly diseases. Our knowledge of how drugs work in the brain, their health consequences, how to treat people already addicted, and what constitutes effective prevention strategies has increased dramatically due to support of this research. However, since the number of individuals continuing to be affected is still rising, we need to continue the work until this disease is both prevented and eliminated from society.

We understand that the fiscal year 2013 budget cycle will involve setting priorities and accepting compromise, however, in the current climate we believe a focus on substance abuse and addiction, which according to the World Health Organization account for nearly 20 percent of disabilities among 15–44 year olds, deserve to be prioritized accordingly. We look forward to working with you to make this a reality. Thank you for your support for the National Institute on Drug Abuse.

PREPARED STATEMENT OF THE CHARLES R. DREW UNIVERSITY OF MEDICINE AND
SCIENCE

Mr. Chairman and members of the Subcommittee, thank you for the opportunity to present you with testimony. The Charles Drew University is distinctive in being the only dually designated Historically Black Graduate Institution and Hispanic Serving Institution in the Nation. We would like to thank you, Mr. Chairman, for the support that this subcommittee has given to our University to produce minority health professionals to eliminate health disparities as well as do groundbreaking research to save lives.

The Charles Drew University is located in the Watts-Willowbrook area of South Los Angeles. Its mission is to prepare predominantly minority doctors and other health professionals to care for underserved communities with compassion and excellence through education, clinical care, outreach, pipeline programs and advanced research that makes a rapid difference in clinical practice. The Charles Drew University has established a national reputation for translational research that addresses the health disparities and social issues that strike hardest and deepest among urban and minority populations.

Health Resources and Services Administration

Title VII Health Professions Training Programs.—The health professions training programs administered by the Health Resources and Services Administration (HRSA) are the only Federal initiatives designed to address the longstanding underrepresentation of minorities in health careers. HRSA’s own report, “The Rationale for Diversity in the Health Professions: A Review of the Evidence,” found that minority health professionals disproportionately serve minority and other medically underserved populations, minority populations tend to receive better care from practitioners of their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health professions institutions, they are significantly more likely to: (1) serve in medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

Minority Centers of Excellence.—The purpose of the COE program is to assist schools, like Charles Drew University, that train minority health professionals, by supporting programs of excellence. The COE program focuses on improving student recruitment and performance; improving curricula and cultural competence of graduates; facilitating faculty and student research on minority health issues; and training students to provide health services to minority individuals by providing clinical teaching at community-based health facilities. For fiscal year 2013, the funding level for COE should be \$24.602 million.

Health Careers Opportunity Program.—Grants made to health professions schools and educational entities under HCOP enhance the ability of individuals from disadvantaged backgrounds to improve their competitiveness to enter and graduate from health professions schools. HCOP funds activities that are designed to develop a more competitive applicant pool through partnerships with institutions of higher education, school districts, and other community based entities. HCOP also provides for mentoring, counseling, primary care exposure activities, and information regarding careers in a primary care discipline. Sources of financial aid are provided to stu-

dents as well as assistance in entering into health professions schools. For fiscal year 2013, the HCOP funding level of \$22.133 million is recommended.

National Institutes of Health

National Institute on Minority Health and Health Disparities.—The NIMHD is charged with addressing the longstanding health status gap between under-represented minority and non-minority populations. The NIMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, telemedicine technology and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and developed a comprehensive plan for research on minority health at NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the COE program and HCOP. For fiscal year 2013, an increase proportional to NIH's increase is recommended for NIMHD as well as additional FTEs.

Research Centers at Minority Institutions.—RCMI, now at NIMHD, has a long and distinguished record of helping institutions like The Charles Drew University develop the research infrastructure necessary to be leaders in the area of translational research focused on reducing health disparities research. Although NIH has received some budget increases over the last 5 years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2013.

Department of Health and Human Services

Office of Minority Health.—Specific programs at OMH include: assisting medically underserved communities, supporting conferences for high school and undergraduate students to interest them in health careers, and supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions. For fiscal year 2013, I recommend a funding level of \$65 million for OMH to support these critical activities.

Department of Education

Strengthening Historically Black Graduate Institutions.—The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2013, an appropriation of \$65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Conclusion

Despite all the knowledge that exists about racial/ethnic, socio-cultural and gender-based disparities in health outcomes, the gap continues to widen. Not only are minority and underserved communities burdened by higher disease rates, they are less likely to have access to quality care upon diagnosis. As you are aware, in many minority and underserved communities preventative care and research are inaccessible either due to distance or lack of facilities and expertise. As noted earlier, in just one underserved area, South Los Angeles, the number and distribution of beds, doctors, nurses and other health professionals are as parlous as they were at the time of the Watts Rebellion, after which the McCone Commission attributed the so-named "Los Angeles Riots" to poor services—particularly access to affordable, quality healthcare. The Charles Drew University has proven that it can produce excellent health professionals who "get" the mission—years after graduation they remain committed to serving people in the most need. But, the university needs investment and committed increased support from Federal, State and local governments and is actively seeking foundation, philanthropic and corporate support.

Even though institutions like The Charles Drew University are ideally situated (by location, population, community linkages and mission) to study conditions in which health disparities have been well documented, research is limited by the paucity of appropriate research facilities. With your help, the Life Sciences Research Facility will translate insight gained through research into greater understanding of disparities and improved clinical outcomes. Additionally, programs like Title VII Health Professions Training programs will help strengthen and staff facilities like our Life Sciences Research Facility.

We look forward to working with you to lessen the huge negative impact of health disparities on our Nation's increasingly diverse populations, the economy and the whole American community.

Mr. Chairman, thank you again for the opportunity to present testimony on behalf of The Charles Drew University. It is indeed an honor.

PREPARED STATEMENT OF THE COUNCIL ON SOCIAL WORK EDUCATION

On behalf of the Council on Social Work Education (CSWE), I am pleased to offer this written testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies for inclusion in the official subcommittee record. I will focus my testimony on the importance of fostering a skilled, sustainable, and diverse social work workforce to meet the healthcare needs of the Nation through professional education, training and financial support programs for social workers at the Department of Health and Human Services (HHS).

CSWE is a nonprofit national association representing more than 3,000 individual members and more than 650 master's and baccalaureate programs of professional social work education. Founded in 1952, this partnership of educational and professional institutions, social welfare agencies, and private citizens is recognized by the Council for Higher Education Accreditation (CHEA) as the single accrediting agency for social work education in the United States. Social work education focuses students on leadership and direct practice roles helping individuals, families, groups, and communities by creating new opportunities that empower people to be productive, contributing members of their communities.

Recruitment and retention in social work continues to be a serious challenge that threatens the workforce's ability to meet societal needs. The Bureau of Labor Statistics estimates that employment for social workers is expected to grow faster than the average for all occupations through 2018, particularly for social workers specializing in the aging population and working in rural areas. In addition, the need for social workers specializing in mental health and substance use is expected to grow by almost 20 percent more than the 2008–2018 decade.¹

CSWE understands the difficult funding decisions the Congress is faced with this year given the fragile state of the United States economy. In these challenging times, it is my hope that the subcommittee will prioritize funding for health professions training in fiscal year 2013 to help to ensure that the Nation continues to foster a sustainable, skilled, and culturally competent workforce that will be able to keep up with the increasing demand for social work services and meet the unique healthcare needs of diverse communities.

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) TITLE VII AND TITLE VIII
HEALTH PROFESSIONS PROGRAMS

CSWE urges the subcommittee to provide \$520 million in fiscal year 2013 for the health professions education programs authorized under titles VII and VIII of the Public Health Service Act and administered through HRSA. HRSA's title VII and title VIII health professions programs represent the only Federal programs designed to train healthcare providers in an interdisciplinary way to meet the healthcare needs of all Americans, including the underserved and those with special needs. These programs also serve to increase minority representation in the healthcare workforce through targeted programs that improve the quality, diversity, and geographic distribution of the health professions workforce. The title VII and title VIII programs provide loans, loan guarantees and scholarships to students, and grants to institutions of higher education and nonprofit organizations to help build and maintain a robust healthcare workforce. Social workers and social work students are eligible for funding from the suite of title VII health professions programs.

The title VII and title VIII programs were reauthorized in 2010, which helped to improve the efficiency of the programs as well as enhance efforts to recruit and retain health professionals in underserved communities. Recognizing the severe shortages of mental and behavioral health providers within the healthcare workforce, a new title VII program was authorized in the Patient Protection and Affordable Care Act (Public Law 111–148). The Mental and Behavioral Health Education and Training Grants program would provide grants to institutions of higher education (schools of social work and other mental health professions) for faculty and student recruitment and professional education and training. The program received first-time fund-

¹U.S. Bureau of Labor Statistics. 2009. *Occupational Outlook Handbook, 2010–11 Edition: Social Workers*, <http://data.bls.gov/cgi-bin/print.pl/oco/ocos060.htm>. Retrieved March 28, 2012.

ing of \$10 million in the final fiscal year 2012 appropriations bill. The President's budget request for fiscal year 2013 would reduce funding to \$5 million. CSWE urges the subcommittee to maintain funding for this new and critically needed program at \$10 million in fiscal year 2013. This is the only program in the Federal Government that is explicitly focused on recruitment and retention of social workers and other mental and behavioral health professionals.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)
MINORITY FELLOWSHIP PROGRAM

The goal of the SAMHSA Minority Fellowship Program (MFP) is to achieve greater numbers of minority doctoral students preparing for leadership roles in the mental health and substance use fields. According to SAMHSA, minorities make up approximately one-fourth of the population, but only 10 percent of mental health providers come from ethnic minority communities. CSWE is one of six grantees of this critical program and administers funds to exceptional minority doctoral social work students. Other grantees include national organizations representing nursing, psychology, psychiatry, marriage and family therapy, and professional counselors. SAMHSA makes grants to these six organizations, who in turn recruit minority doctoral students into the program from the six distinct professions.

CSWE urges the subcommittee to appropriate \$5.7 million for the MFP in fiscal year 2013, which is equal to the fiscal year 2012 enacted level. The President's budget request for fiscal year 2013 proposes a 23.4 percent cut to the program, which if appropriated would significantly reverse progress made over the last several years by bringing funding down to the lowest level in nearly 5 years. This cut would translate to a reduction in the number of minority mental health professions trained to serve vulnerable populations. Each of the MFP grantee organizations, including CSWE, would be forced to significantly scale back the support provided to minority doctoral students. With respect to the social work doctoral fellows, a 23 percent cut would have the following impacts:

- The program would not have sufficient funds to cover the stipend increase for CSWE's current class of 25 fellows and would need to eliminate all other financial support to the fellows;
- Fellows would not have funds to attend CSWE's Annual Program Meeting, which represents the only face-to-face meeting of fellows from doctoral programs located in different parts of the United States and is essential to professional development and collaborative networking; and
- There would be no tuition support (currently set at \$500 per student) to fellows to assist them in timely degree completion.

SAMHSA BREAKDOWN OF THE MINORITY FELLOWSHIP PROGRAM FUNDING REQUEST

[This program is funded through three separate accounts within SAMHSA]

	Requested program funding	President's fiscal year 2013 request	Fiscal year 2012 funding
Programs of Regional and National Significance, Center for Mental Health Services (CMHS)	\$5,089,000	\$3,755,000	\$5,089,000
Programs of Regional and National Significance, Center for Substance Abuse Treatment (CSAT)	546,000	546,000	546,000
Programs of Regional and National Significance, Center for Substance Abuse Prevention (CSAP)	71,000	71,000	71,000
Total, MFP funding	5,706,000

Since its inception, the MFP has helped support doctoral-level professional education for more than 1,000 ethnic minority social workers, psychiatrists, psychologists, psychiatric nurses, and family and marriage therapists. Still, the program continues to struggle to keep up with the demands that are plaguing these health professions. Severe shortages of mental health professionals often arise in underserved areas due to the difficulty of recruitment and retention in the public sector. Nowhere are these shortages more prevalent than within Tribal communities, where mental illness and substance use go largely untreated and incidences of suicide continue to increase. Studies have shown that ethnic minority mental health professionals practice in underserved areas at a higher rate than nonminorities. Furthermore, a direct positive relationship exists between the numbers of ethnic minority

mental health professionals and the utilization of needed services by ethnic minorities.

Level funding is needed simply to maintain the program's current capacities to provide education and training for minority mental health and substance use professionals. Much work is still needed in order to adequately address the mental health needs of minority populations; maintaining funding for the MFP is a small step the subcommittee can take in fiscal year 2013.

Thank you for the opportunity to express these views. Please do not hesitate to call on CSWE should you have any questions or require additional information.

PREPARED STATEMENT OF THE COLLEGE OF VETERINARY MEDICINE, NURSING &
ALLIED HEALTH, TUSKEGEE UNIVERSITY

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Tsegaye Habtemariam, dean of the College of Veterinary Medicine, Nursing, and Allied Health at Tuskegee University. The mission (purpose) of Research and Advanced Studies at the College of Veterinary Medicine, Nursing & Allied Health (CVMNAH) is to transform trainees into ambassadors of the Tuskegee tradition to benefit man and animals. Such a tradition is honed in the "one medicine-one health" concept that for decades has guided our academic mission, to expand biosciences and create bridges between veterinary medicine, agricultural and food sciences on one side and human health and welfare on the other.

Mr. Chairman, I speak for our institutions, when I say that the minority health professions institutions and the Title VII Health Professions Training programs address a critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, even after the landmark passage of health reform, it is important to note that our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. Mr. Chairman, I would like to share with you how your committee can help Tuskegee continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need—even in austere financial times.

An October 2006 study by the Health Resources and Services Administration (HRSA)—during the Bush administration—entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

In fiscal year 2013, funding for the Title VII Health Professions Training programs must be robust, especially the funding for the Minority Centers of Excellence (COEs) and Health Careers Opportunity Program (HCOPs). In addition, the funding for the National Institutes of Health (NIH)'s National Institute on Minority Health

and Health Disparities (NIMHD), as well as the Department of Health and Human Services (HHS)'s Office of Minority Health (OMH), should be preserved.

Minority Centers of Excellence.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions to the training of minorities in the health professions. Congress later went on to authorize the establishment of “Hispanic”, “Native American” and “Other” Historically black COEs. For fiscal year 2013, I recommend a funding level of \$24.602 million for COEs.

Health Careers Opportunity Program (HCOP).—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. For fiscal year 2013, I recommend a funding level of \$22.133 million for HCOPs.

National Institutes of Health

Research Centers at Minority Institutions.—The Research Centers at Minority Institutions program (RCMI), newly moved to the National Institute on Minority Health and Health Disparities has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2013.

National Institute on Minority Health and Health Disparities.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professions institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through its Centers of Excellence program. For fiscal year 2013, I recommend funded increases proportional with the funding of the overall NIH, with increased FTEs.

Department of Health and Human Services

Office of Minority Health.—Specific programs at OMH include: assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals; assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers; supporting conferences for high school and undergraduate students to interest them in health careers, and supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. For fiscal year 2013, I recommend a funding level of \$65 million for the OMH.

Department of Education

Strengthening Historically Black Graduate Institutions.—The Department of Education's Strengthening Historically Black Graduate Institutions (HBGI) program (Title III, Part B, Section 326) is extremely important to AMHPS. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2013, an appropriation of \$65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, AMHPS' member institutions and the Title VII Health Professions Training programs and the historically black health professions schools can help this country to overcome health disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. CVMNAH seeks to close the

ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work toward the goal of eliminating that disparity everyday.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE DYSTONIA MEDICAL RESEARCH FOUNDATION

Summary of recommendations for fiscal year 2013:

- \$32 billion for the National Institutes of Health (NIH) and concurrent percentage increases across its institutes and centers.
- Continue to support the Dystonia Coalition within the Rare Disease Clinical Research Network (RDCRN) coordinated by the Office of Rare Diseases Research (ORDR).
- Expand dystonia research at NIH through the National Institute on Neurological Disorders and Stroke (NINDS), the National Institute on Deafness and Other Communication Disorders (NIDCD), and the National Eye Institute (NEI).

Dystonia is a neurological movement disorder characterized by involuntary muscle spasms that cause the body to twist, repetitively jerk, and sustain postural deformities. Focal dystonia affects specific parts of the body, while generalized dystonia affects multiple parts of the body at the same time. Some forms of dystonia are genetic but dystonia can also be caused by injury or illness. Although dystonia is a chronic and progressive disease, it does not impact cognition, intelligence, or shorten a person's life span. Conservative estimates indicate that between 300,000 and 500,000 individuals suffer from some form of dystonia in North America alone. Dystonia does not discriminate, affecting all demographic groups. There is no known cure for dystonia and treatment options remain limited.

Although little is known regarding the causes and onset of dystonia, two therapies have been developed and proved particularly useful to control patients' symptoms. Botulinum toxin (Botox/Myobloc) injections and deep brain stimulation (DBS) have shown varying degrees of success alleviating dystonia symptoms. Until a cure is discovered, the development of management therapies such as these remains vital, and more research is needed to fully understand the onset and progression of the disease in order to better treat patients.

Dystonia Research at the National Institutes of Health

Currently, dystonia research at NIH is conducted through the National Institutes on Neurological Disorders and Stroke (NINDS), the National Institute on Deafness and Other Communication Disorders (NIDCD), the National Eye Institute (NEI), and the Office of Rare Diseases Research (ORDR).

ORDR coordinates the Rare Disease Clinical Research Network (RDCRN) which provides support for studies on the natural history, epidemiology, diagnosis, and treatment of rare diseases. RDCRN includes the Dystonia Coalition, a partnership between researchers, patients, and patient advocacy groups to advance the pace of clinical research on cervical dystonia, blepharospasm, spasmodic dysphonia, craniofacial dystonia, and limb dystonia. The Dystonia Coalition has made tremendous progress in recruiting patients for clinical trials and funding four promising studies that hold great hope for advancing understanding and treatment of primary focal dystonias. The DMRF urges the subcommittee to continue its support for the Dystonia Coalition within the Rare Disease Clinical Research Network at ORDR.

The majority of dystonia research at NIH is conducted through NINDS. NINDS has utilized a number of funding mechanisms in recent years to study the causes and mechanisms of dystonia. These grants cover a wide range of research including the genetics and genomics of dystonia, the development of animal models of primary and secondary dystonia, molecular and cellular studies in inherited forms of dystonia, epidemiology studies, and brain imaging. The DMRF urges the subcommittee to support NINDS in conducting and expanding critical research on dystonia.

NIDCD and NEI also support research on dystonia. NIDCD has funded many studies on brainstem systems and their role in spasmodic dysphonia. Spasmodic dysphonia is a form of focal dystonia which involves involuntary spasms of the vocal cords causing interruptions of speech and affecting voice quality. NEI focuses some of its resources on the study of blepharospasm. Blepharospasm is an abnormal, involuntary blinking of the eyelids which can cause blindness due to a patient's inability to open their eyelids. DMRF encourages partnerships between NINDS, NIDCD and NEI to further dystonia research.

In summary, the DMRF recommends the following for fiscal year 2013:

- \$32 billion for NIH and a proportional increase for its Institutes and Centers.
- Continued support for the Dystonia Coalition within the Rare Diseases Clinical Research Network at ORDR.
- Increased portfolio of dystonia research at NIH through NINDS, NIDCD, NEI, and ORDR.

The Dystonia Medical Research Foundation

The Dystonia Medical Research Foundation was founded over 30 years ago and has been a membership-driven organization since 1993. Since its inception, the goals of DMRF have remained to advance research for more effective treatments of dystonia and ultimately find a cure; to promote awareness and education; and support the needs and well being of affected individuals and their families.

Thank you for the opportunity to present the views of the dystonia community, we look forward to providing any additional information.

PREPARED STATEMENT OF THE ELDER JUSTICE COALITION

The Elder Justice Coalition (EJC) thanks you for providing an opportunity to submit testimony as you consider a fiscal year 2013 Labor-HHS, and Education appropriations bill. The EJC is a 3,000 member strong, nonpartisan organization dedicated to advocating for funding for the Elder Justice Act (EJA) and related elder abuse prevention legislation. The EJA was passed over 2 years ago and while authorized funding for the EJA is \$195 million per year, for the second year in a row, zero funds have been appropriated for the EJA. Two years later, vulnerable older adults who should be protected by the law are confronted with the same threats of abuse, neglect, and exploitation.

The President's fiscal year 2012 budget requested a total of \$21.5 million for the EJA. We strongly supported that level last year and continue to this year. This funding was targeted for State adult protective services (APS) operations and the Long-Term Care Ombudsman Program. APS workers are often the first responders to cases of abuse and neglect. They are faced with increasing and complex caseloads yet; there is no dedicated Federal funding stream for APS programs. The Long-Term Care Ombudsman Program provides resident advocacy to elders and adults with disabilities who live in long-term care settings. This program is consistently underfunded.

According to the Department of Justice, 1 out of every 10 older adults are victims of elder abuse. A 2011 study on elder abuse prevalence indicated that out of 23.5 elder abuse cases, only 1 is reported. For financial exploitation, the ratio is an astounding 43.9 to 1 reported. A 2011 study found that the annual financial loss by victims of elder financial abuse is at least \$2.9 billion, a 12 percent increase from the \$2.6 billion estimated in a similar 2009 study.

We urge you to include a minimum appropriation of \$21.5 million for the Elder Justice Act in your fiscal year 2013 Labor-HHS appropriations bill. We feel the President's fiscal year 2013 request of \$8 million is simply inadequate. We ask you to consider the fact that funds we invest in elder abuse prevention today will save Medicaid and Medicare dollars that elder abuse victims might otherwise need.

We thank you for your consideration and please feel free to contact me with questions or concerns.

PREPARED STATEMENT OF THE ELDERCARE WORKFORCE ALLIANCE

Mr. Chairman and Members of the Subcommittee: We are writing on behalf of the Eldercare Workforce Alliance (EWA), which is comprised of 29 national organizations united to address the immediate and future workforce crisis in caring for an aging America. As the Subcommittee begins consideration of funding for programs in fiscal year 2013, the Alliance¹ asks that you consider \$48.7 million in funding for the geriatrics health professions and direct-care worker training programs that are authorized under Titles VII and VIII of the Public Health Service Act as follows:

- \$40.3 million for Title VII Geriatrics Health Professions Programs;
- \$3.4 million for direct care workforce training; and
- \$5 million for Title VIII Comprehensive Geriatric Education Programs.

¹The positions of the Eldercare Workforce Alliance reflect a consensus of 75 percent or more of its members. This testimony reflects the consensus of the Alliance and does not necessarily represent the position of individual Alliance member organizations.

Geriatrics health profession and direct-care worker training programs are integral to ensuring that America's healthcare workforce is prepared to care for the Nation's rapidly expanding population of older adults.

We appreciate President Obama's commitment to targeting resources to the programs which are most critical to meeting our Nation's challenges in a time of fiscal constraint. Funding included in his fiscal year 2013 budget for the Geriatrics Health Professions programs administered through the Health Resources and Services Administration (HRSA) under Title VII and Title VIII of the Public Health Service Act is one such critical target. His request represents a welcome, though still inadequate, investment in equipping the Nation's healthcare workforce to meet the needs of America's older adults. HRSA's budget justification recognizes the immediacy of the eldercare workforce crisis by identifying "enhancing geriatric/elder care training and expertise" as one of their top five priorities.

At a minimum, EWA asks the Congress to support the full amount of the President's request for these programs, and to consider the importance of the additional investments needed in order to realize the healthcare workforce goals set forth in the recently released draft National Action Plan on Alzheimer's and the bipartisan commitment to enhancing the primary care workforce of which geriatrics is a part. According to a 2008 MedPAC report, among physicians who specifically train in and provide primary care, geriatricians spend the most time providing non-procedural primary care with 65 percent of their payments derived from primary care services such as office and home visits and visits to patients in non-acute settings.² Geriatrics and gerontological health professionals typically care for the 20 percent of Medicare beneficiaries who account for 80 percent of Medicare costs. The Geriatrics Health Professions programs support geriatrics faculty and programs that we need to train other members of the care team to provide the type of multidisciplinary care that is the hallmark of geriatrics.

In light of current fiscal constraints, EWA specifically requests \$48.7 million in funding for the following programs administered through the Health Resources and Services Administration (HRSA) under Title VII and VIII of the Public Health Service Act.

Title VII: Geriatrics Health Professions Appropriations Request: \$40.3 Million

Title VII Geriatrics Health Professions programs are the only Federal programs that: (1) seek to increase the number of faculty with geriatrics expertise in a variety of disciplines; and (2) offer critically important training for the healthcare workforce overall to improve the quality of care for America's elders.

Geriatric Academic Career Awards (GACA).—The goal of this program is to promote the development of academic clinician educators in geriatrics.

—*Program Accomplishments.*—In Academic Year 2010–2011, the GACA Program funded 68 full-time junior faculty awardees. These awardees provided interdisciplinary training in geriatrics to 38,392 health professionals in clinical geriatrics; provided interdisciplinary team training to 6,617 clinical staff in various geriatric clinical settings; and provided geriatric services to 57,364 geriatric patients who are underserved and uninsured patients in acute care, geriatric ambulatory care, long-term care, and geriatric consultation services settings. HRSA, through the Affordable Care Act, expanded the awards to be available to more disciplines. EWA strongly supports and requests adequate funding for future expansion. Currently, new awardees are selected only every 5 years and to meet the need for clinician educators in all disciplines, EWA believes that we need to invest more in this program in order to develop adequate numbers of faculty to provide this training. Specifically, these academic career development awards should be available to clinician educators annually. EWA's fiscal year 2013 request of \$5.5 million includes will support current GAC Awardees in their development as clinician educators.

Geriatric Education Centers (GEC).—The goal of the Geriatric Education Centers is to provide quality interdisciplinary geriatric education and training to the health professions workforce including geriatrics specialists and non-specialists.

—*Program Accomplishments.*—In Academic Year 2010–2011, the 45 GEC grantees developed and provided 2,103 education and training offerings to health professions students, faculty, and practitioners related to care of older adults. Interdisciplinary education and training was provided to 10,703 interdisciplinary teams. The grantees provided education and training to 64,414 health professions students, faculty, and practitioners. The GECs provide much needed education and training. As part of the ACA, the Congress authorized a supple-

² Medicare Payment Advisory Commission, Report to the Congress: Reforming the Delivery System (Washington: MedPAC, June 2008), chap. 2, p.34.

mental grant award program that will train additional faculty through a mini-fellowship program. The program provides training to family caregivers and direct care workers. Our funding request of \$22.7 million includes support for the core work of 45 GECs and \$2.7 million awarded to 24 GECs that would be funded to undertake development of mini-fellowships under the supplemental grants program included in ACA.

Geriatric Training Program for Physicians, Dentists, (GTPD) and Behavioral and Mental Health Professions.—The goal of the GTPD is to increase the number and quality of clinical faculty with geriatrics and cultural competence, including retraining mid-career faculty in geriatrics.

—*Program Accomplishments.*—In Academic Year 2010–2011, 13 non-competing continuation grants were supported. A total of 54 physicians, dentists and psychiatry fellows provided geriatric care to 24,139 older adults across the care continuum. Geriatric physician fellows provided healthcare to 13,788 older adults; geriatric dental fellows provided healthcare to 4,834 older adults; and geriatric psychiatric fellows provided healthcare to 5,516 older adults. This program supports training additional faculty in medicine, dentistry, and behavioral and mental health so that they have the expertise, skills and knowledge to teach geriatrics and gerontology to the next generation of health professionals in their disciplines. EWA's funding request of \$8.8 million will support 13 institutions to continue this important faculty development program.

Geriatric Career Incentive Awards Program.—Congress authorized this new program through the ACA. It offers grants to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management. EWA's funding request of \$3.3 million supports implementation of this new program.

Title VII Direct-Care Worker Training Program Appropriations Request: \$3.4 Million

Direct-care workers help older people carry out the basic activities of daily living and are critical to ensuring an adequate geriatrics workforce. More than 1 million additional direct-care workers will be needed by 2018, according to the latest employment projections.

Training Opportunities for Direct Care Workers.—In the ACA Congress approved a program administered by HHS that will offer advanced training opportunities for direct care workers. While this vital training program was left out of President Obama's budget, EWA believes the Congress must fund it to create new employment opportunities by offering new skills through training. EWA's funding request of \$3.4 million will support the Department of Labor to establish this unique grant program to support community colleges in increasing the geriatrics knowledge and expertise of this workforce.

Title VIII Geriatrics Nursing Workforce Development Programs Appropriations Request: \$5 Million

These programs, administered by the HRSA, are the primary source of Federal funding for advanced education nursing, workforce diversity, nursing faculty loan programs, nurse education, practice and retention, comprehensive geriatric education, loan repayment, and scholarship.

Comprehensive Geriatric Education Program.—The goal of this program is to provide quality geriatric education to individuals caring for the elderly.

—*Program Accomplishments.*—In Academic Year 2010–2011, 27 non-competing Comprehensive Geriatric Education (CGEP) grantees provided education and training to 3,645 registered nurses, 1,238 registered nursing students, 870 direct service workers, 569 licensed practical/vocational nurses, 264 faculty and 5,344 allied health professionals. This program supports additional training for nurses who care for the elderly; development and dissemination of curricula relating to geriatric care; and training of faculty in geriatrics. It also provides continuing education for nurses practicing in geriatrics.

Traineeships for Advanced Practice Nurses.—Through the ACA, the Comprehensive Geriatric Education Program is being expanded to include advanced practice nurses who are pursuing long-term care, geropsychiatric nursing or other nursing areas that specialize in care of elderly.

EWA's funding request of \$5 million supports the training of nurses who care for older adults and offer traineeships to nurses under the newly implemented traineeship program.

On behalf of the members of the Eldercare Workforce Alliance, we commend you on your past support for geriatric workforce programs and ask that you join us in supporting the geriatrics workforce at this critical time—for all older Americans deserve quality of care, now and in the future.

Thank you for your consideration.

PREPARED STATEMENT OF THE FEDERATION OF AMERICAN SOCIETIES FOR
EXPERIMENTAL BIOLOGY

The Federation of American Societies for Experimental Biology (FASEB) respectfully requests a fiscal year 2013 appropriation of \$32 billion for the National Institutes of Health (NIH) as the first step of a program of sustained growth that will keep pace with increasing scientific opportunities and return to the demonstrated capacity of the research enterprise.

As a federation of 26 scientific societies, FASEB represents more than 100,000 life scientists and engineers, making it the largest coalition of biomedical research associations in the United States. FASEB's mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences, including the research funded by NIH, through service to its member societies and collaborative advocacy. FASEB enhances the ability of scientists and engineers to improve—through their research—the health, well-being, and productivity of all people.

Research funded by NIH is essential for improving health, reducing human suffering, and protecting the Nation against new and emerging health threats. As a result of the prior investment in medical research at NIH, scientists have developed vaccines to protect our citizens from cervical cancer, flu, and meningitis; increased survival rates from the most common form of childhood leukemia, which are now at 90 percent; and combined effective medicines and a broad base of knowledge about lifestyle changes to reduce the death rate for heart disease by more than 60 percent and stroke by 70 percent. Many of these advances arose from non-medically targeted investigations designed to explain basic molecular, cellular, and biological mechanisms.

More recently, researchers supported by NIH found that a saliva sample from a newborn can be used to quickly and effectively detect cytomegalovirus (CMV) infection, a major cause of hearing loss in children. CMV is the most common infection passed by a mother to her unborn child. As many as 30,000 children are infected with the virus at birth; and 10 to 15 percent of them are at risk for developing hearing loss. Monitoring infected children for signs of hearing loss as they grow is the best way to ensure they get early treatment, but they often show no symptoms. Better CMV screening at birth could help doctors determine which patients to monitor for symptoms so they can be treated as quickly as possible. NIH researchers also discovered that a noninvasive technique that uses light therapy to selectively destroy cancerous cells in mice without harming surrounding tissue could eventually be used to treat tumors in humans, a process known as photoimmunotherapy. Using photoimmunotherapy, scientists were able to dramatically shrink tumors in mice after a single dose of infrared light therapy. This method has the potential to replace some surgical, radiation, and chemotherapy treatments. Last year, an international HIV prevention trial funded by NIH was named the "Breakthrough of the Year" by the journal *Science*. Researchers found that if HIV-infected heterosexual individuals began taking antiretroviral medicines when their immune systems are relatively healthy, as opposed to delaying therapy until the disease has advanced, they are 96 percent less likely to transmit the virus to their uninfected partners. The study convincingly demonstrated that antiretroviral medications cannot only treat but also prevent the transmission of HIV infection among heterosexual individuals, adding to the existing base of public health strategies that can be used to make a significant impact on the HIV pandemic.

These successes are the direct result of a vigorous medical research effort. Sustaining this robust enterprise is crucial for meeting the known and unknown challenges that are surely coming, such as the increasing numbers of Alzheimer's disease sufferers as the baby boomer generation ages, the increasing incidence of obesity-associated type 2 diabetes, and potential threats through bioterrorism.

In addition to improving health, support for medical research contributes to the Nation's economy. More than 80 percent of NIH funds are distributed through competitive grants to more than 300,000 scientists who work at universities, medical schools, and other research institutions in nearly every congressional district in the United States. It is critically important that the Nation continue to capitalize on previous investments to drive research progress, train the next generation of scientists, promote economic growth, and maintain leadership in the global innovation economy, particularly as other countries increase their investments in scientific research.

Predictable and Sustainable Funding Will Drive Innovation and Progress

The broad program of research supported by NIH is essential for improving our understanding of diseases and is a primary source of new innovations in healthcare and other areas, but because of the scale, scope, and time involved, it is the kind of investment that private industry could not afford to undertake. Unfortunately, due to several years of flat funding and spending cuts enacted in 2011, the NIH budget is insufficient to fund all of the critical research that needs to be done. Furthermore, the rising costs of research and a loss of purchasing power in the NIH budget have led to a decrease in the number of research grants awarded to investigators. Data¹ from the NIH website recently analyzed by FASEB demonstrate how difficult times have become:

—In constant dollars (adjusted for inflation), the fiscal year 2012 budget and the President's proposal for fiscal year 2013 are \$4 billion lower than the peak year (fiscal year 2003) and at the lowest level since fiscal year 2001.

—The number of research project grants funded by NIH has declined every year since 2004. This trend is projected to continue in fiscal year 2012 and fiscal year 2013, when NIH will fund 3,100 fewer grants than in fiscal year 2004.

—Success rates have fallen more than 14 percentage points in the past decade and are expected to decline even further in fiscal year 2012 and 2013.

This analysis clearly demonstrates that we have lost ground. If supplemental appropriations are considered, the decline is much greater. NIH reached a capacity of more than \$35 billion in fiscal year 2010–2011. The high demand for stimulus funding, and the exceptional research that it yielded, illustrate that the capacity of the research system is at least \$35 billion.

NIH needs sustainable and predictable budget growth in order to continue important scientific investigations that improve the health of all Americans. Advances in research will enhance our ability to respond quickly to new health threats and exciting NIH initiatives currently underway are poised to accelerate our progress in the search for cures. It would be tragic if we could not capitalize on the many opportunities before us. The discovery of a universal vaccine to protect adults and children against both seasonal and pandemic flu; nanomedicine that can target cancer cells precisely, with limited impact on healthy cells; and development of gene chips and DNA sequencing technologies that can predict risk for high blood pressure, kidney disease, diabetes, and obesity are just a few of the research breakthroughs that will be delayed if we fail to sustain the investment in NIH.

Maintaining the current level of effort requires an increase equal to the biomedical research and development price index (BRDPI), which is projected to be 2.8 percent for fiscal year 2013, and additional funds are essential to take advantage of the exciting and urgent opportunities in science and medicine available today. A 1.7 percent increase above BRDPI could provide support for nearly 170 additional research grants. To prevent further erosion of the Nation's capacity for biomedical research, FASEB recommends an appropriation of at least \$32 billion for NIH in fiscal year 2013.

Thank you for the opportunity to offer FASEB's support for NIH.

PREPARED STATEMENT OF FRIENDS OF THE HEALTH RESOURCES AND SERVICES
ADMINISTRATION

On behalf of the Friends of the Health Resources and Services Administration (HRSA), we write to respectfully request a minimum overall funding level of \$7 billion for fiscal year 2013 for HRSA. As a national leader in providing health services for individuals and families, HRSA, operates programs in every State, territory, and thousands of communities across the country. The agency serves as a health safety net for the medically underserved, including the 50 million Americans who were uninsured in 2010 and 60 million Americans who live in neighborhoods with scarce primary healthcare services.

The Friends of HRSA is a nonprofit and non-partisan alliance of more than 180 national organizations, collectively representing millions of public health and healthcare professionals, academicians, and consumers. The coalition's principal goal is to ensure that HRSA's broad health programs have continued support in order to reach the populations presently underserved by the Nation's patchwork of health services.

While we recognize the reality of the current fiscal climate, our request of \$7 billion represents the minimum amount necessary for HRSA to continue meeting the healthcare needs of the American public—anything less will undermine the efforts

¹ <http://www.faseb.org/LinkClick.aspx?fileticket=aDQlNW4adp0%3d&tabid=431>.

of HRSA programs to improve access to quality healthcare for millions of our Nation's most vulnerable citizens. Additionally, the Friends of HRSA remains concerned about the deep cuts the agency has endured over the past few years—HRSA's discretionary budget has been reduced by more than \$1.2 billion since fiscal year 2010. Cuts of this magnitude have had a serious negative impact on the agency's ability to carry out critical public health programs and services for millions of Americans, and as a result, have the potential to lead to significant increased costs to our healthcare system in the long term. Therefore, our requested level of funding is necessary to ensure support for the continued implementation of HRSA programs including:

- Health Professions programs that support the education and training of primary care physicians, nurses, dentists, optometrists, physician assistants, nurse practitioners, clinical nurse specialists, public health personnel, mental and behavioral health professionals, pharmacists, and other allied health providers; improve the distribution and diversity of health professionals in medically underserved communities and ensure a sufficient and capable health workforce able to provide care for all Americans and respond to the growing demands of our aging and increasingly diverse population. In addition, the Patient Navigator Program helps individuals in underserved communities, who suffer disproportionately from chronic diseases, navigate our complex health system.
- Primary Care programs that support more than 7,000 community health centers and clinics in every State and territory, improving access to preventive and primary care in geographically isolated and economically distressed communities. In addition, the health centers program targets populations with special needs, including migrant and seasonal farm workers, homeless individuals and families, and those living in public housing.
- Maternal and Child Health programs that include the Title V Maternal and Child Health Block Grant, Healthy Start, and others support a myriad of initiatives designed to promote optimal health, reduce disparities, combat infant mortality, prevent chronic conditions, and improve access to quality healthcare for more than 40 million women and children, including children with special healthcare needs.
- HIV/AIDS programs that provide assistance to metropolitan and other areas most severely affected by the HIV/AIDS epidemic; support comprehensive care, drug assistance and support services for people living with HIV/AIDS; provide education and training for health professionals treating people with HIV/AIDS; and, address the disproportionate impact of HIV/AIDS on women and minorities.
- Family Planning Title X services that ensure access to a broad range of reproductive, sexual, and related preventive healthcare for more than 5.2 million poor and low-income women, men, and adolescents at nearly 4,400 health centers nationwide. This program helps improve maternal and child health outcomes and promotes healthy families.
- Rural Health programs that improve access to care for the more than 60 million Americans who live in rural areas. Rural Health Outreach and Network Development Grants, Rural Health Research Centers, Rural and Community Access to Emergency Devices Program, among other programs support community-based disease prevention and health promotion projects, help rural hospitals and clinics implement new technologies and strategies, and build health system capacity in rural and frontier areas.
- Special Programs that include the Organ Procurement and Transplantation Network, the National Marrow Donor Program, the C.W. Bill Young Cell Transplantation Program, and National Cord Blood Inventory, which help people who need potentially life-saving transplants by connecting patients, doctors, donors, and researchers to the resources they need to live longer, healthier lives.

This investment is necessary to sufficiently fund these important HRSA services and programs that continue to face increasing demands. We urge you to consider HRSA's role in strengthening the foundation of health service delivery and safety net programs, which are critical components of any comprehensive plan to secure our Nation's progress and drive down long-term healthcare costs. By supporting HRSA today, we can build on the successes of the past to improve the public's health and achieve health equity through access to quality services, a skilled health workforce, and innovative programs in the future.

The members of the Friends of HRSA thank you for considering our request for \$7 billion for HRSA in the fiscal year 2013 Labor-HHS-Education appropriations bill and we appreciate the opportunity to submit our recommendation to the Subcommittee.

PREPARED STATEMENT OF THE FRIENDS OF THE NATIONAL INSTITUTE ON AGING

Senator Harkin, Senator Shelby, and members of the Subcommittee, on behalf of the Friends of the National Institute on Aging (FoNIA) at the National Institutes of Health (NIH), thank you for the opportunity to provide testimony in support of the National Institute on Aging (NIA) and to comment on the need for sustained, long-term growth in aging research.

The FoNIA is a coalition of more than 50 academic, patient-centered and not-for-profit organizations that conduct, fund or advocate for scientific endeavors to improve the health and quality of life for Americans as we age. As a coalition, we support the continuation and expansion of NIA research activities and seek to raise awareness about important scientific progress in the area of aging research currently sponsored by the Institute.

To ensure that progress in Nation's biomedical, social, and behavioral research continues, the Coalition endorses the Ad Hoc Group for Medical Research in supporting \$32 billion for NIH in fiscal year 2013. Given the unique funding challenges facing the NIA, and the range of promising scientific opportunities in the vast, diverse field of aging research, the FoNIA ask the subcommittee to recommend that NIA receive \$1.4 billion in fiscal year 2013.

The National Institute on Aging Mission

Established in 1974, NIA leads the national scientific effort to understand the nature of aging in order to promote the health and well being of older adults. NIA's mission consists of four components:

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging.
- Foster the development of research and clinician scientists in aging.
- Provide research resources.
- Disseminate information about aging and advances in research to the public, healthcare professionals, and the scientific community, among a variety of audiences.

The NIA fulfills this mission by supporting both extramural research at universities and medical centers across the United States and intramural research at laboratories in Baltimore and Bethesda, Maryland.

Research Activities and Advances

Adding to its strong record of progress throughout its 38-year history, recent NIA-supported activities and advances have contributed to improving the health and well-being of older people worldwide. Below is a summary of some of these most recent activities and advances.

Alzheimer's Disease

Alzheimer's disease (AD) is the most common cause of dementia in the elderly. Between 2.6 million and 5.1 million Americans aged 65 years and older may have AD, with a predicted increase to 13.2 million by 2050. While researchers have achieved greater understanding of the disease, there is no cure. In light of the exploding aging population, which will more than double between 2010 and 2050 to 88.5 million or 20 percent of the population, scientists are in a race against time to prevent an unprecedented AD epidemic threatening our older population.

NIA is the lead Federal research agency for Alzheimer's disease (AD). In this regard, the Institute coordinates trans-NIH AD initiatives and encourages collaboration with other Federal agencies and private research entities. As illustration of its leadership role, NIA is leading the Alzheimer's Disease Research Summit on May 14 and 15, 2012 at which officials representing Federal agencies, scientific researchers, providers, caregivers, patients and their families will convene to develop final recommendations to the National Alzheimer's Project Act Advisory Council.

The NIA's support of important AD research has contributed to important recent advances. For example, the identification of relevant Alzheimer's Disease (AD) biomarkers through the groundbreaking Alzheimer's Disease Neuroimaging Initiative, along with a deeper understanding of the disease's pathology and clinical course, have facilitated the first revision of the clinical diagnostic criteria for AD in 27 years. These new criteria address for the first time the use of imaging and biomarkers in blood and spinal fluid, and unlike the previous guidelines they cover the full spectrum of the disease, from mild cognitive impairment (MCI) through clinical dementia. To expand and intensify the translation of basic research findings into clinical studies and human trials, NIA, the National Institute of Neurological Diseases and Stroke, and the National Institute of Mental Health support an AD Translational and Drug Discovery Initiative that currently funds more than 40 projects, including a number of pilot clinical trials. In a recent, highly promising

pilot trial, a nasal-spray form of insulin delayed memory loss and preserved cognition in people with cognitive deficits ranging from MCI to moderate AD. A larger-scale study to confirm and extend these results is under development.

Increasing Healthy Life Span

Through its Division of Aging Biology, NIA supports research to improve understanding of the basic biological mechanisms underlying the process of aging and age-related diseases. The program's primary goal is to provide the biological basis for interventions in the process of aging, which is the major risk factor for many chronic diseases affecting older people. Recent significant findings that could help advance understanding of a range of chronic diseases, include the discovery of the drug rapamycin, which has been shown to extend median lifespan in a mouse model. Grantees supported by this program have also identified genetic pathways that regulate the maintenance of the stem cell microenvironment in aging tissues.

In 2011, the NIA Division of Aging Biology led the formation of the Trans-NIH GeroScience Interest Group (GIG). This working group, which is comprised currently of 19 NIH Institutes and Centers was formed to encourage trans-NIH discussion and coordination of research activities focusing on mechanisms underlying age-related changes, including those that could lead to increased disease susceptibility (e.g. stress, inflammation, etc.). Another major goal of the GIG is to raise awareness both inside and outside the NIH of the relevant role aging biology plays in the development of age-related processes and chronic disease. To achieve this goal, the working group is planning seminars that will feature internal and external speakers, as well as symposia and workshops. With additional funding, the GIG could play an instrumental role in developing trans-NIH initiatives, including funding opportunities and Common Fund initiatives, to encourage research on basic biology of aging and its relationship to earlier life events, exposures, and diseases. The FoNIA believe the GIG is an important development that will result in greater coordination of aging research activities and resources across the NIH.

Behavioral and Social Science Research

The Division of Behavioral and Social Research Program supports social and behavioral research to increase understanding of the aging process at the individual, institutional, and societal levels. Research areas include the behavioral, psychological, and social changes individuals undergo throughout the adult lifespan; participation of older people in the economy, families, and communities; the development of interventions to improve the health and cognition of older adults; and the societal impact of population aging and of trends in labor force participation, including fiscal effects on the Medicare and Social Security programs.

One of the Division's signature projects, the Health and Retirement Study (HRS), is recognized as the Nation's leading source of combined data on health and financial circumstances of Americans over age 50. HRS data have been cited in more than 1,700 scientific papers and have informed findings regarding the effects of early-life exposures on later-life health, variables associated with cognitive and functional decline in later life, and trends in retirement, savings, and other economic behaviors. It is so respected that the study is being replicated in 30 other countries. In March 2012, HRS took an important step forward by announcing that genetic data from approximately 13,000 individuals were posted to dbGAP, the NIH's online genetics database. The data are comprised of approximately 2.5 million genetic markers from each person and are immediately available for analysis by qualified researchers. These data will enhance the ability of researchers to track the onset and progression of diseases and conditions affecting the elderly.

NIA also continues to support research on the economic implications of aging and healthcare reform. In an ongoing study, the State of Oregon randomly assigned 10,000 low-income uninsured adults to the State's Medicaid program (out of a pool of 90,000 individuals who applied). The initial results from this study indicate that enrollees increased use of healthcare services and therefore program costs, but also reported improved health and well-being and reduced financial strain.

Funding Challenges

Despite its ability to support important research projects and programs, the NIA faces unique funding challenges. While the current dollars appropriated to NIA seem to have risen significantly since fiscal year 2003, when adjusted for inflation, they have decreased almost 18 percent in the last 9 years. Further, according to the NIH Almanac, out of each dollar appropriated to NIH, only 3.6 cents goes toward supporting the work of the NIA-compared to 16.5 cents to the National Cancer Institute, 14.6 cents to the National Institute of Allergy and Infectious Diseases, 10 cents to the National Heart, Lung and Blood Institute, and 6.3 cents to the National Institute of Diabetes and Digestive and Kidney Diseases. Finally, despite enacting cost

cutting measures, such as differing paylines for projects costing above and below \$500,000 and a decrease in non-competing commitments, NIA's success rate remained below the average NIH success rate between 2008 and 2011.

The undeniable rise in the U.S. aging population is another factor justifying the need for increasing the NIA budget. According to the U.S. Census Bureau, the number of people age 65 and older will more than double between 2010 and 2050 to 88.5 million or 20 percent of the population; and those 85 and older will increase three-fold to 19 million. Aging is a major risk factor for numerous diseases and disorders. These factors justify the need to provide NIA with \$1.4 billion, an increase of \$300 million over the Institute's fiscal year 2011 level, in fiscal year 2013. It is important to note that this funding level is not only endorsed by the FoNIA and the Leadership Conference on Aging, but also was endorsed by more than 500 scientists nationwide who signed a letter to Dr. Collins in December 2011, requesting this amount.

Conclusion

We thank you, Mr. Chairman, and the Subcommittee for supporting the NIA and, again, for the opportunity to express our support for the Institute and its important research.

PREPARED STATEMENT OF THE FRIENDS OF THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The Friends of the National Institute of Child Health and Human Development (NICHD) is a coalition of more than 100 organizations, representing scientists, physicians, healthcare providers, patients, and parents, concerned with the health and welfare of women, children, families, and people with disabilities. We are pleased to submit testimony to support the extraordinary work of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

We would like to urge all Members of Congress to continue sustained and predictable funding for the National Institutes of Health (NIH). To ensure that progress in basic, translational and clinical research is sustained, the Coalition joins the Ad Hoc Group for Medical Research in supporting a fiscal year 2013 appropriation of at least \$32 billion for NIH.

The Coalition has a particular interest in the important research conducted and supported by the NICHD. Since its establishment in 1963, the NICHD has made great strides in meeting the objectives of its broad biomedical and behavioral research mission. The NICHD mission and portfolio includes a focus on women's health and human development, including research on child development, before and after birth; maternal, child, and family health; learning and language development; reproductive biology and population issues; and medical rehabilitation.

Although the NICHD has made significant contributions to the well-being of children, women, and families, much remains to be done. With sufficient resources, the NICHD could build upon the promising initiatives described in this testimony and produce new insights into human development and solutions to health and developmental problems for the world and for the Nation—including the families living in your districts. For fiscal year 2013, the Friends of NICHD support an appropriation of at least \$1.37 billion for NICHD.

New Discoveries

Scientific breakthroughs supported by NICHD specifically serve to prevent and treat many of the Nation's most devastating health problems, such as infant mortality and low birthweight, birth defects, intellectual and developmental disabilities, pediatric AIDS, and the reproductive and gynecologic health of women throughout their lifespans. Adding to its strong record of progress over the past 50 years, recent advances by the NICHD have contributed to the health and well-being of our Nation and world. Several highlights are:

Prematurity.—Biomedical research is critically important to understanding the causes of prematurity and developing effective prevention and treatment methods. Prematurity rates have increased almost 35 percent since 1981 at a cost to the Nation of \$26 billion annually—\$51,600 for every infant born prematurely. Direct healthcare costs to employers for a premature baby average \$41,610, 15 times higher than the \$2,830 for a healthy, full-term delivery. A breakthrough study conducted by NICHD last year showed a significant reduction in preterm delivery among women with short cervixes who are administered vaginal progesterone. The results were especially positive in reducing births pre-28 weeks. The results of this study are expected to save the healthcare system \$500 million a year. Additional research can help drive down our prematurity rates further, saving dollars and lives.

Autism.—Scientists funded through an NICHD-funded Infant Brain Imaging Study have discovered patterns of brain development in the first 2 years of life that are distinct in children who are later diagnosed with autism spectrum disorder (ASD). The study results show differences in brain structure at 6 months of age, the earliest such structural changes have been recorded in ASDs. ASDs involve communication and social difficulties as well as repetitive behavior and restricted interests. Many early behavioral signs of ASDs are not apparent until the first year of age. Typically, ASDs are diagnosed at age 3 or older. According to the U.S. Centers for Disease Control and Prevention (CDC), ASDs affect 1 of 88 children in the United States (1 in 54 for boys).

Childhood Obesity.—According to the CDC, obesity now affects 17 percent of all children and adolescents in the United States—triple the rate from just one generation ago and nearly one-third of all adults are now classified as obese, a figure that has more than doubled over the last 30 years. Health risks associated with being overweight or obese include type 2 diabetes, high blood pressure, high cholesterol, asthma, and arthritis, among other risks. While promoting healthy behaviors and physical activity is critical to child health, studies have also demonstrated that genetics could also play a factor. NIH-supported researchers have also identified locations at two genes, which, when mutated, appear to increase the likelihood of common childhood obesity. Earlier studies have identified genes associated with obesity in extremely obese youth and in adults, but the current study is the first to identify two genes associated with the less severe, more common form of obesity.

Cognitive Development.—NICHD sponsors research on reading and reading disabilities, with the goal of identifying those factors that help English speaking children, bilinguals, and children who learn English as a second language become proficient in reading and writing in English. In 2009, 21 percent of U.S. children spoke a language other than English at home. According to a recent study sponsored by the NICHD, children who grow up learning to speak two languages are better at switching between tasks than are children who learn to speak only one language, which serves as an indicator of executive functioning skills such as the ability to pay attention, plan organize, and strategize. However, the study also found that bilinguals are slower to acquire vocabulary than are monolinguals, because bilinguals must divide their time between two languages while monolinguals focus on only one.

Population Research.—In late 2011, an NICHD-supported analysis of more than 5 million medical records showed that pregnant women assaulted by an intimate partner are at increased risk of giving birth to infants at lower birth weights. Babies born at low birth weights are at higher risk for SIDS, heart and breathing problems, and learning disabilities. The American College of Obstetricians and Gynecologists used this information in developing physician training materials for screening patients for intimate partner violence.

Future Research Opportunities

Although the studies mentioned above have unquestionably made significant contributions to the well-being of our children and families, there is still much to discover about ways to improve health, learning, and quality of life. NICHD recently undertook a “visioning” process to identify critical scientific opportunities and goals for the coming decade to explore how biomedical, social and behavioral research could improve public health and prevention across its research portfolio. We support the Institute’s efforts to achieve their goals as well as those scientific opportunities below, all of which can only be achieved with adequate Federal investments.

Learning to Read, Write and Compute.—There is valuable research underway at NICHD on behavioral science, genetics, trans-disciplinary topics examining issues related to etiology, classification and definition, and prevention and remediation of learning disabilities (LD) impacting listening, speaking, reading, writing and math with an emphasis on co-morbid conditions (e.g., ADHD). Because individuals with LD continue to represent the largest population of school-age students identified for special education services in K–12 schools and continue to struggle to read, write and compute at the same rate as their peers—yet individuals with LD do not have intellectual disabilities—NICHD continues to conduct innovative research to study the neurological processes of the brain with an integrative approach, including the use of fMRI and MRI. Such integration in the research includes pursuing answers to how the brain processes information including the underlying neurological processes that support learning to read, write and compute. NICHD’s ongoing work continues to better inform best practices to improve classroom instruction and learning so that more struggling students successfully exit high school ready to attend college or receive career training.

Intellectual and Developmental Disabilities.—Ongoing support of the research in intellectual and developmental disabilities being undertaken at the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers (IDDRC) is essential. The IDDRCs have made outstanding contributions toward understanding the causes of a wide range of developmental disabilities including autism, Fragile X syndrome, Down syndrome, autism spectrum disorders (ASD), mitochondrial and other genetic/genomic disorders and environmentally induced disorders. IDDRCs have collaborated with each other to leverage resources and scientific capital on such efforts as developing a shared contact registry of individuals with Fragile X syndrome that will become a national resource to support investigators interested in studies involving this condition. Recent genetic and biomedical advances over the past few years hold the promise for understanding the threats to healthy and full development and ultimately to the prevention and amelioration of the impact of many disabilities. Additional resources are needed to help bring about progress in expanding registries to include larger samples across different disorders, support and mentor new investigators, and develop opportunities for translational research efforts to take advantage of recent findings.

Contraceptive Research and Development.—Through its investment in contraceptive evaluation research, NICHD plays a key leadership role in ensuring acceptability and effective use of existing products in various settings and populations and in addressing behavioral issues related to fertility and contraceptive use. Specific opportunities and research priorities in the area of contraceptive evaluation include evaluation of the safety and effectiveness of hormonal contraceptive options for women who are overweight or obese. The Institute's investment in contraceptive development research is critical for producing new contraceptive modalities that offer couples options with fewer side-effects and additional non-contraceptive health benefits. Specific opportunities and research priorities in the area of contraceptive development include the need for non-hormonal contraception, post-coital contraception and multipurpose prevention technologies that would prevent both pregnancy and sexually transmitted infections.

Reproductive Sciences.—Through its investment in reproductive science, NICHD conducts research to improve women's health by developing innovative medical therapies and technologies and improving existing treatment options for gynecological conditions affecting overall health and fertility. The Institute's reproductive science research makes a vital contribution to women's health by focusing on serious conditions that have been overlooked and underfunded, despite the fact that the impact many women. For example, the NICHD's Pelvic Floor Disorders Network is conducting research to improve treatment of extremely painful gynecological conditions that affect 25 percent of American women. Specific opportunities and research priorities in infertility research include the need for treatments for disorders such as endometriosis, polycystic ovarian syndrome (PCOS) and uterine fibroids which can prevent couples from achieving desired pregnancies.

Rehabilitation Research.—The NICHD houses the National Center for Medical Rehabilitation Research (NCMRR). This Center fosters the development of scientific knowledge needed to enhance the health, productivity, independence, and quality-of-life of people with disabilities. A primary goal of Center-supported research is to bring the health related problems of people with disabilities to the attention of the best scientists in order to capitalize upon the myriad advances occurring in the biological, behavioral, and engineering sciences.

Longitudinal Research.—NICHD's investments in longitudinal, large scale databases, provide rich, in-depth resources for researchers across the demographic, behavioral, social and population sciences. As public resources, these accessible databases enable scientists worldwide to conduct research on linkages between family, neighborhood and school environments, socio-economic status and behaviors that impact health outcomes in particular. Among the most important databases are the Add Health Study, the Panel Study of Income Dynamics, Fragile Families and Child Well Being.

Building Scientific Capacity.—Adequate levels of research require a robust research workforce. The average investigator is in his/her forties before receiving their first NIH grant, a huge disincentive for students considering biomedical research as a career. Complicating matters, there is a gap between the number of women's reproductive health researchers being trained and the need for such research. The NICHD-coordinated Women's Reproductive Health Research (WRHR) Career Development program seeks to increase the number of ob-gyns conducting scientific research in women's health in order to address this gap. To date 170 WRHR Scholars have received faculty positions, and 7 new and competing WRHR sites were added in 2010.

Conclusion

We deeply appreciate the consistent interest and support the Congress has shown for the NIH and NICHD. As your committee moves forward on the Labor, HHS Appropriations bill, we urge you to provide NIH and NICHD with funding levels that meet current needs for addressing health issues across the lifespan. Thank you in advance for your consideration of our views and we look forward to continuing to work with you on these critical issues.

PREPARED STATEMENT OF THE FRIENDS OF THE NATIONAL INSTITUTE ON DRUG ABUSE

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit testimony to the Subcommittee in support of the National Institute on Drug Abuse. The Friends of the National Institute on Drug Abuse (FON) is a coalition of more than 150 scientific and professional societies, patient groups, and other organizations committed to, preventing and treating substance use disorders as well as understanding their causes through the research agenda of the National Institute on Drug Abuse (NIDA). We are pleased to provide testimony in support of the work carried out by scholars around the country whose work is supported by NIDA.

Drug abuse is costly to Americans; it ruins lives, while tearing at the fabric of our society and taking a huge financial toll on our resources. Beyond the unacceptably high rates of morbidity and mortality, drug abuse is often implicated in family disintegration, loss of employment, failure in school, domestic violence, child abuse, and other crimes. Placing dollar figures on the problem; smoking, alcohol and illegal drug use results in an exorbitant economic cost on our Nation, estimated at more than \$600 billion annually. We know that many of these problems can be prevented entirely, and that the longer we can delay initiation of any use, the more successfully we mitigate future morbidity, mortality and economic burdens.

Over the past three decades, NIDA-supported research has revolutionized our understanding of addiction as a chronic, often-relapsing brain disease—this new knowledge has helped to correctly situate drug addiction as a serious public health issue that demands strategic solutions. By supporting research that reveals how drugs affect the brain and behavior and how multiple factors influence drug abuse and its consequences, scholars supported by NIDA continue to advance effective strategies to prevent people from ever using drugs and to treat them when they cannot stop.

NIDA supports a comprehensive research portfolio that spans the continuum of basic neuroscience, behavior and genetics research through medications development and applied health services research and epidemiology. While supporting research on the positive effects of evidence-based prevention and treatment approaches, NIDA also recognizes the need to keep pace with emerging problems. We have seen encouraging trends—significant declines in a wide array of youth drug use—over the past several years that we think are due, at least in part, to NIDA's public education and awareness efforts. However, areas of significant concern, such as prescription drug abuse, remain and we support NIDA in its efforts to find successful approaches to these difficult problems.

Recognizing that so many health research issues are inter-related, we request that the subcommittee provide at least \$32 billion for the National Institutes of Health, which is a \$1.3 billion or 4.3 percent increase over fiscal year 2012. This will allow NIH to keep up with inflation. Because of the critical importance of drug abuse research for the health and economy of our Nation, we also request that you provide a proportionate increase for the National Institute on Drug Abuse.

In addition, to highlight certain priority research areas within NIDA's portfolio, we respectfully request that you include the following language in the committee report accompanying the fiscal year 2013 funding recommendation for the National Institute on Drug Abuse:

“Medications Development.—With the recent reduction in the efforts of the pharmaceutical industry to develop new medications to treat diseases of the brain, the Committee encourages NIDA to continue to increase their efforts to develop medications to treat diseases of addiction. Reasonable success has occurred in the past and recent advances in knowledge support this effort.

“Translational Research.—The Committee encourages NIDA to continue its efforts to increase our knowledge of how genetics, age, environment and other factors affect the use of experimental drugs and the development of addiction.

“Education.—The educational efforts of NIDA to inform the public of the deleterious effects of abused substances and the life-threatening dangers of drug addiction

are recognized and encouraged. Progress in this area has contributed to the decreased abuse of nicotine and its long term medical consequences, including death. Adolescents and returning veterans and their families are at a high risk for drug abuse and therefore should be areas of concentration for these educational efforts.

“Prevention and Treatment.—The Committee recognizes the reported increase in abuse of marijuana and prescription drugs and encourages NIDA to support innovative approaches to prevent and treat this abuse and the resulting harmful effects. The concentration in these areas should compliment efforts to prevent and treat addiction of all abused substances.

“Prescription Drug Abuse.—Prescription drug abuse has been the focus of much work by NIDA and its grantees and although significant progress has been made, the Committee encourages NIDA to maintain its comprehensive leadership role in the effort to halt this epidemic.

“Military Personnel, Veterans, and Their Families.—The Committee commends NIDA for its successful efforts to coordinate and support research with the Department of Veterans Affairs and other NIH Institutes on substance abuse and associated problems among U.S. military personnel, veterans and their families. Many military personnel need help confronting war-related problems including traumatic brain injury, post-traumatic stress disorder, depression, anxiety, sleep disturbances, and substance abuse, including tobacco, alcohol and other drugs. Many of these problems are interconnected and contribute to individual health and family relationship crises, yet there has been little research on how to prevent and treat the unique characteristics of wartime-related substance abuse issues. The Committee encourages NIDA to continue work in this area.”

The Nation’s previous investment in scientific research to further understand the effects of abused drugs on the body has increased our ability to prevent and treat addiction. As with other diseases, much more needs be done to improve prevention and treatment of these dangerous and costly diseases. Our knowledge of how drugs work in the brain, their health consequences, how to treat people already addicted, and what constitutes effective prevention strategies has increased dramatically due to support of this research. However, since the number of individuals continuing to be affected is still rising, we need to continue the work until this disease is both prevented and eliminated from society.

We understand that the fiscal year 2013 budget cycle will involve setting priorities and accepting compromise, however, in the current climate we believe a focus on substance abuse and addiction, which according to the World Health Organization account for nearly 20 percent of disabilities among 15–44 year olds, deserve to be prioritized accordingly. We look forward to working with you to make this a reality. Thank you for your support for the National Institute on Drug Abuse.

PREPARED STATEMENT OF THE FSH SOCIETY, INC.

Honorable Chairmen Inouye and Harkin and Ranking Members Cochran and Shelby, thank you for the opportunity to submit this testimony.

I am Daniel Paul Perez, of Bedford, Massachusetts, President and CEO of the FSH Society, Inc. and an individual who has lived with facioscapulohumeral muscular dystrophy (FSHD) for 49 years. For hundreds of thousands of men, women, and children the major consequence of inheriting this form of muscular dystrophy is a lifelong progressive loss of all skeletal muscles. FSHD is a crippling and life shortening disease. No one is immune. It is both genetically and spontaneously transmitted to children. It can affect multiple generations and entire family constellations.

I have testified many times before the Congress. When I first testified, we did not know the mechanism of this disease. Now we do. When I first testified, we assumed that FSHD was a rare form of muscular dystrophy. Now we understand it to be one of the most, if not the most, prevalent form of muscular dystrophy. Congress is responsible for this success, through its sustaining support of the National Institutes of Health (NIH), enactment of the Muscular Dystrophy CARE Act and the collaborations of NIH, the Centers for Disease Control and Prevention (CDC), patient groups, and researchers, both here and internationally.

I am testifying in order to document this success and call on the Congress to take advantage of the system of discovery it has set in motion.

Mechanism of Facioscapulohumeral Muscular Dystrophy Has Been Described

On August 19, 2010, Dutch and American researchers published a paper which dramatically expanded our understanding of the mechanism of FSHD.¹ The front page story in the New York Times quoted the NIH Director, Dr. Francis Collins saying, "If we were thinking of a collection of the genome's greatest hits, this would go on the list."²

Two months later, another paper was published that made a second critical advance in determining the cause of FSHD.³ The research shows that FSHD is caused by the inefficient suppression of a gene that may be normally expressed only in early development.

On January 17, 2012, an international team of researchers led by Stephen J. Tapscott, M.D., Ph.D., of the Seattle Fred Hutchinson Center's Biology Division, published a third major advance further elucidating the mechanisms that can cause the disease genes and proteins that damage FSHD muscle cells. The research also discovered that one of the genes required for FSHD, called, DUX4 regulates cancer/testis antigens.⁴ Cancer and testis antigens are abnormally expressed in various tumor types, including melanoma and carcinomas of the bladder, lung and liver. This allows for the potential of using these antigens to create cancer vaccines.

This past week has brought five publications with significant developments on FSHD. On this day, April 26, 2012, another major breakthrough was announced. Researchers who began their careers with FSH Society fellowships reported in *Cell* of an epigenetic activatory long non-coding RNA (lncRNA) switch involved in FSHD and human genetic disease. This opens the potential to control FSHD by going after the master switch that regulates DUX4 and other genes that are necessary to cause FSHD. The master switch is a non-protein encoding lncRNA that has a normal developmental function and that can cause disease by allowing normally quiescent genes to produce too much protein at the wrong time and wrong place.⁵ This study published in *Cell* is important for several reasons. First, it further defines a mechanism of disease that could help explain the workings of diseases other than FSHD, including some forms of diabetes or cancer. Second, it clarifies the mechanism at work in FSHD and has identified specific therapeutic targets to achieve a treatment for FSHD.

I am proud to say that many of these researchers have started their efforts in FSHD with seed funding from the FSH Society and have received continued support from the FSH Society, the National Institutes of Health, and the Muscular Dystrophy Association and other partners. This shows the power of the collaboration among funders, patient groups and researchers to advance the search for cures and treatments.

The renowned FSH Society Scientific Advisory Board (SAB) led and chaired by M.I.T. Professor David E. Housman, Ph.D. has made great strides in the past 20 years. FSHD had long been thought of as a Mendelian disease caused by a defect in a single gene inherited in an autosomal dominant fashion. Two decades of work by a small group of patients and scientists have shown that, FSHD, is free of damage from any protein-encoding gene on the chromosomes that define human life. FSH Society seed funding has allowed researchers to understand how FSHD works, first in the cell, then at the chromosome level, then at a specific address on the chromosome called 4q35, then by discovering that the disease is associated with a shortening or modification of repetitive sequences of DNA at 4q35 called D4Z4, then by studying the expression of genes and different types of RNA messages from within each repeat of D4Z4, and finally how D4Z4 repeat sequences regulate gene expression and that mutations and changes of such elements can influence the progression of a human genetic disease.

Even with these breakthroughs, much work remains to be done. Given the recent developments in our definition of FSHD, the current potential is even greater for intervention strategies, therapeutics, and the planning and conducting of trials. We

¹Lemmers, R.J., et al, A Unifying Genetic Model for Facioscapulohumeral Muscular Dystrophy, *Science* 24 September 2010: Vol. 329 no. 5999 pp. 1650–1653.

²Kolata, G., Reanimated "Junk" DNA Is Found to Cause Disease. *New York Times*, Science. Published online: August 19, 2010 <http://www.nytimes.com/2010/08/20/science/20gene.html>.

³Snider, L., Geng, L.N., Lemmers, R.J., Kyba, M., Ware, C.B., Nelson, A.M., Tawil, R., Filippova, G.N., van der Maarel, S.M., Tapscott, S.J., and Miller, D.G. (2010). Facioscapulohumeral dystrophy: incomplete suppression of a retrotransposed gene. *PLoS Genet.* 6, e1001181.

⁴Geng et al., DUX4 Activates Germline Genes, Retroelements, and Immune Mediators: Implications for Facioscapulohumeral Dystrophy, *Developmental Cell* (2012), doi:10.1016/j.devcel.2011.11.013.

⁵Cabianca et al., A Long ncRNA Links Copy Number Variation to a Polycomb/Trithorax Epigenetic Switch in FSHD Muscular Dystrophy, *Cell* (2012), doi:10.1016/j.cell.2012.03.035.

need to be prepared for this new era in the science of FSHD by accelerating efforts in the following four areas:⁶

Genetics/epigenetics

It is now broadly accepted that the dysregulation of the expression of D4Z4/DUX4 plays a major role in FSHD1 (FSHD1A) and FSHD2 (FSHD1B). Additional FSHD (modifier) loci are likely to exist.

FSHD molecular networks.—The relaxation of the chromatin structure on permissive chromosome 4 haplotypes leads to activation of downstream molecular networks. Importantly, the upstream processes—triggering of activation—are equally important. Detailed studies on these processes are crucial for insight into the molecular mechanisms of FSHD pathogenesis and may contribute to explaining the large intra- and interfamily clinical variability. Importantly such work will lead to intervention (possibly also prevention) targets.

Additional FSHD genes.—FSHD2 is characterized by hypomethylation of D4Z4 on chromosome 4 as well as chromosome 10. This also leads to bursts of DUX4 expression. Identification of the responsible factor (gene) and molecular mechanisms is of utmost importance.

Clinical trial readiness

It is now broadly accepted that dysregulation of the expression of D4Z4/DUX4 is at the heart of FSHD1 and FSHD2. This finding opens perspectives for intervention along different avenues.

Clinical Trial Readiness.—Intervention trials are envisaged within the next several years. The FSHD field needs to be prepared for this crucial step. To design and coordinate this important translational process, it was envisaged to install an international task force Clinical Trial Readiness (FSHD-CTR), with a proven FSHD-clinician as leader.

Biomarkers.—Sensitive biomarkers are needed to monitor intervention: they may also improve diagnosis.

Model systems

There are a plethora of cellular and animal models, based on different pathogenic (candidate gene) hypotheses. Moreover, the phenotypes are very diverse and often difficult to compare with the human FSHD phenotype.

FSHD Model Data Base.—The importance of a systematic database was recognized. This data base should contain detailed information on the molecular characteristics of the model (design and phenotype).

Human Pathology and Bio-Banking.—Importantly, this data base should also contain well-documented muscle pathology data of patients—astonishingly difficult to find in the literature. Human cellular resources continuously deserve attention.

Sharing

Timely sharing of information and resources significantly contributes to the progress in the field. There are several initiatives that create large repositories of data and resources. Their websites should be used for sharing of information (e.g. protocols, guide to FSHD muscle pathology (images), model systems, contact information, reagents, and resources).

The pace of discovery and numbers of experts in the field of biological science and clinical medicine working on FSHD are rapidly expanding. Many leading experts are now turning to work on FSHD not only because it is one of the most complicated and challenging problems seen in science, but because it represents the potential for great discoveries, insights into stem cells and transcriptional processes and new ways of treating multiple human diseases.

Surveillance Systems Have Improved Understanding of Prevalence

The consortium, Orphanet, has issued new prevalence data for hundreds of orphan diseases in Europe. That report ranks FSHD as the most prevalent form of muscular dystrophy.⁷

Likewise, the U.S. Centers for Disease Control and Prevention (CDC) has presented new data on the prevalence of muscular dystrophies which shows FSHD with

⁶2011 FSH Society FSHD International Research Consortium, held November 7–8, 2011 at DHHS NIH NICHD Boston Biomedical Research Institute Senator Paul D. Wellstone MD CRC for FSHD. To read the expanded summary and recommendations of the group see: <http://www.fshsociety.org/assets/pdf/IRCWorkshop2011WorkingConsensusOfPrioritiesGalley.pdf>.

⁷Prevalence of rare diseases: Bibliographic data, Orphanet Report Series, Rare Diseases collection, November 2011, Number 1: Listed in alphabetical order of diseases, http://www.orpha.net/orphacom/cahiers/docs/GB/Prevalence_of_rare_diseases_by_alphabetical_list.pdf.

the second highest prevalence rate 4.4/100,000 (the first was myotonic muscular dystrophy.)⁸ ⁹ This enhanced understanding is due to the Congress' foresight in charging CDC to enhance its surveillance of muscular dystrophy. We cannot say whether FSHD is becoming more prevalent, if the prevalence of other dystrophies such as Duchenne's 2.1/100,000 is declining or if older information was just inaccurate.⁹ But we can say that congressional action is producing better information enabling all of us to make decisions.

Funding Picture Has Improved but More is Needed

Mr. Chairman, these major advances in scientific understanding and epidemiological surveillance are not free. They come at a cost. Since the Congress passed the MD CARE Act, research funding at NIH for muscular dystrophy has increased 4-fold. While FSHD research funding has increased 12-fold during this period, the level of funding is still exceedingly low.

⁸Centers for Disease Control and Prevention. November 7–8, 2011, CDC meeting “Defining a public health approach for muscular dystrophy: A model for conditions with high impact/low prevalence”.

⁹Centers for Disease Control and Prevention. Prevalence of Duchenne/Becker muscular dystrophy among males aged 5–24 years—four States, 2007. *MMWR Morb Mortal Wkly Rep.* 2009 Oct 16; 58(40): 1119–22.

[Dollars in millions]

	Fiscal Year											
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
All MD	\$12.6	\$21	\$27.6	\$39.1	\$38.7	\$39.5	\$39.9	\$47.2	\$56	\$83	\$86	\$75
FSHD	\$0.4	\$0.5	\$1.3	\$1.5	\$2.2	\$2.0	\$1.7	\$3	\$3	\$5	\$6	\$6
FSHD (percent total MD)	3	2	5	4	6	5	4	5	5	6	7	8

Source: National Institutes of Health (NIH) FSHD Funding and Appropriations.
 FSHD Research Dollars (in millions) and FSHD as a Percentage of Total NIH Muscular Dystrophy Funding.
 Sources: NIH/OD Budget Office and NIH OCPL and NIH RDCDC RePORT.

We request for fiscal year 2013, a doubling of the facioscapulohumeral muscular dystrophy (FSHD) or facioscapulohumeral disease research budget at the NIH to \$12 million. This will allow an expansion of the DHHS NIH Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers, an increase in much needed research awards, expansion of post-doctoral and clinical training fellowships, and a dedicated center to design and conduct clinical trials on animal models of FSHD. We need to translate discoveries and treatments for FSHD that, according to Dr. Collins “if we were thinking of a collection of the genome’s greatest hits, this would go on the list,”² can be rapidly realized if FSHD is one of the diseases that the NIH National Center for Advancing Translational Sciences (NCATS), chooses to work on.

Mr. Chairman, the patients and researchers of the FSH Society are grateful for the support from the Congress and the tremendous efforts of many people at the NIH Office of the Director, the National Institute of Arthritis and Musculoskeletal and Skin Disease, the National Institute on Neurological Disorders and Stroke and the National Institute for Child Health and Human Development. We are aware of the great pressures on the Federal budget, but cutting the NIH budget and research funding for FSHD at this time would be the wrong decision. We have come so far with such modest funding. This is not the time to lessen our endeavor. This is the time to fully and expeditiously exploit the advances for which the American taxpayer has paid.

As president of a patient organization which raises about \$1 million a year for research, I can tell you that the private sector cannot touch the level of funding NIH provides. And we fully appreciate your support.

Thank you for this opportunity to testify before your committee.

PREPARED STATEMENT OF THE GLOBAL HEALTH TECHNOLOGIES COALITION

Chairman Rehberg, Ranking Member DeLauro, and members of the subcommittee, thank you for the opportunity to provide testimony on the fiscal year 2013 appropriations funding for the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). We appreciate your leadership in promoting the importance of international development, in particular global health. We hope that your support will continue. I am submitting this testimony on behalf of the Global Health Technologies Coalition (GHTC), a group of nearly 40 nonprofit organizations working together to promote the advancement of research and development (R&D) of new global health innovations—including new vaccines, drugs, diagnostics, microbicides, and other tools—to combat global health diseases. The GHTC’s members strongly believe that to meet the global health needs of tomorrow, it is critical to invest in research today so that the most effective health solutions are available when we need them. My testimony reflects the needs expressed by our member organizations which include nonprofit advocacy organizations, policy think-tanks, implementing organizations, and many others.¹ Also, one-third of our members are nonprofit product development partnerships (PDPs), which work with partners in the private biotechnology, pharmaceutical, and medical device sectors, as well as public research institutions, academia, and nongovernmental organizations to develop new and more effective life-saving technologies for the world’s most pressing health issues. We strongly urge the Committee to continue its established support for global health R&D by (1) sustaining and supporting the U.S. investment in global health research and product development, (2) instructing the NIH and CDC, in collaboration with other agencies involved in global health, to continue their commitment to global health in their R&D programs, and to document coordination efforts between agencies for the use of the Congress and the public, and (3) to encourage the newly formed National Center for Advancing Translational Sciences (NCATS) to explore supporting all stages of research.

Critical Need for New Global Health Tools

Our Nation’s investments have made historic strides in promoting better health around the world: nearly 6 million people living with HIV/AIDS now have access to life-saving medicines; new, cost-effective tools help us diagnose diseases quicker and more efficiently than ever before; and innovative new vaccines are making significant dents in childhood mortality. While we must increase access to these and other proven, existing health tools to tackle global health problems, it is just as critical that we continue to invest in developing the next generation of tools to stamp out disease and address current and emerging threats. For instance, newer, more

¹ GHTC member list: <http://www.ghtcoalition.org/coalition-members.php>.

robust, and easier to use antiretroviral drugs (ARV), particularly for infants and young children, are needed to treat and prevent HIV, and even an AIDS vaccine that is 50 percent effective has the potential to prevent 1 million HIV infections every year. Drug-resistant tuberculosis (TB) is on the rise globally, including in the United States, however the only vaccine on the market is insufficient at 90 years old, and most therapies are more than 50 years old, extremely toxic, and too expensive. New tools are also urgently needed to address fatal neglected tropical diseases (NTDs) such as sleeping sickness, for which diagnostic tools are inadequate and the few drugs available are toxic or difficult to use. There are many very promising technology candidates in the R&D pipeline to address these and other health issues; however, these tools will never be available if the support needed to continue R&D is not supported and sustained.

Research and U.S. Global Health Efforts

The United States is at the forefront of innovation in global health technologies. For example, in November 2010, the NIH announced the results of the iPrEx clinical trial, a large, multi-country research study examining pre-exposure prophylaxis (PrEP).² The study found that a daily dose of two anti-retroviral drugs could provide an average of 44 percent additional protection to high-risk populations who also received a comprehensive package of HIV prevention services. Additional studies supported by the CDC and the University of Washington confirmed that a daily oral dose of ARV drugs used to treat HIV infection can reduce the risk of HIV acquisition among uninfected individuals by between 63 and 73 percent.

The NIH is the largest funder of global health research in the U.S. Government, and the agency continues to demonstrate growing interest in global health issues, particularly in the area of translational research. NIH Director Francis Collins has made global health one of his top five priorities for the future of the NIH, and our coalition members have been pleased to see this implemented via the launch of a new Center for Global Health Studies at the Fogarty International Center, new initiatives on global health at the National Cancer Institute, and the creation of the new National Center for Advancing Translational Sciences (NCATS). Fogarty continues to collaborate with the U.S. Department of State's Office of the U.S. Global AIDS Coordinator and other agencies on the Medical Education Partnership Initiative (MEPI) to develop, expand, and enhance models of medical education. This includes enhancing the capacity of local individuals to conduct research on global health diseases. Additionally, the Model Non-Profit License Agreement for NTDs, HIV, TB, and Malaria Technologies was created for nonprofit institutions and PDPs with a demonstrated commitment to neglected diseases to apply for the use of patented inventions and non-patented biological materials from the NIH and the FDA intramural laboratories. Also very recently, a partnership between the NIH, the FDA, and GHTC member organization BIO Ventures for Global Health has proposed the Global Health Connector—a knowledge sharing system for scientists to improve access to valuable compound information and data to inform research into neglected tropical diseases. Each of these efforts built on the historic work carried out by the agency which contributes to improved health around the world.

With operations in more than 54 countries, the CDC is engaged in many global health research efforts. The work of CDC scientists has led to major advances against devastating diseases, including the eradication of smallpox and early identification of the disease that became known as AIDS. Although the CDC is known for its expertise and participation in HIV, TB, and malaria programs, it also operates several activities for neglected diseases in its National Center for Zoonotic, Vector-Borne, and Enteric Diseases. The CDC's Center for Global Health employs 1,100 staff members, and has people on the ground in 55 countries. The CDC is one of many partners providing support to research conducted on the PATH Malaria Vaccine Initiative's RTS,S vaccine candidate, as well as vaccine research for dengue and Rift Valley Fever. The CDC also conducts important global disease mapping and surveillance, including operational research on integrated mapping of NTDs over the past year. These activities also increase the reliability of estimates of disease burden, measure impact of NTD control efforts, and provide a planning tool for national control programs. To combat HIV/AIDS, the CDC was involved with the ground-breaking HIV Prevention Trials Network (HPTN) 052 study, which was the first randomized clinical trial to show that treating HIV-infected individuals with ART can reduce the risk of sexual transmission of HIV to their uninfected partners. Additionally, the CDC's involvement with expansion of rapid HIV testing has had a big impact in improving HIV/AIDS diagnostics. All of these efforts at the CDC and

²iPrEx trial. <http://www.niaid.nih.gov/news/newsreleases/2010/Pages/iPrEx.aspx>.

NIH also align with the new global health strategy developed by the Office of Global Affairs at the U.S. Department of Health and Human Services.

Leveraging the Private Sector for Innovation

The NIH, CDC, and other U.S. agencies involved in global health R&D regularly collaborate with the private sector in developing, manufacturing, and introducing important technologies such as those described above through public-private partnerships, including product development partnerships. These partnerships leverage public-sector expertise in developing new tools, partnering with academia, large pharmaceutical companies, the biotechnology industry, and governments in developing countries to drive greater development of products for neglected diseases in which private industries have not historically invested. This unique model has generated 16 new global health products and has enormous potential for continued success if robustly supported. NIH Director Francis Collins has stated that such partnership is key to the development of therapies and health tools based on NIH-funded research.

Innovation as a Smart Economic Choice

Global health R&D brings life-saving tools to those who need them most, however the benefits of these efforts bring are much broader than preventing and treating disease. Global health R&D is also a smart economic investment in the United States, where it drives job creation, spurs business activity, and benefits academic institutions. Biomedical research, including global health, is a \$100 billion enterprise in the United States. In a time of global financial uncertainty, it is important that the United States support industries, such as global health R&D, which build the economy at home and abroad.

History has shown that investing in global health research not only saves lives but is also a cost-effective approach to addressing health challenges. And an investment made today can help save significant money in the future. In the United States alone, for example, polio vaccinations during the last 50 years have resulted in a net savings of \$180 billion, funds that would have otherwise been spent to treat those suffering from polio. In addition, new therapies to treat drug-resistant tuberculosis have the potential to reduce the price of tuberculosis treatment by 90 percent and cut health system costs significantly. The United States has made smart investments in research in the past that have resulted in lifesaving breakthroughs for global health diseases, as well as important advances in diseases endemic to the United States. We must now build on those investments to turn those discoveries into new vaccines, drugs, tests, and other tools.

Recommendations

In this time of fiscal constraint, support for global health research that improves the lives of people around the world—while at the same time creating jobs and spurring economic growth at home—should unquestionably be one of the Nation's highest priorities. In keeping with this value, the GHTC respectfully requests that the Committee do the following:

- Sustain and support U.S. investments in global health research and product development within both the CDC and NIH budgets. We ask that this not come at the expense of robust funding for the entire set of global public health accounts, all of which complement each other and ultimately serve the common goal of building a healthier and more prosperous world.
- Instruct all U.S. agencies in its jurisdiction to continue their commitment to global health in their R&D programs and that leaders at the CDC and NIH work with leaders at other U.S. agencies to ensure that efforts in global health R&D are coordinated, efficient, and streamlined by establishing transparency mechanisms designed to show what global health R&D efforts are taking place and how U.S. agencies are collaborating with each other to make efficient use of the U.S. investment.
- Request that relevant agencies report on their progress to the Congress and that these reports be made publicly available. Past accounting of the health R&D activities at individual agencies, such as the Research, Condition, and Disease Categorization at the NIH, have been very helpful in coordinating efforts between agencies and informing the public and such efforts should be expanded to include neglected disease categorization and extended to provide a comprehensive picture of this investment from all agencies involved in global health R&D. The Committee should request that the CDC and NIH each develop comprehensive strategies to include global health research, product development, and regulation in their activities, in line with the recently released HHS Global Health Strategy.

—Request that the new National Center for Advancing Translational Sciences (NCATS) explore the benefits of supporting all stages of research instead of stopping at stage two, and that neglected diseases be given the same priority as rare diseases, in order to realize the full potential of the NCATS.

We respectfully request that the Committee consider inclusion of the following language in the report on the fiscal year 2013 Labor, Health and Human Services, and Education appropriations legislation:

“The Committee recognizes the urgent need for new global health technologies in the fight against neglected diseases that disproportionately affect low- and middle-income countries, and the critical contribution that the NIH, CDC, and FDA make to this through health research training operations, research, and regulatory capabilities. The Committee also acknowledges the urgent need to sustain and support U.S. investment in this important research by fully funding these three agencies to carry out their work.

“New global health products such as drugs, vaccines, diagnostics, and devices are cost-effective public health interventions that play an important role in improving global health. The Committee understands the positive impact that global health research and development has on the U.S. economy through the creation of U.S. jobs and the development of foreign markets for U.S. products. The NIH is widely recognized as the world leader in basic research, and has supplied invaluable breakthroughs that have led to new health tools, saving millions of lives globally. Through its Fogarty International Center, the NIH also harnesses its wealth of expertise to train the next generation of health scientists. The Committee recognizes the important role that late-stage research has in fostering the development of urgently needed health tools, and encourages the new National Center for Advancing Translational Sciences (NCATS) to explore supporting all stages of research, particularly for neglected diseases.

“The Committee directs the CDC, FDA, and NIH to each develop concrete plans to prioritize and incorporate global health research, product development, and regulation into the U.S. global health and development strategies. These efforts should be undertaken in line with the new Health and Human Services (HHS) Global Health Strategy. The Committee directs the CDC, FDA, and NIH to work with the Department of State, the U.S. Agency for International Development, and the Office of the U.S. Global AIDS Coordinator to ensure that these efforts are coordinated, efficient, and streamlined across the U.S. Government. The CDC, FDA, and NIH shall each make the documentation and results of these efforts available to the Congress and the public.”

As a leader in science and technology, the United States has the ability to capitalize upon our strengths to help reduce illness and death and ultimately eliminate disabling and fatal diseases for people worldwide, contributing to a healthier world and a more stable global economy. Sustained investments in global health research to develop new drugs, vaccines, tests, and other health tools—combined with better access to existing methods to prevent and treat disease—present the United States with an opportunity to dramatically alter the course of global health while building political and economic security across the globe.

On behalf of the members of the GHTC, I would like to extend my gratitude to the Committee for the opportunity to submit written testimony for the record.

PREPARED STATEMENT OF GOODWILL INDUSTRIES INTERNATIONAL

Mr. Chairman, Ranking Member, and members of the subcommittee, on behalf of Goodwill Industries International (GII), I appreciate this opportunity to submit written testimony on Goodwill’s fiscal year 2013 priorities for funding programs administered by the U.S. Departments of Labor, Health and Human Services, and Education.

In 2011, Goodwill raised approximately \$4.4 billion in its retail stores and other social enterprises and invested 82 percent of its privately raised revenues to supplement Federal investments in programs that give people the skills they need to reenter the workforce. Goodwill provided job training, employment services, and supportive services to approximately 4.2 million people, placing nearly 190,000 people in jobs and employing more than 105,000.

Now more than ever, with unemployment slowly declining from the highest levels experienced in a generation, local Goodwill agencies are on the front lines of the fragile recovery assisting people with employment barriers, including individuals with disabilities, older workers, and Temporary Assistance to Needy Families

(TANF) recipients who are struggling to find and keep jobs during a stubbornly tight job market.

While Goodwill is proud of these and other achievements, they are truly the result of a public-private partnership. As the recovery from the worst recession since the Great Depression continues and unemployment rates slowly decline from near 10 percent, Goodwill Industries understands the difficult challenge that appropriators face as they struggle to reduce the deficit while stretching limited resources to support an ever-increasing list of national priorities. Reducing the deficit is a serious issue that will require all to make sacrifices to address the Nation's spending problem while investing in integrated strategies that build upon and leverage existing resources that will address our Nation's revenue problem.

While local Goodwill agencies care about a range of Federal funding sources, Goodwill urges appropriators to demonstrate that employment and training programs are a top priority by providing adequate funding for the Workforce Investment Act's adult, dislocated worker, and youth funding streams; Community College Partnerships; and the Senior Community Service Employment Program (SCSEP).

Goodwill understands that appropriators face a difficult challenge in stretching limited resources to cover an increasing and dynamic range of priorities; and Goodwill shares concerns about the Nation's mounting debt and the deficit. This year, in particular, Goodwill is very concerned that the Budget Control Act's sequestration provision could result in an automatic across-the-board cut of approximately 9 percent. Over the past several years, funding for a number of Goodwill's funding priorities has declined significantly, stretching resources critically thin. Goodwill is very concerned that decreasing funding by an additional 9 percent would have a drastic effect on its programs and the people who participate in them.

WORKFORCE INVESTMENT ACT

Funding for the Workforce Investment Act's youth, adult, dislocated worker formulas is one of Goodwill's top funding priorities for fiscal year 2013. The U.S. Department of Labor estimates that WIA's three core funding streams will help more than 5.2 million people this year to receive help finding jobs and accessing education and training that aims to improve their future employment prospects. In 2011, approximately 125,000 people were referred to local Goodwill agencies for employment services through the Workforce Investment Act (WIA).

Investing 82 percent of its privately raise revenues in 2011, Goodwill is doing all it can to supplement the Federal investment in job training, employment services, and services that support people's efforts to find jobs and advance in careers. In fact, some agencies have been doing more than they can by deliberately using their reserves in order to provide help to more people than their current revenues support. Nevertheless, WIA funds support many agencies' efforts to provide skills training, job placement and job retention services to people with employment challenges including people with disabilities, people who receive welfare, and other job seekers. In addition, several agencies are one-stop lead operators or operators in association with other service providers. Many agencies are also active on State and local workforce boards, and most Goodwill agencies have people referred to them through the workforce system.

The administration's fiscal year 2013 budget proposes approximately \$2.6 billion for WIA's three main funding streams, and an additional \$100 million to pay the U.S. Department of Labor's portion of a Workforce Innovation Fund to "support and test promising approaches to training, and breaking down program silos, building evidence about effective practices, and investing in what works." Goodwill believes that a Workforce Innovation Fund is a promising idea, is very interested in the details, and is encouraged by the administration's efforts to increase interagency collaborations and leverage resources provided by community-based organizations.

Goodwill continues to be alarmed by the steady erosion of funding for WIA's adult, youth, and dislocated worker funding streams. In 2002, when the unemployment rate was 5.8 percent, combined funding for WIA's youth, adult, dislocated worker, and funding streams was more than \$3.67 billion. Ten years later, combined fiscal year 2012 funding for WIA's core funding streams and the Workforce Innovation fund is \$2.65 billion—more than \$1 billion or 25 percent less than in 2002—yet at a time when unemployment remains stubbornly high at more than 8 percent.

The workforce system is vastly underfunded and preservation of WIA's formula funding streams should be a high priority. Therefore, Goodwill urges the Congress to sustain WIA's adult, dislocated worker, and youth funding streams at current funding levels at a minimum. In addition, Goodwill supports the administration's proposal to increase funding for the Workforce Innovation Fund from \$50 million in fiscal year 2012 to \$100 million in fiscal year 2013.

COMMUNITY COLLEGE PARTNERSHIPS

Goodwill continues to hear employers express that it remains difficult to find workers that have the skills employers seek. In response, Goodwill launched the Community College/Career Collaboration (C⁴) in 2009 to enhance local agencies' collaboration with community colleges to combine their assets and resources to provide easy access to education, job training and other supportive services to individuals who lack a college or career credential that employers look for.

Pell grants are an important component of C⁴ because they increase access to training and education that lead to high-growth and good paying jobs that sustain families and build vibrant communities. Therefore the importance of Pell grants has increased dramatically for Goodwill. As a result, Goodwill was concerned that the fiscal year 2012 omnibus appropriations bill included provisions that reduced Pell eligibility for many students.

As members of the subcommittee know, the administration's fiscal year 2013 budget proposes to slightly increase the maximum Pell Grant to \$5,635. In addition, the budget proposes to include up to \$8 billion for the U.S. Departments of Labor and Education to create a Community College Initiative "to support State and community college partnerships with businesses to build the skills of American workers." Goodwill is intrigued by the proposal and believes that such partnerships should leverage the expertise and resources of community-based organizations that provide the supports students need to develop the skills and earn the credentials that employers seek.

Goodwill urges the Congress to protect Pell Grants from efforts to further reduce eligibility for many low-income students, and approve the President's proposal to increase the maximum Pell Grant to \$5,635.

SENIOR COMMUNITY SERVICE EMPLOYMENT PROGRAM (SCSEP)

Although the economy is now slowly starting to recover, in 2011, millions of people—including more than 2 million who are 55 and older were unemployed. Workers who are 55 and older have multiple barriers to employment and will be among the last rehired as the economy improves. The President's fiscal year 2013 budget again proposes to move SCSEP from DOL to the Department of Health and Human Services' Administration on Aging. Goodwill is interested in learning more about the move to HHS and encourages the Congress to debate the proposal when it considers reauthorization of the Older Americans Act.

SCSEP helps provide low-income older workers with community services employment and private sector job placements. Goodwill is one of the newest SCSEP grantees. In 2011, Goodwill's SCSEP participants contributed nearly 1.4 million community service hours. Private sector placements averaged a starting wage of \$9.34 per hour. Individuals placed in unsubsidized employment worked an average of nearly 30 hours per week. In addition, nearly 35 percent of those placed were into positions that offered benefits including health, vacation, and retirement.

Goodwill urges the Subcommittee to increase SCSEP funding by 12 percent to \$500 million. This increase would help absorb increased costs and account for an increasing number of people who are over age 55. Goodwill urges the Congress to discuss the proposal to move SCSEP from DOL to HHS when it considers reauthorization of the Older Americans Act.

CONCLUSION

Goodwill thanks you for considering these requests, and looks forward to working with you to help Government meet the serious challenges our Nation faces.

PREPARED STATEMENT OF THE HEALTH PROFESSIONS AND NURSING EDUCATION COALITION

The members of the Health Professions and Nursing Education Coalition (HPNEC) are pleased to submit this statement for the record recommending \$520 million in fiscal year 2013 for the health professions education programs authorized under Titles VII and VIII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA). HPNEC is an informal alliance of national organizations (<https://www.aamc.org/advocacy/hpniec/members.htm>) dedicated to ensuring the healthcare workforce is trained to meet the needs of the country's growing, aging, and diverse population.

The Title VII health professions and Title VIII nursing programs provide education and training opportunities to a wide variety of aspiring healthcare professionals, both preparing them for careers in the health professions and helping bring

healthcare services to our rural and underserved communities. Authorized since 1963, the programs are designed to help the workforce adapt to Americans' changing healthcare needs. Through loans, loan guarantees, and scholarships to students, as well as grants and contracts to academic institutions and nonprofit organizations, they are the only Federal programs designed to train providers in interdisciplinary settings to meet the needs of the country's special and underserved populations, increase minority representation in the healthcare workforce, and fill the gaps in the supply of health professionals not met by traditional market forces.

While HPNEC recognizes the Subcommittee faces difficult decisions in a constrained budget environment, a continued commitment to programs supporting healthcare workforce development should remain a high priority. HPNEC's recommendation of \$520 million would support continuation of all Title VII and Title VIII programs at least at their fiscal year 2012 enacted levels, while accommodating additional investments recommended by HRSA and HPNEC member organizations based on assessments of the Nation's growing workforce needs.

Residents of underserved rural and urban areas alike already struggle to access health providers. Currently, HRSA estimates that more than 31,000 additional health practitioners are needed to alleviate existing shortages. As the Nation's 77 million baby boomers age, they will only require more care; coupled with the millions of newly insured individuals entering the system, this increased demand for health services will only exacerbate the existing deficit of health professionals.

Failure to fully fund the Title VII and VIII programs would jeopardize activities to fill these vacancies and to prepare health professionals: to coordinate care for the Nation's expanding elderly population; to meet the unique needs of sick and ailing children; to practice in rural and other underserved communities; and to improve the diversity and cultural competence of the workforce. Given the synergistic nature of the programs, significant cuts to or elimination of any of the Title VII and Title VIII programs may also reverse the progress to date in mitigating such challenges.

The Title VII and Title VIII programs can be considered in seven general categories:

- The Primary Care Medicine and Oral Health Training programs support education and training of primary care professionals to improve access and quality of healthcare in underserved areas. Two-thirds of Americans interact with a primary care provider every year. Approximately one-half of primary care providers trained through these programs work in underserved areas, compared to 10 percent of those trained in other programs. The General Pediatrics, General Internal Medicine, and Family Medicine programs provide critical funding for primary care physician training in community-based settings and support a range of initiatives, including medical student and residency training, faculty development, and the development of academic administrative units. The primary care cluster also provides grants for Physician Assistant programs to encourage and prepare students for primary care practice in rural and urban Health Professional Shortage Areas. The General Dentistry, Pediatric Dentistry, and Public Health Dentistry programs provide grants to dental schools and hospitals to create or expand primary care and public health dental residency training programs.
- Because much of the Nation's healthcare is delivered in remote areas, the Interdisciplinary, Community-Based Linkages cluster supports community-based training of health professionals. These programs are designed to encourage health professionals to return to such settings after completing their training and to encourage collaboration between two or more disciplines. The Area Health Education Centers (AHECs) offer clinical training opportunities to health professions and nursing students in rural and other underserved communities by extending the resources of academic health centers to these areas. AHECs, which leverage State and local matching funds, form networks of health-related institutions to provide education services to students, faculty and practitioners. Geriatric Health Professions programs support geriatric faculty fellowships, the Geriatric Academic Career Award, and Geriatric Education Centers, all designed to bolster the number and quality of healthcare providers caring for older generations. The Graduate Psychology Education program, which supports interdisciplinary training of doctoral-level psychology students with other health professionals, provides mental and behavioral health services to underserved populations (i.e., older adults, children, chronically ill, and victims of abuse and trauma, including returning military personnel and their families), especially in rural and urban communities. The Mental and Behavioral Health Education and Training Grant Program supports the training of psychologists, social workers, and child and adolescent professionals. These programs together work to close the gap in access to quality mental and behavioral

- healthcare services by increasing the number of trained mental and behavioral health providers since 2002.
- The Minority and Disadvantaged Health Professionals Training cluster helps improve healthcare access in underserved areas and the representation of minority and disadvantaged individuals in the health professions. Minority Centers of Excellence support increased research on minority health issues, establishment of an educational pipeline, and the provision of clinical opportunities in community-based health facilities. The Health Careers Opportunity Program seeks to improve the development of a competitive applicant pool through partnerships with local educational and community organizations. The Faculty Loan Repayment and Faculty Fellowship programs provide incentives for schools to recruit underrepresented minority faculty. The Scholarships for Disadvantaged Students make funds available to eligible students from disadvantaged backgrounds who are enrolled as full-time health professions students.
 - The Health Professions Workforce Information and Analysis program provides grants to institutions to collect and analyze data to advise future decision-making on the health professions and nursing programs. The Health Professions Research and Health Professions Data programs have developed valuable, policy-relevant studies on the distribution and training of health professionals, including the Eighth National Sample Survey of Registered Nurses, the Nation's most extensive and comprehensive source of statistics on registered nurses. Reflecting the need for better health workforce data to inform both public and private decisionmaking, the National Center for Workforce Analysis serves as a source of such analyses.
 - The Public Health Workforce Development programs help increase the number of individuals trained in public health, identify the causes of health problems, and respond to such issues as managed care, new disease strains, food supply, and bioterrorism. The Public Health Traineeships and Public Health Training Centers seek to alleviate the critical shortage of public health professionals by providing up-to-date training for current and future public health workers, particularly in underserved areas. Preventive Medicine Residencies, which receive minimal funding through Medicare GME, provide training in the only medical specialty that teaches both clinical and population medicine to improve community health. This cluster also includes a focus on loan repayment as an incentive for health professionals to practice in disciplines and settings experiencing shortages. The Pediatric Subspecialty Loan Repayment Program offers loan repayment for pediatric medical subspecialists, pediatric surgical specialists, and child and adolescent mental and behavioral health specialists, in exchange for service in underserved areas.
 - The Nursing Workforce Development programs under Title VIII provide training for entry-level and advanced degree nurses to improve the access to, and quality of, healthcare in underserved areas. These programs provide the largest source of Federal funding for nursing education, providing loans, scholarships, traineeships, and programmatic support that, between fiscal year 2005 and 2010, supported more than 400,000 nurses and nursing students as well as numerous academic nursing institutions and healthcare facilities. Each year, nursing schools turn away tens of thousands of qualified applications at all degree levels due to an insufficient number of faculty, clinical sites, classroom space, clinical preceptors, and budget constraints. At the same time, the need for nursing services and licensed, registered nurses is expected to increase significantly over the next 20 years. The Advanced Education Nursing program awards grants to train a variety of nurses with advanced education, including clinical nurse specialists, nurse practitioners, certified nurse-midwives, nurse anesthetists, public health nurses, nurse educators, and nurse administrators. Workforce Diversity grants support opportunities for nursing education for students from disadvantaged backgrounds through scholarships, stipends, and retention activities. Nurse Education, Practice, and Retention grants help schools of nursing, academic health centers, nurse-managed health centers, State and local governments, and other healthcare facilities to develop programs that provide nursing education, promote best practices, and enhance nurse retention. The Loan Repayment and Scholarship Program repays up to 85 percent of nursing student loans and offers full-time and part-time nursing students the opportunity to apply for scholarship funds in exchange for 2 years of practice in a designated nursing shortage area. The Comprehensive Geriatric Education grants are used to train RNs who will provide direct care to older Americans, develop and disseminate geriatric curriculum, train faculty members, and provide continuing education. The Nurse Faculty Loan program provides a student

loan fund administered by schools of nursing to increase the number of qualified nurse faculty.

—The loan programs under Student Financial Assistance support financially disadvantaged health professions students. The Nursing Student Loan (NSL) is for undergraduate and graduate nursing students with a preference for those with the greatest financial need. The Primary Care Loan (PCL) program provides loans in return for dedicated service in primary care. The Health Professional Student Loan (HPSL) program provides loans for financially needy health professions students based on institutional determination. These programs are funded out of each institution's revolving fund and do not receive Federal appropriations. The Loans for Disadvantaged Students program provides grants to institutions to make loans to health professions students from disadvantaged backgrounds.

By improving the supply, distribution, and diversity of the Nation's healthcare professionals, the Title VII and Title VIII programs not only prepare aspiring professionals to meet the Nation's workforce needs, but also help to improve access to care across all populations. Further, with the Bureau of Labor Statistics projecting that the healthcare industry will generate 3.2 million jobs through 2018 (more than any other industry), these programs can help individuals in reaching their career goals and communities in filling their health needs. The multi-year nature of health professions education and training, coupled with provider shortages across many disciplines and in many communities, necessitate a strong, continued, and reliable commitment to the Title VII and Title VIII programs.

While HPNEC members understand the immense fiscal pressures facing the Subcommittee, we respectfully urge support for \$520 million for the Title VII and VIII programs to ensure the next generation of health professionals is equipped to address the Nation's healthcare complexities. We look forward to working with the Subcommittee to prioritize the health professions programs in fiscal year 2013 and into the future.

PREPARED STATEMENT OF THE HARM REDUCTION COALITION

We thank you for the opportunity to submit testimony regarding fiscal year 2013 Appropriations. Our testimony focuses on the urgency of scaling up Federal overdose prevention efforts.

The Centers for Disease Control and Prevention (CDC) reports that "Drug overdose death rates in the United States have more than tripled since 1990 and have never been higher. In 2008, more than 36,000 people died from drug overdoses, and most of these deaths were caused by prescription drugs . . . there is currently a growing, deadly epidemic of prescription painkiller abuse . . . the misuse and abuse of prescription painkillers was responsible for more than 475,000 emergency department visits in 2009, a number that doubled in just 5 years."

In a recent CDC Morbidity and Mortality Weekly Report (MMWR), findings "suggest that distribution of naloxone and training in its administration might have prevented numerous deaths from opioid overdoses . . . To address the substantial increases in opioid-related drug overdose deaths, public health agencies could consider comprehensive measures that include teaching laypersons how to respond to overdoses and administer naloxone to those in need."

Naloxone is a prescription medication and opioid antidote which effectively reverses the effects of an opioid overdose. Within moments of its administration, naloxone restores breathing to a normal rate. There is no potential for abuse of naloxone and it will cause no effect in a person who has not taken opioids. However despite the powerful life-saving properties of naloxone, it is underutilized. Many health professionals lack awareness of the value of layperson-administered naloxone, and do not prescribe it to their patients for whom they have prescribed opioids.

Broader recognition of the signs and symptoms of an overdose—and knowledge of how to respond (e.g., rescue breathing, administering naloxone, calling emergency services, etc.)—are essential to saving lives. HHS, the Department of Justice, and other agencies have been working to address prescription drug misuse, abuse, and diversion, but there is no coordinated Federal public health effort focused on helping the public and health professionals understand the signs and risks of overdose and learn how to prevent deaths from drug overdose.

To that end, as advocates dedicated to preventing deaths from opioid overdose, we request that the Subcommittee consider including report language in the fiscal year 2013 appropriations bill which urges the Department of Health and Human Services and appropriate Federal agencies to adopt the following priorities:

- Take steps to increase awareness of—and access to—the use of Naloxone, a prescription drug that when administered can prevent opioid overdose death. Specifically:
 - All Federal agencies involved in research, policies, regulation, and programs related to opioid misuse should coordinate efforts and develop and disseminate information about naloxone to healthcare professionals, individuals, and families and otherwise take other steps to facilitate its use, so that lives can be saved.
 - The Department of Health and Human Services should coordinate a national public health campaign to increase awareness of the signs and symptoms of overdose and improve understanding of the steps that individuals can take to save the life of someone who is experiencing an overdose. Such a national campaign should include information regarding the use of naloxone, rescue breathing, and calling emergency services, such as 9–1–1 and/or poison control centers.
 - CDC, working in collaboration with the Substance Abuse Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA), should enable best practices, by providing technical assistance and toolkits for community programs and health professionals who wish to distribute naloxone.
 - Increase Federal surveillance and data collection regarding opioid use, misuse, and deaths to ensure that policies and programs are designed to target the actual causes of opioid misuse and death and to monitor the impact of any new efforts on: access to pain management; incidence and prevalence of opioid misuse; and overdose deaths from opioids.
 - Support increased access to—and funding of—drug treatment and recovery.
 - Continue Federal investment in the basic, clinical, and translational research supported by the National Institute of Drug Abuse (NIDA).
- The Harm Reduction Coalition believes that these measures are critical to meeting the goal of reversing the overdose epidemic in the United States.
- We thank you for your consideration of the important issues.

PREPARED STATEMENT OF THE INTERSTITIAL CYSTITIS ASSOCIATION

Thank you for the opportunity to present the views of the Interstitial Cystitis Association (ICA) regarding the importance of interstitial cystitis (IC) public awareness activities and research.

ICA was founded in 1984 and remains the only nonprofit organization dedicated to improving the lives of those affected by IC. The Association provides an important avenue for advocacy, research, and education relating to this painful condition. Since its founding, the ICA has acted as a voice for those living with IC, enabling support groups and empowering patients. The ICA advocates for the expansion of the IC knowledge-base and the development of new treatments, including investigator initiated research. Finally, ICA works to educate patients, healthcare providers, and the public at large about IC.

IC is a condition that consists of recurring pelvic pain, pressure, or discomfort in the bladder and pelvic region; it is often associated with urinary frequency and urgency. This condition may also be referred to as painful bladder syndrome (PBS), bladder pain syndrome (BPS), and chronic pelvic pain. It is estimated that as many as 12 million Americans have IC symptoms, more people than Alzheimer's, breast cancer, and autism combined. Approximately two-thirds of these patients are women, though this condition does severely impact the lives of men as well. IC has also been seen in children; in fact, many adults with IC report having experienced urinary problems during childhood. However, there has been little information published about children and IC, therefore statistics on IC, diagnostic tools, and treatments specific to children and IC are very limited.

The exact cause of IC is unknown and treatment options are limited. There is no diagnostic test for IC, so diagnosis is made only after excluding other urinary/bladder conditions, possibly causing 1 or more years delay between onset of the symptoms and treatment. When healthcare providers are not properly educated about IC, patients may suffer for years before receiving an accurate diagnosis and appropriate treatment.

The effects of IC are pervasive and insidious, damaging work life, psychological well-being, personal relationships, and general health. The impact of IC on quality of life is equally as severe as rheumatoid arthritis and end-stage renal disease. Health-related quality of life in women with IC is worse than in women with endo-

metriosis, vulvodynia, and overactive bladder. IC patients have significantly more sleep dysfunction, higher rates of depression, anxiety, and sexual dysfunction.

Some studies also suggest that certain conditions occur more commonly in people with IC than in the general population. Some of these include allergies, irritable bowel syndrome, endometriosis, vulvodynia, fibromyalgia, and migraine headaches. Chronic fatigue syndrome, pelvic floor dysfunction, and Sjogren's syndrome have also been reported.

Interstitial Cystitis Public Awareness and Education

As IC is a condition that often takes years diagnosis, patients live in pain with no answers for many years. The IC Education and Awareness Program at the Centers for Disease Control and Prevention (CDC) plays a major role in increasing the public's awareness of this devastating disease and is the only program in the Nation which promotes public awareness of IC.

The public outreach of the CDC program includes public service announcements on major networks and the Internet. Further, the CDC program has provided resources to make information on IC available to patients and the public through videos, booklets, publications, presentations, educational kits, websites, blogs, Facebook pages, and a YouTube channel. For providers, this program has included the development of an IC newsletter with information on IC treatments, research, news, and events; targeted mailings to providers; and exhibits at national medical conferences.

This program is a source of information for patients whose doctors have limited time or information, and many doctors recommend it to their patients as a resource. Many doctors are hesitant to treat IC patients because of the amount of time it takes to treat the condition and the lack of answers available. For this reason, it is especially critical for this program to provide patients with information about what they can do to manage this painful condition and lead a normal life.

In order to continue these vitally important initiatives, it is critical that the CDC IC Education and Awareness Program be continued and receive a specific appropriation of \$660,000 for fiscal year 2013. The ICA also encourages continued support for the National Center for Chronic Disease Prevention and Health Promotion, through which the IC program is supported.

Research Through the National Institutes of Health

The National Institutes of Health (NIH), mainly through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), maintains a robust research portfolio on IC, including five major studies that yielded significant new information. The RAND IC Epidemiology (RICE) study found that nearly 2.7–6.7 percent of adult women have symptoms consistent with IC and will prove important to the future development of clinical trials and epidemiological studies. The IC Genetic Twin study found environmental factors, rather than genetic factors, to be substantial risk factors of developing IC. The Events Preceding Interstitial Cystitis (EPIC) study yielded significant information linking non-bladder conditions and infectious agents to the development of IC in many newly diagnosed IC patients. The findings of the EPIC study have been reinforced in a Northwestern University study which found that an unusual form of toxic bacterial molecule (LPS) has an impact the development of IC as a result of an infectious agent. Finally, the Urologic Pelvic Pain Collaborative Research Network (UPPCRN) indicated promising results for a new therapy for IC patients.

Research currently underway also holds great promise to increase our understanding of IC, and thus find new treatments and a cure. The Multidisciplinary Approach to the Study of Chronic Pelvic Pain (MAPP) Research Network holds great potential to understanding the underlying issues related to IC, other conditions possibly associated with IC, and new information related to flares of the condition. Research at the Office of Research on Women's Health (ORWH), specifically through Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health, also shows great promise for learning more about IC. Additionally, the investigator-initiated research portfolio will continue to support research relating to fundamental issues relating to IC and pelvic pain, including new avenues for interdisciplinary research and new treatment options. Continued research will assist in the development of new treatment and therapies to relieve this condition.

We applaud the recent establishment of the National Center for Advancing Translational Sciences (NCATS) at NIH. Housing translational research activities at a single Center at NIH will allow these programs to achieve new levels of success. Initiatives like CAN are critical to overhauling the translational research process and overcoming the research "valley of death" that currently plagues treatment development. In addition, new efforts like taking the lead on drug repurposing hold

the potential to speed new treatment to patients. We ask that you support NCATS and provide adequate resources for the Center in fiscal year 2013.

In order for positive IC research to reach its full potential, it is essential that NIH continue to receive funding which will allow it to continue and expand on past and current research. For this reason, we recommend a funding level of \$32 billion for fiscal year 2013. We also recommend the continuation of the MAPP study and research focused on IC in children.

Thank you for the opportunity to present the views of the interstitial cystitis community.

PREPARED STATEMENT OF THE INFECTIOUS DISEASES SOCIETY OF AMERICA

The Infectious Diseases Society of America (IDSA) represents more than 10,000 infectious diseases (ID) physicians and scientists devoted to patient care, prevention, public health, education, and research. Investment in ID research and public health efforts, through lead Department of Health and Human Services (HHS) agencies, can reduce healthcare costs, save lives, and create jobs. IDSA urges you to provide strong funding for the following agencies:

National Institutes of Health

National Institute of Allergy and Infectious Disease

IDSA supports funding for NIH of at least \$32 billion for fiscal year 2013, as well as an additional \$500 million to support National Institute of Allergy and Infectious Disease's (NIAID) antibacterial resistance and antibacterial drug and diagnostics R&D program. NIAID conducts and supports needed research on antibiotic resistance as well as research and development (R&D) of new antibiotics and diagnostics. Infections are becoming increasingly resistant to existing antibiotics, and the number of new antibiotics in development has plummeted. NIAID is establishing a vital new clinical trials network on antibiotic-resistant infections and it needs sufficient funding. The Committee also should urge NIAID to form a blue ribbon panel of experts to create an antibacterial resistance strategic plan to assist in prioritizing research in this area.

Advancements in diagnostic tools are needed as well. Rapid point-of-care diagnostics improve physicians' ability to prescribe antibiotics appropriately, which can improve patient care and survival, limit the development of resistance, contain healthcare costs, and identify patients eligible for antibiotic clinical trials. IDSA requests that the Committee report urge NIAID to consult with stakeholders to explore the feasibility of creating a biorepository of prospectively collected specimens (e.g., tissue, sputum, blood, urine) to ease diagnostics R&D by reducing redundant specimen collection and assuring quality specimens and data.

NIAID also plays an important role in funding research leading to new types of treatments for tuberculosis, fungal and viral diseases, as well as vaccines.

IDSA remains concerned with limiting the salary of NIH extramural researchers to Executive Level II (\$179,700—a reduction of \$20,000 from the Executive Level I cap used the past 10 years). The reduction will disproportionately affect physician investigators and serve as a deterrent to their research careers at a time when we are already struggling to remain globally competitive. IDSA urges the Congress to restore the NIH grantee salary cap to Executive Level I.

Centers for Disease Control and Prevention

IDSA supports at least \$7.8 billion in funding for the Centers for Disease Control and Prevention's (CDC) programs for fiscal year 2013.

National Center for Emerging and Zoonotic Infectious Diseases

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) houses CDC's antimicrobial resistance activities. CDC should be commended for creating an advisory group of non-government experts on antimicrobial resistance. Funding reductions to State and local public health laboratories (which are part of the National Antimicrobial Resistance Monitoring System—NARMS) hamper efforts to track resistance and understand its causes. Public health laboratories and PulseNet are also vital to detecting and tracking foodborne disease and identifying opportunities to increase food safety. The Emerging Infections Program (EIP) is a national resource for surveillance, prevention, and control of emerging infectious diseases whose activities include bacterial and food borne disease surveillance, influenza activities, and efforts to track and prevent healthcare-associated infections, about 70 percent of which are caused by resistant pathogens.

The United States must improve data collection on antibiotic use to define the overuse and misuse of antibiotics that drives resistance. Specifically, IDSA recommends that the Committee report encourage CDC, in coordination with its partners on the Interagency Task Force on Antimicrobial Resistance (ITFAR), to issue a report to the Congress comparing European and American antibiotic surveillance and data collection capacities, including recommendations for the collection of more comprehensive data in the United States.

The adoption of antimicrobial stewardship programs is crucial to foster the appropriate use of antibiotics and preserve these drugs' effectiveness. The Committee report should urge CDC to work in partnership with the Centers for Medicare and Medicaid Services (CMS) to continue promoting the uptake of stewardship programs in all healthcare facilities.

National Healthcare Safety Network and the EpiCenter Program

IDSA supports the President's request for \$27.5 million for National Healthcare Safety Network (NHSN), which conducts high-quality tracking and monitoring of deadly healthcare-associated infections (HAIs), of which more than 70 percent are caused by resistant pathogens. NHSN also funds the EpiCenter Program—a CDC collaboration with five academic centers focused on developing, implementing, and evaluating strategies to improve healthcare quality and assure patient safety. Past investment has yielded significant healthcare cost-savings and produced more than 150 peer-review publications.

National Center for Immunization and Respiratory Diseases

Section 317 Immunization Program.—Support for CDC's Section 317 must be sustained. Section 317 supports access to (including obtaining and storing) vaccines, establishment and maintenance of vaccine registries, education of providers and the public, and promoting vaccination of healthcare workers (HCWs). Of tremendous concern, vaccination rates for adults range from 26 percent to 65 percent. Registries are one vital tool to improve these rates. Forty-nine States have childhood vaccination registries, but only 20 percent of adults have immunization information in a registry. The Committee should urge CDC to continue helping States expand immunization registries with a focus on improving information-sharing about patients' vaccination histories across providers and generating vaccination reminders, especially for adults.

It is critical that HCWs receive the influenza vaccination. During the last influenza season, 63.5 percent of healthcare workers received the influenza vaccination according to CDC. The Committee should urge CDC to work in partnership with CMS to ensure that all healthcare workers receive the annual influenza vaccination.

Public Health Preparedness and Response Activities

CDC plays a central role in public health emergency preparedness and response. Funding is needed to provide coordination, guidance and technical assistance to State and local governments; support the Strategic National Stockpile; strengthen epidemiologic and public health laboratory capacity; and provide effective communications during an emergency.

The National Center for HIV, Viral Hepatitis, STD and TB Prevention

IDSA supports a minimum increase of \$40.2 million for HIV prevention and \$10 million for viral hepatitis at the CDC. CDC plays a vital role in reducing new HIV infections through evidence-based prevention, including routine HIV screening. Hepatitis B and C affect nearly 6 million Americans and can lead to chronic liver disease, cirrhosis, liver cancer and liver failure that claim 15,000 lives each year. Increasing rates of gonorrhea are a critical concern because drug resistant strains have reduced our ability to treat these infections. Outbreaks of tuberculosis (TB) continue to occur throughout the United States. Multi-drug-resistant TB poses a particular challenge due to the very high costs of treatment. Funding is needed to detect, treat, and prevent these infections.

Prevention and Public Health Fund

The PPHF has filled gaps in core public health funding that should be sustained in CDC's base appropriation. The PPHF should be maintained for its true purpose—investment in innovative public health efforts. The PPHF has made important new investments in epidemiology and laboratory capacity; public health workforce training; preventing HIV/AIDS and viral hepatitis; increasing immunization rates; and reducing health care-associated infections.

*Assistant Secretary for Preparedness and Response**Biomedical Advanced Research and Development Authority*

IDSAs support the administration's proposed \$547 million for Biomedical Advanced Research and Development Authority (BARDA). BARDA facilitates advanced R&D of medical countermeasures (MCMs), including new antibiotics for intentional attacks and naturally emerging infections. This funding is particularly needed for antibiotic R&D, given the plummeting private investment in this area.

Independent Strategic Investment Firm

IDSAs also support the administration's proposal to establish an MCM Strategic Investor with an initial funding level of \$50 million. This new entity will fill a significant void by partnering with small "innovator" companies and private investors to address urgent needs, including novel antimicrobials for multidrug-resistant organisms and diagnostics.

Designate Leads on Antibiotic Development and Resistance

The Committee report should urge HHS to designate leaders to fill voids and facilitate coordination and expert input into Federal antimicrobial resistance efforts by: (1) designating a lead agency to explore antibiotic R&D public private collaborations similar to those being established in the European Union; (2) establishing a lead office and director for the Interagency Task Force on Antimicrobial Resistance (ITFAR) and providing funding for the ITFAR to implement its action plan; (3) creating an advisory board of non-government experts that would work with the ITFAR and its director to establish priorities and ensure progress toward achieving their goals; (4) permitting non-government experts to serve on the US/EU Trans-Atlantic Task Force on Antimicrobial Resistance.

PREPARED STATEMENT OF THE INTERNATIONAL FOUNDATION FOR FUNCTIONAL
GASTROINTESTINAL DISORDERS

Thank you for the opportunity to present the views of the International Foundation for Functional Gastrointestinal Disorders (IFFGD) regarding the importance of functional gastrointestinal and motility disorders (FGIMD) research.

Established in 1991, IFFGD is a patient-driven nonprofit organization dedicated to assisting individuals affected by FGIMDs, and providing education and support for patients, healthcare providers, and the public. IFFGD also works to advance critical research on FGIMDs in order to provide patients with better treatment options, and to eventually find cures. IFFGD has worked closely with NIH on many priorities, including the NIH State-of-the-Science Conference on the Prevention of Fecal and Urinary Incontinence in Adults through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Child Health and Human Development (NICHD), and the Office of Medical Applications of Research (OMAR). I served on the National Commission on Digestive Diseases (NCDD), which released a long-range road map for digestive disease research in 2009, entitled *Opportunities and Challenges in Digestive Diseases Research: Recommendations of the National Commission on Digestive Diseases*.

The need for increased research, more effective and efficient treatments, and the hope for discovering a cure for FGIMDs are close to my heart. My own personal experiences of suffering from FGIMDs motivated me to establish IFFGD 20 years ago. I was shocked to discover that despite the high prevalence of these conditions among all demographic groups worldwide, such an appalling lack of dedicated research existed. This lack of research translates into a dearth of diagnostic tools, treatments, and patient supports. Even more shocking is the lack of awareness among both the medical community and the general public, leading to significant delays in diagnosis, frequent misdiagnosis, and inappropriate treatments including unnecessary medication and surgery. It is unacceptable for patients to suffer unnecessarily from the severe, painful, life-altering symptoms of FGIMDs due to a lack of awareness and education.

The majority of FGIMDs have no cure and treatment options are limited. Although progress has been made, the medical community still does not completely understand the mechanisms of the underlying conditions. Without a known cause or cure, patients suffering from FGIMDs face a lifetime of chronic disease management, learning to adapt to intolerable, disruptive symptoms. The medical and indirect costs associated with these diseases are enormous; estimates range from \$25–\$30 billion annually. Economic costs spill over into the workplace, and are reflected in work absenteeism and lost productivity. Furthermore, the emotional toll of these

conditions affects not only the individual but also the family. FGIMDs do not discriminate, affecting all ages, races and ethnicities, and genders.

Irritable Bowel Syndrome

Irritable Bowel Syndrome (IBS) affects 30 to 45 million Americans; conservatively, at least 1 out of every 10 people. Between 9 to 23 percent of the worldwide population suffers from IBS, resulting in significant human suffering and disability. IBS as a chronic disease is characterized by a group of symptoms that may vary from person to person, but typically include abdominal pain and discomfort associated with a change in bowel pattern, such as diarrhea and/or constipation. As a “functional disorder,” IBS affects the way the muscles and nerves work, but the bowel does not appear to be damaged on medical tests. Without a definitive diagnostic test, many cases of IBS go undiagnosed or misdiagnosed for years. It is not uncommon for IBS sufferers to have unnecessary tests and treatments, including surgery, before receiving a proper diagnosis. Even after IBS is identified, treatment options are sorely lacking and vary widely from patient to patient. What is known is that IBS often requires a multidisciplinary approach to research and treatment.

IBS can be emotionally and physically debilitating. Due to persistent pain and bowel unpredictability, individuals who suffer from this disorder may distance themselves from social events and work, and may even fear leaving their home. Stigma surrounding bowel habits may act as barrier to treatment, as patients are not comfortable discussing their symptoms with doctors. Because IBS symptoms are relatively common and not life-threatening, many people dismiss their symptoms or attempt to self-medicate with over-the-counter medications. In order to overcome these barriers to treatment, ensure more timely and accurate diagnosis, and reduce costly, unnecessary procedures, outreach to physicians and the general public remains critical.

Fecal Incontinence

At least 12 million Americans suffer from fecal incontinence. Incontinence is neither part of the aging process nor is it something that affects only the elderly; it crosses all age groups from children to older adults, but is more common among women and the elderly of both sexes. Often it is a symptom associated with neurological diseases and many cancer treatments. Yet, as a society, we rarely hear or talk about the bowel disorders associated with spinal cord injuries, multiple sclerosis, diabetes, prostate cancer, colon cancer, uterine cancer, and other diseases.

Causes of fecal incontinence include: damage to the anal sphincter muscles, damage to the nerves of the anal sphincter muscles or the rectum, loss of storage capacity in the rectum, diarrhea, or pelvic floor dysfunction. Several of these injuries may occur as a result of military service. People who have fecal incontinence may feel ashamed, embarrassed, or humiliated. Some don't want to leave the house out of fear they might have an accident in public. Most attempt to hide the problem for as long as possible. They withdraw from friends and family, and often limit work or education efforts. Incontinence in the elderly burdens families and is the primary reason for nursing home admissions, an already significant social and economic burden in our aging population.

In November 2002, IFFGD sponsored a consensus conference entitled, *Advancing the Treatment of Fecal and Urinary Incontinence Through Research: Trial Design, Outcome Measures, and Research Priorities*. Among other outcomes, the conference resulted in six key research recommendations including more comprehensive identification of quality of life issues, improved diagnostic tests for affecting management strategies and treatment outcomes, development of new drug treatment compounds, development of strategies for primary prevention of fecal incontinence associated with childbirth, and attention to the stigmas that apply to individuals with fecal incontinence.

In December 2007, IFFGD collaborated with NIDDK, NICHD, and OMAR on the NIH State-of-the-Science Conference on the Prevention of Fecal and Urinary Incontinence in Adults. The goal of this conference was to assess the state of the science and outline future priorities for research on both fecal and urinary incontinence, including the prevalence and incidence of fecal and urinary incontinence, risk factors and potential prevention, pathophysiology, economic and quality of life impact, current tools available to measure symptom severity and burden, and the effectiveness of both short and long term treatment. More research in these priority areas is necessary to improve the lives of those who suffer from fecal incontinence.

NIDDK recently launched a Bowel Control Awareness Campaign (BCAC) to educate the public about fecal incontinence. This campaign provides resources for healthcare providers, information about clinical trials, and information about lifestyle changes and advice for individuals suffering from bowel control issues. The

BCAC is an important step in reaching out to patients, and we encouraged continued support for this campaign. Further research on fecal incontinence is critical to improve patient quality of life and implement the research goals of the NCDD.

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease, or GERD, is a common disorder affecting both adults and children, which results from the back-flow of stomach contents into the esophagus. GERD is often accompanied by persistent symptoms, such as chronic heartburn and acid regurgitation. Sometimes there are no apparent symptoms, and the presence of GERD is revealed when complications become evident. One uncommon but serious complication is Barrett's esophagus, a potentially pre-cancerous condition. Symptoms of GERD vary from person to person. The majority of people with GERD have mild symptoms, with no visible evidence of tissue damage and little risk of developing complications. There are several treatment options available for individuals suffering from GERD. Nonetheless, treatment is not always effective, and long-term medication use and surgery expose individuals to risks of side-effects or complications.

Gastroesophageal reflux (GER) affects as many as one-third of all full term infants born in America each year. GER results from an immature upper gastrointestinal motor development. The prevalence of GER is increased in premature infants. Many infants require medical therapy in order for their symptoms to be controlled. Up to 8 percent of older children and adolescents will have GER or GERD due to lower esophageal sphincter dysfunction. In this population, the natural history of GER is similar to that of adult patients, in whom GER tends to be persistent and may require long-term treatment.

Gastroparesis

Gastroparesis, or delayed gastric emptying, refers to a stomach that empties slowly. Gastroparesis is characterized by symptoms from the delayed emptying of food, namely: bloating, nausea, vomiting, or feeling full after eating only a small amount of food. Gastroparesis can occur as a result of several conditions, including being present in 30 percent to 50 percent of patients who have diabetes mellitus. A person with diabetic gastroparesis may have episodes of high and low blood sugar levels due to the unpredictable emptying of food from the stomach, leading to diabetic complications. Other causes of gastroparesis include Parkinson's disease and some medications. In many patients, the cause of the gastroparesis cannot be found and the disorder is termed idiopathic gastroparesis.

Cyclic Vomiting Syndrome

Cyclic vomiting syndrome (CVS) is a disorder with recurrent episodes of severe nausea and vomiting interspersed with symptom free periods. The periods of intense, persistent nausea, vomiting, and other symptoms (abdominal pain, prostration, and lethargy) last hours to days. Previously thought to occur primarily in pediatric populations, it is increasingly understood that this crippling syndrome can occur in a variety of age groups including adults. Patients with these symptoms often go for years without correct diagnosis. CVS leads to significant time lost from school and from work, as well as substantial medical morbidity. The cause of CVS is not known. Better understanding, through research, of mechanisms that underlie upper gastrointestinal function and motility involved in sensations of nausea, vomiting, and abdominal pain is needed to help identify at-risk individuals and develop more effective treatment strategies.

Support for Critical Research

IFFGD urges the Congress to fund the NIH at level of \$32 billion for fiscal year 2013. Strengthening and preserving our Nation's biomedical research enterprise fosters economic growth and supports innovations that enhance the health and well-being of the Nation. Concurrent with overall NIH funding, the IFFGD supports growth of research activities on FGIMDs, particularly through NIDDK. Increased support for NIDDK will facilitate necessary expansion of the research portfolio on FGIMDs necessary to grow the medical knowledge base and improve treatment. Such support would expedite the implementation of recommendations from the NCDD. It is also vital for NIDDK to work with NICHD to expand its research on the impact these disorders have on pediatric populations. Following years of near level-funding at NIH, research opportunities have been negatively impacted across all NIH Institutes and Centers. Without additional funding, medical researchers run the risk of losing promising research opportunities.

We applaud the recent establishment of the National Center for Advancing Translational Sciences (NCATS) at NIH. Housing translational research activities at a single Center at NIH will allow these programs to achieve new levels of success.

Initiatives like Cures Acceleration Network (CAN) are critical to overhauling the research process and overcoming the gap in translating basic into clinical research that currently plagues treatment development. In addition, new efforts like taking the lead on drug repurposing hold the potential to speed new treatment to patients. We ask that you support NCATS and provide adequate resources for the Center in fiscal year 2013.

Thank you for the opportunity to present these views on behalf of the FGIMD community.

PREPARED STATEMENT OF THE INTERSTATE MINING COMPACT COMMISSION

We are writing in opposition to the fiscal year 2013 budget request for the Mine Safety and Health Administration (MSHA), which is part of the U.S. Department of Labor. In particular, we urge the subcommittee to reject MSHA's proposed reduction of \$5 million for grants to States for safety and health training of our Nation's miners pursuant to section 503(a) of the Mine Safety and Health Act of 1977. Over the past several fiscal years, MSHA's budget request for State grants was approximately \$9 million, which approached the statutorily authorized level of \$10 million but still did not fully consider inflationary and programmatic increases being experienced by the States. We therefore urge the subcommittee to restore funding to the statutorily authorized level of \$10 million for State grants so that States are able to meet the training needs of miners and to fully and effectively carry out State responsibilities under sections 502 and 503(a) of the Act.

The Interstate Mining Compact Commission is a multi-state governmental organization that represents the natural resource, environmental protection and mine safety and health interests of its 24 member States. The States are represented by their Governors who serve as Commissioners.

IMCC's member States are concerned that without full funding of the State grants program, the federally required training for miners employed throughout the United States will suffer. States are struggling to maintain efficient and effective miner training and certification programs in spite of increased numbers of trainees and the incremental costs associated therewith. State grants have flattened out over the past several years and are not keeping pace with inflationary impacts or increased demands for training. The situation will likely be further exacerbated by new statutory, regulatory and policy requirements that grow out of the various reports and recommendations attending the Upper Big Branch accident.

In MSHA's own budget justification document (at page 72), the agency states that: "Training plays a critical role in preventing deaths, injuries, and illnesses on the job. By providing effective training, miners are able to recognize possible hazards and understand the safe procedures to follow. MSHA will continue its increased visibility and emphasis on training because it is critically important to making progress in reducing the number of injuries and fatalities." Furthermore, in a March 5, 2012 communication to State training grant recipients, MSHA specifically asked for the States' assistance "by including in your training, as appropriate, information on the ["Rules To Live By" campaign]." In this same letter, MSHA went on to note that "the number of miners you reach yearly through the training your program provides makes your contribution to the success of the program all that more important."

We are mystified about how MSHA intends to accomplish these stated objectives without the training programs that are provided by the States pursuant to the grants they receive from MSHA—as has been the case since the enactment of the Mine Safety and Health Act in 1977. By way of an explanation for the drastic cut to training grants, MSHA states on page 73 of its budget justification document that because of the "higher priorities" placed on its enforcement activities, \$5 million will be "reallocated" and that it will "shift responsibility for training back to mine operators." As a follow on, MSHA recognizes that some training services now provided by States will be "reduced or eliminated" and that "operators will become more actively involved with their training or find other resources to provide training." This appears to be an effort by MSHA to begin shifting training responsibilities and costs entirely to mine operators. While this idea may have merit, we are uncertain about the ability of the mining industry to accommodate these new costs (especially small operators) and suspect that any realignment of training responsibilities from the States to the industry will take considerable time and planning. Furthermore, our experience over the past 35 years has demonstrated that the States are often in the best place to design and offer this training in a way that insures that the goals and objectives of sections 502 and 503 of the Mine Safety and Health Act are adequately met.

The first time that the States became aware of this effort to shift responsibilities for miner training (and to reduce State grants) was upon the release of the Department of Labor's budget on February 13. There have been no discussions with the States about the impacts that this proposal will have on State training programs or about any sort of transition in the way we are currently doing business. To propose such a dramatic shift without first consulting the States is inappropriate and a denigration of the role the States have played in protecting our Nation's miners. Furthermore, to expect such a drastic change in operations to occur within a single fiscal year is unrealistic and will only result in confusion and potential negative impacts to the availability and quality of miner training.

While we can appreciate MSHA's desire to realign its resources to focus on inspection and enforcement, one of the most effective ways to insure miner health and safety in the first place is through comprehensive and excellent training. MSHA Assistant Secretary Main specifically spoke to this in a recent letter he sent to State grant recipients wherein he stated: "As in the past, we are reaching out to the grantees, recognizing the positive impact you have in delivering training to miners. I am asking that you incorporate, as appropriate, training on these types of [fatal] accidents as well as measures needed to prevent them. Increased training and awareness is necessary if we are to prevent these types of deaths." The States have been in the forefront of providing this training for more than 35 years and are best positioned to continue that work into the future. Furthermore, the Federal Government's relatively modest investment of money in supporting the States to handle this training has paid huge dividends in protecting lives and preventing injuries. The States are also able to provide these services at a cost well below what it would cost the Federal Government to do so.

As you consider our request to reject MSHA's proposed cut and instead to increase MSHA's budget for State training grants, please keep in mind that the States play a particularly critical role in providing special assistance to small mine operators (those coal mine operators who employ 50 or fewer miners or 20 or fewer miners in the metal/nonmetal area) in meeting their required training needs. This has been a particular focus in those States where metal/non-metal mining operations predominate. These are often small operators who cannot afford to offer the comprehensive training that is required under Section 502 of the Mine Safety and Health Act. Given this administration's articulated concerns about the impacts of regulatory decisions on small businesses, it is surprising that MSHA would propose significant cuts to the training that States provide to these small operators. Some States have also recently received requests from the VFW to provide "new miner training" for returning war veterans in order to prepare them for potential employment in the mining industry. Without the funding provided to States by MSHA, this may be difficult to accomplish in a timely manner, if at all.

We appreciate the opportunity to submit our views on the MSHA budget request as part of the overall Department of Labor budget. Please feel free to contact us for additional information or to answer any questions you may have.

PREPARED STATEMENT OF THE LUMMI INDIAN BUSINESS COUNCIL

Good morning to the distinguished Committee Members. Thank you for this opportunity. I am honored to present the appropriations request of the Lummi Nation for fiscal year 2013.

BACKGROUND INFORMATION

The Lummi Nation is located on the northern coast of Washington State, and is the third largest Tribe in Washington State serving a population of more than 5,200. The Lummi Nation is a fishing Nation. We have drawn our physical and spiritual sustenance from the marine tidelands and waters for hundreds of thousands of years. Now the abundance of wild salmon is gone, and the remaining salmon stocks do not support commercial fisheries. Consequently, our fishers are trying to survive off the sale of shellfish products. In 1999 we had 700 licensed fishers who supported nearly 3,000 tribal members. Today, we have about 523 remaining. This means that more than 200 small businesses in our community have gone bankrupt in the past 15 years. This is the inescapable reality the Lummi Nation fishers face without salmon. We were the last surviving society of hunters/gatherers within the contiguous United States, but we can no longer survive living by the traditional ways of our ancestors.

LUMMI SPECIFIC REQUESTS—DEPARTMENT OF LABOR

Direct the DOL Office of Indian Energy, Economic and Workforce Development to work with the Lummi Nation in support of its comprehensive Fisherman's Cove Harbor and Working Water Front Project which addresses Indian Energy, Economic and Workforce Development needs of the Lummi Nation membership.

Unemployment on the reservation has been very difficult to address with limited on-reservation jobs. Tribal governments need to be able to meet the employment and training needs of our membership as well as the business development needs of our communities. This is the objective of the Lummi Nation Fisherman's Cove Harbor and Working Waterfront Project. We need financial assistance to enable our membership to get the job skills the local (Reservation and Non-Reservation) labor market demands. The Lummi Nation needs to fully develop the Working Waterfront Project for the benefit of and to create jobs for the Lummi Nation fishers, members and others invested in the marine economy of the extreme northwest corner of the United States.

LUMMI SPECIFIC REQUESTS—DEPARTMENT OF HEALTH AND HUMAN SERVICES

Implement ACA and IHCIA.—Direct the Department and the U.S. Indian Health Services to fully and completely implement the Indian Specific provision of the Affordable Care Act and the newly reauthorized Indian Health Care Improvement Act (IHCIA).

Affordable Care Act and Newly Reauthorized Indian Health Care Improvement Act.—Tribes are dismayed by the lack of support they have received in the development and implementation of the following:

—*Long Term and Community Based Care.*—The authorization of long term and community based care Tribal communities are among the last to receive access to this all important healthcare option.

—*Tribal Medicaid Program Demonstration Project.*—The Act authorizes a demonstration project to enable Tribes to demonstrate their ability to successfully plan, develop, implement and operate Medicaid Programs for the benefit of their membership.

—*Healthcare Insurance Exchanges.*—To support the planning development, implementation and operation of tribes as providers of healthcare insurance on the same basis as State are receiving this technical and financial assistance from the Department.

Support for full and complete implementation of the Indian Specific provision of the Lummi Nation requests the committee support the SAMHSA Proposed Tribal Block Grant to combat Drug Epidemic among the Lummi Nation membership.

Wellness is the #1 Priority of the Council in 2012-13.—Drug abuse is at epidemic proportions on the Lummi Reservation. The proximity of the Lummi Reservation to the United States and Canadian borders makes for a key ingredient in successful drug trafficking. With that prime ingredient add production, transportation, distribution, abuse and drug related crimes . . . this is our reality where my people are becoming prisoners in our own homes.

What We Have Done: Our people are seeking a return to health through massive consumption of Lummi Nation Health Care resources. We have increased the number of Tribal members receiving substance abuse treatment and mental health counseling.

What We Still Need: We are not equipped to keep pace with the increasing access and use of heroin and other opiate additive drugs that have besieged our ports, borders, communities and citizens. Lummi Nation and other Tribes cannot successfully compete with politically connected communities and interest groups which receive the majority of the funding that is available through the State block grant system. We need assistance to secure funding to plan develop, construct and implement, programs services and facilities needed to improve health and safety in our communities.

Reauthorization of Head Start.—Lummi Nation is very interested in the process of reauthorizing the Head Start Act. Lummi has operated a Head Start programs since 1966. Several members of the current elected Lummi Nation Tribal Council are graduates of Lummi Nation Head Start.

Self-governance Option.—Lummi Nation requests that Tribes have an option to receive their Head Start program funding as a transfer of funds from the Federal Government to the Tribal government on a government-to-government basis. All Head Start funding is allocated on a continuing basis consistent with the current operations of Self-Governance Tribes. The Head Start Program has evolved away from its original grant based allocation system but has yet to remove the grant documents from its award system. It is a grant that acts like a transfer of funds.

Designation Issues.—Tribal governments must not be subject to the re-designation process as Grantees for Head Start Program. Due to the unique culture of Tribal people, only those competent in the local tribal culture are able to assess and assist in the development of Tribal children. This is not a job that can be performed by others. We ask that the regulations promulgated last year regarding re-designation of tribal programs be withdrawn and replaced with regulations that make it clear that only service providers who are known to the Tribe and approved by the Tribe are eligible participants, in any designation and/or re-designation process.

Head Start Facility.—The Lummi Nation has successfully completed several quality improvement plans required as a result of the Head Start performance Reviews. Each time we have not been able to address the deficits of our Head start Facility. The Tribe has secured a loan in the amount of \$4.2 million to build a new and expanded Head Start Facility. However to meet Head Start performance standards the Tribe needs another \$1.2 million. This amount will insure that four classrooms in the proposed facility will be suitable for special needs children. This amount is beyond the Tribe's ability to increase its debt load and must be contributed by other sources. Lummi Nation needs additional financial assistance to complete this long over-due project.

LUMMI SPECIFIC REQUESTS—DEPARTMENT OF EDUCATION

Head Start for Tribal Development—New Head Start Facility.—The Lummi Nation requests that the Committee directs BIE and DHHS, Children's Bureau support the construction of a new Head Start/day care facility for the Lummi Nation membership with technical and financial assistance. Lummi has operated a Head Start program since 1966 in the same facility. Successive Head Start Performance reviews have consistently identified the building as not meeting Head Start Performance standards. The Tribe is seeking gap financing in the amount of \$1.2 million to complete the proposed new facility. These additional costs are generated by Head Start Performance and tribal Child Care Facility Standards.

Head Start Program.—Head Start is a development program which is supports many early educational objectives. But it is first and foremost a child and family development program. The Lummi Nation does not support the proposal to transfer the Head Start Program to the Department of Education.

BIE Memorandum of Understanding.—The Lummi Nation is aware that the Bureau of Indian Education and the Department of Education are close to signing a memorandum of understanding regarding the role of the Department of Education in the Bureau operate school system. The Lummi Nation notes that no tribes were involved in the development of the MOU and that no tribes will be involved in the operation of the MOU. This is not acceptable. Tribal governments do not rely on the BIA or the BIE to operate their schools. Most of the school operated by the Bureau of Indian Education are contract or grant schools which are actually operated by Tribal governments. Tribal people sit on our Board of Education and Tribal parents participate in the education of their children. We firmly object to any action directed at us taken without us.

Revise Federal education laws to strengthen teaching about family violence/children violence in a school curricula—initiate renewed America by strengthening family values to teaching that all forms of violence hurts everyone, not only children.

Thank you for this opportunity to provide these appropriations priorities of the Lummi Nation.

PREPARED STATEMENT OF THE MESOTHELIOMA APPLIED RESEARCH FOUNDATION

Chairman Harkin and Members of the subcommittee, I am grateful for the opportunity to provide written testimony. My name is Bonnie Anderson and I suffer from peritoneal mesothelioma. I am testifying on behalf of the mesothelioma community composed of patients, physicians, caregivers and family members. I would like to take this time to stress the importance of increased funding for the National Institutes of Health (NIH), including the National Cancer Institute (NCI), and the Centers for Disease Control and Prevention (CDC), both of which play a critical role in finding and delivering treatments for mesothelioma.

Mesothelioma is an aggressive cancer known to be caused by exposure to asbestos. Doctors say it is among the most painful and fatal of cancers, as it invades the chest, abdomen and heart, and crushes the lungs and vital organs.

Early in 2001, I began to experience severe stomach pain, diarrhea and other general symptoms. These were treated as irritable bowel syndrome. Treatment, which included anti-spasmodics and pain medication, proved ineffective. I underwent a ridiculous amount of tests: blood work, gynecological work-ups, a scope of my bladder,

both upper and lower GI colonoscopy and endoscopy. After performing the latter, my gastroenterologist suggested exploratory surgery, but the surgeon thought it unnecessary. A barium enema followed by an X-ray also revealed nothing. Another gastroenterologist ordered a CAT scan.

Finally, in December 2001 my abdomen filled up with ascites. Again a CAT scan was ordered, and my gastroenterologist attempted to remove the fluid. The procedure was so painful the specialist had to end it before he was able to withdraw all of the fluid. Tests taken from the fluid returned negative for any cancer cells. But I was still in pain, the pressure was horrible and unreal. In February 2002, I was sent to a surgeon for a laparoscopy. The surgeon removed 6 liters of fluid and was able to see what he described as indoor-outdoor carpet spread all over the lining of the abdomen. Before I left the operating room, he asked the hospital's pathology department to confirm that he was indeed viewing what he suspected: mesothelioma. Pathology confirmed his assessment. Though he had been in practice for many years, the surgeon confessed he had never seen mesothelioma before—except in a textbook. When I woke up, he told my husband John and me the news.

When we first heard the word “mesothelioma,” we didn't know what it was. Then the doctor explained it in one word: “cancer.” The harsh reality for patients with advanced primary peritoneal cancer is a median survival time of 12.3 months; 5 year survivals are rare. Peritoneal affects the lining of the abdomen. Patients with pleural mesothelioma, which affects the lining of the lungs, comprise 85 percent of the mesothelioma population and face an even more grim survival time of only 9 months. Many never have the opportunity to speak for themselves like this. I am here 10 years after my diagnosis. Fortunately, I am the exception.

At the time, I was told I had about 6 months to live. With that information, my decision was to go into a clinical trial. I participated knowing I could face devastating side effects but with the hope I could help doctors learn how to treat mesothelioma and possibly live a while longer. I am willing to do anything to save my life and add precious more minutes to my time with my family. I went through many agonizing rounds of appeals with my insurance company in order to cover my surgeries and experimental treatment, but I felt this was the best course of treatment. I knew if I was going to die from mesothelioma, I was going to put it to good use in a clinical trial.

There are brilliant researchers dedicated to mesothelioma. The Food and Drug Administration (FDA) has now approved one drug which has some effectiveness, proving that the tumor is not invincible. Biomarkers are being identified. Two of the most exciting areas in cancer research—gene therapy and biomarker discovery for early detection and treatment—look particularly promising in mesothelioma. The Mesothelioma Applied Research Foundation has made a significant investment, funding a total of \$7.6 million to support research in hopes of giving researchers the first seed grant they need to get started. We need the continued partnership with the Federal Government to develop the promising findings into effective treatments.

There are currently several promising research initiatives that are giving hope to mesothelioma patients:

- A vaccine is being developed that would induce an immune response against WT1, a tumor suppressor gene highly expressed in mesothelioma patients. A pilot trial is being conducted in patients with mesothelioma to show that it is safe and immunogenic.
- The National Mesothelioma Virtual Bank has been established due to a grant from the Centers on Disease Control and Prevention's National Institute on Occupational Safety and Health. The Virtual Bank allows researchers to access a virtual biospecimen registry which supports and facilitates research and collaboration.

It is efforts like these that give me faith. I am grateful for the Federal Government's investment in mesothelioma research and I want to see it continued and increased.

In 2010, the National Cancer Institute funded \$8.3 million in mesothelioma research. This is a 6 percent decrease from the 2009 funding level, which had declined 14 percent from 2008. This steady decline in funding terrifies me as a patient anxiously awaiting development of new treatments. At this juncture unless researchers have the funds to continue, patients like myself will have run out of treatment options and will die from this disease.

I pray that improved treatments are developed—ones that aren't so severe and work better! I hope that future patients don't have to suffer the trial and error approach to being properly diagnosed and treated that I endured. More than anything, I wish there was a cure.

The mesothelioma community asks that the Subcommittee recognize the National Institutes of Health (NIH) as a critical national priority by providing at least \$32 billion in funding in the fiscal year 2013 Labor-HHS-Education appropriations bill. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

I look to the Labor, Health and Human Services, Education and Related Agencies Appropriations subcommittee to provide continued leadership and hope to the people like me who develop this deadly cancer. You have the power to lead this battle against meso. Thank you for the opportunity to submit testimony and for funding the National Institutes of Health and the National Cancer Institute at the highest possible level so that patients receiving this deadly diagnosis of mesothelioma may survive.

PREPARED STATEMENT OF THE MARCH OF DIMES FOUNDATION

The 3 million volunteers and 1,200 staff members of the March of Dimes Foundation appreciate the opportunity to submit Federal funding recommendations for fiscal year 2013. The March of Dimes was founded in 1938 by President Franklin D. Roosevelt to support research to prevent polio. Today, the Foundation aims to improve the health of women, infants and children by preventing birth defects, premature birth, and infant mortality through scientific research, community services, education and advocacy. The March of Dimes is a unique partnership of scientists, clinicians, parents, members of the business community and other volunteers affiliated with 51 chapters and 213 divisions in every State, the District of Columbia and Puerto Rico. The March of Dimes recommends the following funding levels for programs and initiatives that are essential investments in maternal and child health.

Preterm Birth

Preterm birth is a serious health problem that costs the United States more than \$26 billion annually. In 2008, one in eight infants was born preterm (before 37 weeks gestation). Preterm birth is the leading cause of newborn mortality (death within the first month) and the second leading cause of infant mortality (death within the first year). Among those who survive, one in five faces health problems that persist for life such as cerebral palsy, intellectual disabilities, chronic lung disease, blindness and deafness.

In 2010, the National Center for Health Statistics (NCHS) announced that the Nation's preterm birth rate fell below 12 percent for the first time in nearly a decade. It represented the fourth consecutive year of decline, bringing the rate down 6 percent from the peak of 12.8 percent in 2006. We believe one of the reasons for the decline was the result of legislation enacted in 2006, the PREEMIE Act (Public Law 109-450), which led to the development of a public-private agenda aimed at reducing preterm labor and delivery. The Act mandated a Surgeon General's conference to address the growing problem of preterm birth. In 2008, more than 200 of the country's foremost experts convened for 2 days to develop a comprehensive, national strategy to address the costly and serious problems of preterm birth. The meeting resulted in an action plan that included several overarching themes and recommendations. The March of Dimes' fiscal year 2013 funding requests regarding preterm birth are based on the recommendations from the 2008 conference and the PREEMIE Act.

National Institutes of Health (NIH)

The March of Dimes supports the recommendation of the Ad Hoc Group for Medical Research and urges the Subcommittee to recognize the NIH as a critical national priority by providing at least \$32 billion in funding in the fiscal year 2013 Labor-HHS-Education appropriations bill. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and at the same time allows the NIH's budget to keep pace with biomedical inflation.

The March of Dimes commends members of the subcommittee for their continuing support of the National Children's Study (NCS). When fully implemented, this study will follow 100,000 children in the United States from before birth until age 21. The data will help scientists at universities and research organizations across the country and around the world identify precursors of diseases and develop new strategies for treatment and prevention. The Foundation remains committed to supporting a well-designed NCS that promotes research of the highest quality and asks the Subcommittee to do the same.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

For fiscal year 2013, the March of Dimes recommends at least \$1.37 billion for the NICHD. This \$46 million increase compared to the fiscal year 2012 enacted level will enable NICHD to sustain its support for intramural preterm birth-related research and clinical research conducted through the Maternal-Fetal Medicine Units, Neonatal Research Network, and Genomic and Proteomic Network for Preterm Birth Research. In addition, the March of Dimes urges the Subcommittee to request that NICHD identify the steps and resources necessary to establish one or more Transdisciplinary Research Centers for Prematurity, as recommended by the Institute of Medicine. The causes of preterm birth are multi-faceted and necessitate a coordinated and collaborative approach integrating many disciplines. In 2011, the March of Dimes and Stanford University School of Medicine launched the Nation's first transdisciplinary research center dedicated to identifying the causes of premature birth. The March of Dimes is committed to opening five transdisciplinary centers across the country. A public-private partnership combining the resources of NICHD and private organizations would significantly enhance the impact of this research.

Centers for Disease Control and Prevention—Preterm Birth

The CDC's National Center for Chronic Disease Prevention and Health Promotion's Safe Motherhood Program works to promote optimal reproductive and infant health. For fiscal year 2013, the March of Dimes recommends a sustained funding level of at least \$44 million, and the inclusion of a \$2 million preterm birth subline as authorized by the PREEMIE Act (Public Law 109-450), to strengthen our national data systems to monitor trends and investigate health issues related to pregnancy and promote the health of women before, during and after pregnancy.

Centers for Disease Control and Prevention—National Center for Health Statistics

The National Center for Health Statistics' (NCHS) vital statistics program collects birth and death data that are used to monitor the Nation's health status, set research and intervention priorities, and evaluate the effectiveness of existing health programs. It is imperative that data collected by NCHS be comprehensive and timely. Unfortunately, a quarter of the States and territories lack the capacity to use the most recent (2003) birth certificate format and only two-thirds have adopted the most recent (2003) death certificate format. The March of Dimes supports the President's recommendation to provide \$162 million—a \$24 million increase over the fiscal year 2012 enacted level, which will support States and territories as they implement the 2003 Certificates of Birth, Death, and Fetal Deaths and aid in the transition to electronic collection of vital events data.

Birth Defects

According to the Centers for Disease Control and Prevention, an estimated 120,000 infants in the United States are born with major structural birth defects each year. Genetic or environmental factors, or a combination of both, can cause various birth defects, yet the causes of more than 70 percent are unknown. Additional Federal resources are sorely needed to support research to discover the causes of all birth defects and for the development of effective interventions to prevent or at least reduce their prevalence.

Centers for Disease Control and Prevention—National Center on Birth Defects and Developmental Disabilities (NCBDDD)

The NCBDDD conducts programs to protect and improve the health of children by preventing birth defects and developmental disabilities and by promoting optimal development and wellness among children with disabilities. For fiscal year 2013, the March of Dimes requests at least level funding of \$137 million for NCBDDD. We also encourage the Subcommittee to provide sustained funding levels of at least \$2 million to support folic acid education and \$22 million to support birth defects research and surveillance—a \$2 million increase from fiscal year 2012 enacted levels.

Allocating an additional \$2 million to birth defects research and surveillance will support genetic analysis of the research samples already obtained through the NCBDDD's National Birth Defects Prevention Study—the largest case-controlled study of birth defects ever conducted. This analysis would enable researchers to identify relevant mutations and potential risk factors, which would then lead to prevention strategies. In addition, this investment would make possible the continuation of NCBDDD's State-based birth defects surveillance grant program. Surveillance is the backbone of the public health network and its support should be a Subcommittee priority. Because of the current fiscal situation facing many States, fund-

ing for State-based surveillance systems is in jeopardy and requires increased Federal support to ensure the survival of essential birth defects surveillance programs.

Further, allocating at least \$2 million to folic acid education will allow the CDC to sustain its effective national education campaign aimed at reducing the incidence of spina bifida and anencephaly by promoting consumption of folic acid. Since the institution of fortification of U.S. enriched grain products with folic acid, the rate of neural tube defects has decreased by 26 percent. However, CDC estimates that up to 70 percent of neural tube defects could be prevented if all women of child-bearing age consumed 400 micrograms of folic acid daily. Sustained funding levels will ensure CDC can continue to educate women on the importance of folic acid.

The March of Dimes is very concerned about the administration's request to consolidate NCBDDD's budget lines into three categories. As proposed, the Birth Defects and Developmental Disabilities budget line would be renamed Child Health and Development and existing sub-categories would be eliminated (e.g. Birth Defects, Fetal Alcohol Syndrome, Folic Acid) with the exception of Autism. While the March of Dimes recognizes and supports program flexibility for CDC management, we are concerned that the title "Child Health and Development" fails to make clear the overall purpose of the programs covered, obscuring the urgency and importance of the need for ongoing support from the Congress. The March of Dimes urges modification of the administration's proposal by retaining the term "Birth Defects" as a sub-line under the category "Child Health and Development." This adjustment is needed to ensure that essential activities to reduce birth defects are not undermined or otherwise put at risk.

Newborn Screening

Newborn screening is a vital public health activity used to identify genetic, metabolic, hormonal and functional disorders in newborns so that treatment can be provided. Screening detects conditions in newborns that, if left untreated, can cause disability, developmental delays, intellectual disabilities, serious illnesses or even death. If diagnosed early, many of these disorders can be successfully managed. Across the Nation, State and local governments experiencing significant budget shortfalls are considering discontinuing screening for certain conditions or postponing the purchase of necessary technology. This situation represents a serious threat that, if left unresolved, will put infants at risk of permanent disability or even death. For fiscal year 2013, the March of Dimes urges the subcommittee to provide at least \$10 million for HRSA's heritable disorders program, as authorized by the Newborn Screening Saves Lives Act (Public Law 110-204).

Agency for Health Care Research and Quality (AHRQ)

AHRQ supports research to improve healthcare quality, reduce costs and broaden access to essential health services. For fiscal year 2013, the March of Dimes recommends \$400 million for AHRQ to continue its important work, including the development and dissemination of maternal and pediatric quality measures and comparative effectiveness research. Moreover, with the historic enactment of health reform last year, AHRQ's research is needed more than ever to build the evidence base that will be used to improve health and healthcare coverage.

Health Resources and Services Administration—Maternal and Child Health Block Grant

Title V of the Social Security Act, the Maternal and Child Health Block Grant, supports community-based programs aimed at decreasing infant mortality, preventing disabling conditions, increasing the number of children immunized and improving the overall health of mothers and children. Reduced funding threatens the ability of these programs to carry on this work. For fiscal year 2013, the March of Dimes recommends at least \$645 million for the Maternal and Child Health Block Grant, level funding from the fiscal year 2012 enacted level.

Centers for Disease Control and Prevention—National Immunization Program

Infants are particularly vulnerable to infectious diseases, which is why it is critical to protect them through immunization. In 2008, the national estimated immunization coverage among children 19–35 months of age was 76 percent. Childhood immunizations are among the most cost-effective preventive health measures. Every dollar invested in immunizing a child saves \$16.50 in medical and societal costs. The CDC's National Immunization Program supports States, communities and territorial public health agencies through grants to reduce the incidence of disability and death resulting from vaccine-preventable diseases. The March of Dimes is requesting \$720 million in fiscal year 2013 for the Section 317 National Immunization Program.

CDC Polio Eradication

Since its creation as an organization dedicated to research and services related to polio, the March of Dimes has been committed to the eradication of this disabling disease. The March of Dimes is requesting \$126.4 million in fiscal year 2013 for CDC's Polio Eradication Program, which would allow CDC to continue its immunization activities in the remaining endemic and high-risk countries in Africa and Asia and interrupt polio transmission in these regions.

Closing

The Foundation's volunteers and staff in every State, the District of Columbia and Puerto Rico look forward to working with Members of this Subcommittee to secure the resources needed to improve the health of the nation's mothers, infants and children.

MARCH OF DIMES: FISCAL YEAR 2013 FEDERAL FUNDING PRIORITIES

[In thousands of dollars]

Program	March of Dimes fiscal year 2013 request
National Institutes of Health (Total)	32,000,000
National Children's Study
Common Fund	569,452
National Institute of Child Health and Development	1,370,000
National Human Genome Research Institute	534,381
National Institute on Minority Health and Disparities	292,524
Centers for Disease Control and Prevention (Total)	7,800,000
National Center for Birth Defects and Developmental Disabilities (NCBDDD)	140,100
Birth Defects Research and Surveillance	22,300
Folic Acid Campaign	2,800
Immunization and Respiratory Diseases
Section 317	720,000
Polio Eradication	126,400
Safe Motherhood	44,000
Preterm Birth	2,000
National Center for Health Statistics	162,000
Health Resources and Services Administration (Total)	7,000,000
Maternal and Child Health Block Grant	640,098
Heritable Disorders	10,000
Universal Newborn Hearing	18,660
Community Health Centers	1,500,000
Healthy Start	103,532
Children's Graduate Medical Education	317,500
Agency for Healthcare Research and Quality (Total)	400,000

PREPARED STATEMENT OF THE MEDICAL LIBRARY ASSOCIATION AND THE ASSOCIATION OF ACADEMIC HEALTH SCIENCES LIBRARIES

SUMMARY OF RECOMMENDATIONS FOR FISCAL YEAR 2013

Continue the commitment to the National Library of Medicine (NLM) by increasing funding levels to \$372.6 million for fiscal year 2013.

Continue to support the medical library community's role in NLM's outreach, telemedicine, disaster preparedness and health information technology initiatives and the implementation of health care reform.

INTRODUCTION

The Medical Library Association (MLA) and the Association of Academic Health Sciences Libraries (AAHSL) thank the Subcommittee for the opportunity to submit testimony regarding fiscal year 2013 appropriations for the National Library of Medicine (NLM), a division of the National Institutes of Health (NIH). Working in partnership with other parts of the NIH and other Federal agencies, NLM is the key link in the chain that translates biomedical research into practice, making the results of research readily available worldwide.

MLA is a nonprofit, educational organization with approximately 4,000 health sciences information individual and institutional members. Founded in 1898, MLA

provides lifelong educational opportunities, supports a knowledge base of health information research, and works with a network of partners to promote the importance of quality information for improved health to the healthcare community and the public. AAHSL is composed of the libraries of 124 accredited U.S. and Canadian medical schools, and 26 associate members. AAHSL supports academic health sciences libraries and directors in advancing the patient care, research, education and community service missions of academic health centers through visionary executive leadership and expertise in health information, scholarly communication, and knowledge management. Together, MLA and AAHSL address health information issues and legislative matters of importance to both our organizations.

THE IMPORTANCE OF ANNUAL FUNDING INCREASES FOR NLM

We are pleased that the President's fiscal year 2013 budget proposal provides a funding increase NLM which will bolster its baseline budget. In today's challenging budget environment, we recognize the difficult decisions the Congress faces as it seeks to improve our Nation's fiscal stability. We appreciate and thank the Subcommittee for its long-time commitment to strengthening NLM's budget and encourage you to also consider increasing the NIH budget by providing at least \$32 billion in your fiscal year 2013 Labor-HHS-Education appropriations bill.

MLA and AAHSL believe that increased funding for NLM is essential to maximize the return on the investment in research conducted by the NIH and other organizations. By collecting, organizing, and making the results of bio-medical information more accessible to other researchers, clinicians, business innovators, and the public, NLM enables such information to be used more efficiently and effectively to drive innovation and improve the Nation's health. This role has become more important as the volume of biomedical data produced each year expands exponentially, driven by the influx of data from high-throughput genome sequencing systems and genome-wide association studies. NLM plays a critical role in accelerating nationwide deployment of health information technology, including electronic health records (EHRs) by leading the development, maintenance and dissemination of key standards for health data interchange that are now required of certified EHRs. NLM also contributes to

Congressional priorities related to drug safety through its efforts to expand its clinical trial registry and results database in response to recent legislation requirements, and to the Nation's ability to prepare for and respond to disasters. We encourage the Subcommittee to provide meaningful annual increases for NLM in the coming years and recommend an increase to \$372.6 million for fiscal year 2013. Beyond fiscal year 2013, it is critical to continue augmenting NLM's baseline budget to accommodate expansion of its information resources, services, and programs which must collect, organize, and make readily accessible rapidly expanding volumes of biomedical knowledge.

Growing Demand for the National Library of Medicine's Basic Services

The National Library of Medicine is the world's largest biomedical library and the source of trusted health information. Every day, medical librarians across the Nation assist clinicians, students, researchers, and the public in accessing the information they need to save lives and improve health. NLM delivers more than a trillion bytes of data to millions of users every day that helps researchers advance scientific discovery and accelerate its translation into new therapies; provides health practitioners with information that improves medical care and lowers its costs; and gives the public access to resources and tools that promote wellness and disease prevention. Without NLM, our Nation's medical libraries would be unable to provide the quality information services that our Nation's health professionals, educators, researchers and patients have come to expect.

NLM's data repositories and online integrated services such as GenBank, PubMed, and PubMed Central are helping to revolutionize medicine and advance science to the next important era which includes individualized medicine based on an individual's unique genetic differences. GenBank, with its international partners, has become the definitive source of gene sequence information and organizing, along with NLM's other genetic databases, the volumes of data that are needed to detect associations between genes and disease, and translate that knowledge into better diagnosis and treatments. Earlier this year, NLM launched the Genetic Testing Registry (GTR), a new resource for quickly finding information about genetic tests and their providers. The registry includes detailed information about available tests, the test's purpose and its limitations; the name and location of the test provider; whether it is a clinical or research test; what methods are used; and what is measured. The registry will provide valuable information to healthcare professionals looking

for answers related to their patients' diseases as well as researchers seeking to identify gaps in scientific knowledge.

PubMed, with more than 20 million citations to the biomedical literature, is the world's most heavily used source of information about published results of biomedical research. Approximately 700,000 new citations are added each year, and it is searched more than 2.2 million times each day. PubMed Central, NLM's freely accessible digital repository of biomedical journal articles, has become a valuable resource for researchers, clinicians, consumers and librarians. On a typical weekday more than 500,000 users download 1 million full-text articles.

We commend the Appropriations Committee for its support of the NIH public access policy which requires all NIH-funded researchers to deposit their final, peer-reviewed manuscripts in NLM's PubMed Central database within 12 months of publication. This highly beneficial policy is improving access to timely and relevant scientific information, stimulating discovery, informing clinical care, and improving public health literacy. We are pleased that other efforts are underway to expand public access policies across Federal agencies. The Federal Research Public Access Acts, H.R. 4004 and S. 2096, would require agencies with annual extramural research portfolios of more than \$100 million to develop public access policies related to research conducted by employees of that agency. Passage of FRPAA would bring the benefits of public access to other research disciplines. Further, because research in other disciplines is increasingly relevant to biomedicine, broadening public access policies across agencies will support better patient care, biomedical research, education, and health information technology. We support the work of the Office of Science and Technology Policy (OSTP) to implement the scholarly publications requirements in Section 103 of the American Competes Reauthorization Act which will ensure long-term stewardship and broad public access to the peer-reviewed scholarly publications resulting from federally funded scientific research. MLA and AAHSL have observed firsthand the significant benefit of providing public access to publications arising from NIH funded research, including its positive benefit-cost ratio, return on investment, and efficacy and efficiency to fuel new research, discoveries, and therapies, and applaud efforts to further this work in other areas.

As the world's largest and most comprehensive medical library, NLM's traditional print and electronic collections continue to steadily increase each year. These collections stand at more than 11.4 million items—books, journals, technical reports, manuscripts, microfilms, photographs and images. By selecting, organizing and ensuring permanent access to health sciences information in all formats, NLM is ensuring the availability of this information for future generations, making it accessible to all Americans, irrespective of geography or ability to pay, and ensuring that citizens can make the best, most informed decisions about their healthcare.

Clearly, NLM is a national treasure which is making a difference in patients' lives and healthcare outcomes. For example, an MLA member shared that recently a surgeon came to the library 12 minutes before surgery to find an article on the complex procedure he was about to perform. By searching NLM's PubMed/Medline database, the librarian found illustrations that guided the surgeon during surgery enabling him to save the man's foot.

ENCOURAGE NLM PARTNERSHIPS WITH THE MEDICAL LIBRARY COMMUNITY

Outreach and Education

NLM's outreach programs are essential to MLA and AAHSL membership and to the profession. These activities are designed to educate medical librarians, health professionals and the general public about NLM's services and to train them in the most effective use of these services. NLM has taken a leadership role in promoting educational outreach aimed at public libraries, secondary schools, senior centers and other consumer-based settings. Furthermore, NLM's emphasis on outreach to underserved populations assists the effort to reduce health disparities among large sections of the American public. One example of NLM's leadership is the "Partners in Information Access" program which is designed to improve the access of local public health officials to information needed to prevent, identify and respond to public health threats. With more than 6,300 members in communities across the country, the National Network of Libraries of Medicine (NN/LM) is well positioned to ensure that every public health worker has electronic health information services that can protect the public's health.

NLM is also at the forefront of efforts to provide consumers with trusted, reliable health information. Its MedlinePlus system provides consumer-friendly information on more than 900 topics in English and Spanish, and has become a top destination for those seeking information on the Internet, attracting more than 750,000 visitors per day. Librarians at Louisiana State University's Health Sciences Center Medical

Library in Shreveport provide in-person support for patients and the public seeking health information and have also established "healthelinks.org", a website with information on diseases and conditions, medicines, procedures and surgical operations, lab tests, and more from NLM's MedlinePlus system. With help from the Congress, NLM, NIH and the Friends of NLM launched NIH MedlinePlus Magazine in September 2006. This quarterly publication is distributed in doctors' waiting rooms and provides the public with access to high-quality, easily understood health information. Its readership is now estimated at 5 million people nationwide and is poised to grow, thanks to the launch of a Spanish/English version, NIH MedlinePlus Salud, in January 2009. NLM also continues to work with medical librarians and health professionals to encourage doctors to provide MedlinePlus "information prescriptions" to their patients, directing them to relevant information on NLM's consumer-oriented MedlinePlus information system. This initiative also encourages genetics counselors to prescribe the use of NLM's Genetic Home Reference website. Using NLM's new MedlinePlus Connect utility, a growing number of clinical care organizations are implementing specific links from their electronic health record systems to relevant patient education materials in MedlinePlus, enabling them to achieve an emerging criterion for achieving meaningful use of health information technology. MedlinePlus Connect was recently named a winner in the HHS Innovates competition.

NLM also provides access to information about clinical research for a wide range of diseases. Launched in February 2000, ClinicalTrials.gov contains registration information for some 117,000 trials. The database is a free and invaluable resource for patients and families who are interested in participating in cutting-edge treatments for serious illnesses. In recent years, it has become more valuable for patients, clinicians, researchers, and others, including librarians, who help patients identify relevant trials and provide clinicians and researchers with access to information about specific products such as new drugs under study. In response to the Food and Drug Administration Amendments Act of 2007, NLM has expanded ClinicalTrials.gov to accept summary results of clinical trials, including adverse events. Such information is not available systematically from other publicly accessible resources, and all too often is not published in the scientific literature. The system currently contains results for more than 5,000 trials, and the Library receives approximately 50 new results submission each week. More than 50,000 users visit the site each day.

MLA and AAHSL applaud the success of NLM's outreach initiatives, particularly those initiatives that reach out to the medical libraries and health consumers. We ask the Committee to encourage NLM to continue to coordinate its outreach activities with the medical library community in fiscal year 2013.

EMERGENCY PREPAREDNESS AND RESPONSE

NLM has a long history of programs and resources that support disaster preparedness and response activities. Building on its experiences in responding to Hurricane Katrina, NLM established a Disaster Information Management Research Center to collect and organize disaster-related health information, ensure effective use of libraries and librarians in disaster planning and response, and develop information services to assist responders. The Library responds to specific disasters worldwide with specialized information resources appropriate to the need, including information on bioterrorism, chemical emergencies, fires and wildfires, earthquakes, tornadoes, and pandemic disease outbreaks. Recently, the Library launched a Disaster Information Apps and Mobile Web sites page designed to provide mobile device users access to Web-based content. MLA and NLM continue to develop the Disaster Information Specialization (DIS) program aimed at building the capacity of librarians and other interested professionals to provide disaster-related health information outreach. Currently MLA is developing five courses on topics assigned by NLM and based on the NLM Disaster Information Curriculum and will include basic and advanced topics in Disaster Health Information.

Working with libraries and U.S. publishers, NLM has established an Emergency Access Initiative that makes available free full-text articles from hundreds of biomedical journals and reference books for use by medical teams responding to disasters. Over the last 2 years, this initiative has assisted relief efforts in Japan, Pakistan, and Haiti. It organized and made available health information resources relevant to the gulf oil spill. MLA and AAHSL see a role for NLM and the Nation's health sciences libraries in disaster preparedness and response activities, and we ask the Subcommittee to support NLM's role in this initiative which has a major objective of ensuring continuous access to health information and effective use of libraries and librarians when disasters occur.

Health Information Technology and Bioinformatics

NLM has played a pivotal role in creating and nurturing the field of medical informatics which is the intersection of information science, computer science and healthcare. Health informatics tools include computers, clinical guidelines, formal medical terminologies, and information and communication systems. For nearly 35 years, NLM has supported informatics research, training and the application of advanced computing and informatics to biomedical research and healthcare delivery including a variety of telemedicine projects. Many of today's informatics leaders are graduates of NLM-funded informatics research programs at universities across the country. Many of the country's exemplary electronic and personal health record systems benefit from NLM grant support.

The importance of NLM's work in health information technology continues to grow as the Nation moves toward more interoperable health information technology systems. A leader in supporting, licensing, developing and disseminating standard clinical terminologies for free nationwide use (e.g., SNOWMED), NLM works closely with the Office of the National Coordinator for Health Information Technology (ONCHIT) to promote the adoption of inter-operable electronic records. It has developed tools to make it easier for EHR developers and users to implement accepted health data standards in their systems.

MLA and AAHSL encourage the Subcommittee to continue their strong support for NLM's medical informatics and genomic science initiatives, at a point when the linking of clinical and genetic data holds increasing promise for enhancing the diagnosis and treatment of disease. MLA and AAHSL also support health information technology initiatives in ONCHIT that build upon initiatives housed at NLM.

Building and Facility Needs

The tremendous growth in NLM's basic functions related to the acquisition, organization and preservation of its ever-expanding collection of biomedical literature, combined with its growing contributions to healthcare reform, health information technology, drug safety, and exploitation of genomic information is straining the Library's physical resources. During times of economic hardship, NLM's role becomes increasingly important and it often serves as an archive of last resort for medical libraries looking for ways to cut back and trim their own collections.

Digital archiving—once thought to be a solution to the problem of housing physical collections—has only added to the challenge, as materials must often be stored in multiple formats as new digital resources consume increasing amounts of data center storage space. As a result, the space needed for computing facilities has also grown, and a new facility is urgently needed. This need has been recognized by the Subcommittee in Senate Report 108–345 that accompanied the fiscal year 2005 appropriations bill. However, the economic challenges of the last several years have hampered movement on this project.

While the Congress continues to face tremendous funding challenges in fiscal year 2013, MLA and AAHSL encourage the Subcommittee to acknowledge the need for construction of the new building to take place when the Federal budget stabilizes so that information-handling capabilities and biomedical research are not jeopardized. At a time when medical and health science libraries across the Nation face growing financial and space constraints, ensuring that NLM continues to serve as the archive of last resort for biomedical collections is critical to the medical library community and the public we serve.

Thank you again for the opportunity to present the views of the medical library community.

 PREPARED STATEMENT OF MEHARRY MEDICAL COLLEGE

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Wayne J. Riley, President and CEO of Meharry Medical College in Nashville, Tennessee. I have previously served as vice-president and vice dean for health affairs and governmental relations and associate professor of medicine at Baylor College of Medicine in Houston, Texas and as assistant chief of medicine and a practicing general internist at Houston's Ben Taub General Hospital. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

Mr. Chairman, time and time again, you have encouraged your colleagues and the rest of us to take a look at our Nation and evaluate our needs over the next 10 years. I took you seriously and came here prepared to offer my best judgments. First, I want to say that it is clear that health disparities among various popu-

lations and across economic status are rampant and overwhelming. Over the next 10 years, we will need to be able to deliver more culturally relevant and culturally competent healthcare services. Bringing healthcare delivery up to this higher standard can serve as our Nation's own preventive healthcare agenda keeping us well positioned for the future.

Minority health professional institutions and the Title VII Health Professions Training programs address this critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example, African-Americans represent approximately 15 percent of the U.S. population while only 2–3 percent of the Nation's healthcare workforce is African-American.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Institutions that cultivate minority health professionals have been particularly hard-hit as a result of the cuts to the Title VII Health Profession Training programs in fiscal year 2006 and fiscal year 2007 funding resolution passed earlier this Congress. Given their historic mission to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The cuts to the Title VII Health Professions Training programs amount to a loss of core funding at these institutions and have been financially devastating.

Mr. Chairman, I feel like I can speak authoritatively on this issue because I received my medical degree from Morehouse School of Medicine, a historically black medical school in Atlanta. I give credit to my career in academia, and my being here today, to Title VII Health Profession Training programs' Faculty Loan Repayment Program. Without that program, I would not be the president of my father's alma mater, Meharry Medical College, another historically black medical school dedicated to eliminating healthcare disparities through education, research and culturally relevant patient care.

Minority Centers of Excellence.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training of minorities in the health professions. Congress later went on to authorize the establishment of "Hispanic", "Native American" and "Other" Historically black COEs. For fiscal year 2013, I recommend a funding level of \$24.602 million for COEs.

Health Careers Opportunity Program (HCOP).—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged

students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. For fiscal year 2013, I recommend a funding level of \$22.133 million for HCOPs.

National Institutes of Health

Research Centers at Minority Institutions.—The Research Centers at Minority Institutions program (RCMI) is now housed at the National Institute on Minority Health and Health Disparities (NIMHD). RCMI has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2013.

National Institute on Minority Health and Health Disparities.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities. For fiscal year 2013, I recommend that this Institute's funding grow proportionally with the funding of the NIH and add additional FTEs.

Department of Health and Human Services

Office of Minority Health.—Specific programs at OMH include:

- Assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals,
- Assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers,
- Supporting conferences for high school and undergraduate students to interest them in health careers, and
- Supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions.

The OMH has the potential to play a critical role in addressing health disparities. For fiscal year 2013, I recommend a funding level of \$65 million for the OMH.

Department of Education

Strengthening Historically Black Graduate Institutions Program.—The Department of Education's Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MMC and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2013, an appropriation of \$65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Meharry Medical College along with other minority health professions institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. Meharry and other minority health professions schools seek to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work toward the goal of eliminating that disparity as we have done for 1,876.

Thank you, Mr. Chairman, for this opportunity.

PREPARED STATEMENT OF THE MOREHOUSE SCHOOL OF MEDICINE

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. John E. Maupin, President of More-

house School of Medicine (MSM) in Atlanta, Georgia. I have previously served as President of Meharry Medical College, executive vice-president at Morehouse School of Medicine, director of a community health center in Atlanta, and deputy director of health in Baltimore, Maryland. In all of these roles, I have seen firsthand the importance of minority health professions institutions and the Title VII Health Professions Training programs.

I want to say that minority health professional institutions and the Title VII Health Professions Training programs address a critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2–3 percent of the Nation's health professions workforce is black. MSM is a private school with a very public mission of educating students from traditionally underserved communities so that they will care for the underserved. Mr. Chairman, I would like to share with you how your committee can help us continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Given the historic mission, of institutions like MSM, to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The slow reinvestment in the Title VII Health Professions Training programs amounts to a loss of core funding at these institutions and have been financially devastating.

Mr. Chairman, I feel like I can speak authoritatively on this issue because I received my dental degree from Meharry Medical College, a historically black medical and dental school in Nashville, Tennessee. I have seen first hand what Title VII funds have done to minority serving institutions like Morehouse and Meharry. I compare my days as a student to my days as president, without that Title VII, our institutions would not be here today. However, Mr. Chairman, since those funds have been slowly replenished, we are standing at a cross roads. This committee has the power to decide if our institutions will go forward and thrive, or if we will continue to try to just survive. We want to work with you to eliminate health disparities and produce world class professionals, but we need your assistance.

Minority Centers of Excellence.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training

of minorities in the health professions. Congress later went on to authorize the establishment of “Hispanic”, “Native American” and “Other” Historically black COEs. For fiscal year 2013, I recommend a funding level of \$24.602 million for COEs.

Health Careers Opportunity Program (HCOP).—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. For fiscal year 2013 I recommend a funding level of \$22.133 million for HCOPs.

National Institutes of Health

National Institute on Minority Health and Health Disparities.—The National Institute on Minority Health and Health Disparities (NIMHD) is charged with addressing the longstanding health status gap between minority and nonminority populations. The NIMHD helps health professional institutions to narrow the health status gap by improving research capabilities through the continued development of faculty, labs, and other learning resources. The NIMHD also supports biomedical research focused on eliminating health disparities and develops a comprehensive plan for research on minority health at the NIH. Furthermore, the NIMHD provides financial support to health professions institutions that have a history and mission of serving minority and medically underserved communities through the Minority Centers of Excellence program. For fiscal year 2013, I recommend a funding increase proportional to any increase given to the NIH and additional FTE positions.

Research Centers at Minority Institutions.—The Research Centers at Minority Institutions program (RCMI), newly moved to NIMHD, has a long and distinguished record of helping our institutions develop the research infrastructure necessary to be leaders in the area of health disparities research. Although NIH has received unprecedented budget increases in recent years, funding for the RCMI program has not increased by the same rate. Therefore, the funding for this important program grow at the same rate as NIH overall in fiscal year 2013.

Department of Health and Human Services

Office of Minority Health.—Specific programs at OMH include: (1) Assisting medically underserved communities with the greatest need in solving health disparities and attracting and retaining health professionals; (2) assisting minority institutions in acquiring real property to expand their campuses and increase their capacity to train minorities for medical careers; (3) supporting conferences for high school and undergraduate students to interest them in health careers; and (4) supporting cooperative agreements with minority institutions for the purpose of strengthening their capacity to train more minorities in the health professions. The OMH has the potential to play a critical role in addressing health disparities, and with the proper funding this role can be enhanced. For fiscal year 2013, I recommend a funding level of \$65 million for the OMH.

Department of Education

Strengthening Historically Black Graduate Institutions.—The Department of Education’s Strengthening Historically Black Graduate Institutions program (Title III, Part B, Section 326) is extremely important to MSM and other minority serving health professions institutions. The funding from this program is used to enhance educational capabilities, establish and strengthen program development offices, initiate endowment campaigns, and support numerous other institutional development activities. In fiscal year 2013, an appropriation of \$65 million is suggested to continue the vital support that this program provides to historically black graduate institutions.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, Morehouse School of Medicine along with other minority health professions institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. MSM and other minority health professions schools seek to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work toward the goal of eliminating that disparity as we have since our founding day.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

The National Association of County and City Health Officials is the voice of the 2,800 local health departments that safeguard the health of approximately 300 million people across the country. These city, county, metropolitan, district, and tribal departments work every day to ensure the safety of the water we drink, the food we eat, and the air we breathe.

Local health departments have a unique and distinctive role and set of responsibilities in the larger health system and within every community. The Nation's current financial challenges are compounded by those in State and local governments that have resulted in diminishing the ability of local health departments to address community health and safety needs. Repeated rounds of budget cuts and layoffs continue to erode local health department capacity. According to recent surveys of local and State health departments, since 2008 52,000 jobs have been lost due to budget reductions.

To help protect the public's health, we urge the Subcommittee on Labor, Health and Human Services, Education and Related Agencies to consider the following fiscal year 2013 funding requests:

Public Health Emergency Preparedness

Center: Center for Public Health Preparedness and Response (CDC)

Funding Line: State and Local Preparedness and Response Capability

Sub-line: Public Health Emergency Preparedness Cooperative Agreements (PHEP)

NACCHO request: \$715 million

Fiscal Year 2013 President's Budget: \$642 million (including CDC Capacity)

Fiscal Year 2012: \$643 million (not including CDC Capacity)

The Public Health Emergency Preparedness (PHEP) cooperative agreement program provides funding to support local and State public health department capacity and capability to effectively respond to public health emergencies including terrorist threats, infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies. Local and State health departments work with the Federal Government, law enforcement, emergency management, health care, business, education, and religious groups to plan, train, and prepare for emergencies so that when disaster strikes, communities are prepared. NACCHO opposes the administration's proposal to eliminate the separate funding line for PHEP and to cut the program by \$8 million to pay for CDC programmatic operating costs. PHEP grants have been cut by 28 percent since 2004; NACCHO supports a return to the fiscal year 2010 funding level of \$715 million.

Hospital Preparedness Program

Assistant Secretary for Preparedness and Response (DHHS)

NACCHO request: \$426 million

Fiscal Year 2013 President's Budget: \$255 million

Fiscal Year 2012: \$380 million

Administered by the Assistant Secretary for Preparedness and Response, the Hospital Preparedness Program (HPP) provides funding to local and State health departments to enhance hospital preparedness and improve overall surge capacity in the case of public health emergencies. The preparedness activities carried out under this program strengthen the capabilities of hospitals throughout the country to respond to floods, hurricanes, or wildfires, and also include training for a potential influenza pandemic or terrorist attack. NACCHO opposes the administration's proposal to cut HPP by \$120 million. While HPP and PHEP grants have been aligned, the first year of alignment is "mechanical" in terms of getting the grant year and the application process for both programs in the same funding period. NACCHO supports a return to the fiscal year 2010 funding level of \$426 million.

Medical Reserve Corps

Office of the Surgeon General (DHHS)

NACCHO request: \$12.6 million

Fiscal Year 2013 President's Budget: \$10.9 million

Fiscal Year 2012: \$11.2 million

Administered by the Office of the Surgeon General, the Medical Reserve Corps (MRC) is a national network of local groups of volunteers that work to strengthen their local public health infrastructure and preparedness capabilities. Over the past 10 years, the program has grown to more than 200,000 volunteers in nearly 1,000 units in 50 States, the District of Columbia, and several territories. The network of MRC volunteers includes medical and public health professionals, as well as non-medical volunteers who provide leadership, logistic and other support. MRC units

are community-based and focus on local needs. The workload for these volunteers will increase as a result of the reduced health department workforce due to preparedness cuts. NACCHO supports a return to the fiscal year 2010 funding level of \$12.6 million.

Chronic Disease Prevention

Center: Center for Chronic Disease Prevention and Health Promotion (CDC)

Funding Line: Community Transformation Grants (CTG)

NACCHO Request: \$226 million (including health department eligibility)

Fiscal Year 2013 President's Budget: \$146 million

Fiscal Year 2012: \$226 million

The Community Transformation Grant (CTG) program provides resources for local communities to address heart attacks, strokes, cancer, diabetes, and other chronic diseases which contribute to the soaring cost of healthcare in the United States. The grants focus on the implementation, evaluation and dissemination of evidence-based community preventive health activities in order to develop strategies and practices that will enable States, counties, cities and tribes to control chronic disease and health disparities. Grantees are charged with a 5 percent reduction in death and disability due to tobacco use, heart disease and stroke and the rate of obesity through nutrition and physical activity in 5 years. Local and State public health departments should remain eligible to apply for funding through this important initiative in fiscal year 2013 and subsequent fiscal years. NACCHO supports the fiscal year 2012 funding level of \$226 million for Community Transformation Grants.

Center: Center for Chronic Disease Prevention and Health Promotion (CDC)

Funding Line: Coordinated Chronic Disease Prevention and Health Promotion Grant Program

NACCHO Request: \$379 million

Fiscal Year 2013 President's Budget: \$379 million (+\$129 million from fiscal year 2012)

Fiscal Year 2012: \$250 million

Chronic diseases such as heart disease, cancer, stroke and diabetes are responsible for 7 of 10 deaths among Americans each year and account for 75 percent of healthcare spending. Today's children are in danger of becoming the first generation to live shorter, less healthy lives than their parents. The Coordinated Chronic Disease Prevention and Health Promotion Grants, as proposed in the President's budget, will provide local and State health departments flexibility to streamline funding to prevent, control, and reduce the burden of chronic illness and to address the underlying causes of chronic diseases in a more integrated and coordinated fashion. Local health departments seek relief from duplicative administrative burden for the multiple siloed funding streams resulting in more funding going into programs and out to the community.

At a minimum, NACCHO recommends that the Congress encourage CDC to provide greater coordination among chronic disease programs and reduce duplicative administrative burden. NACCHO recommends the continuation of funding for State coordination grants begun in fiscal year 2011 for this purpose if funds are not made available for the coordinated Chronic Disease Prevention and Health Promotion Grant Program.

Food Safety

Center: Center for Emerging and Zoonotic Infectious Diseases (CDC)

Funding Line: Food Safety

NACCHO Request: \$44 million

Fiscal Year 2013 President's Budget: \$44 million (+\$17 million from fiscal year 2012)

Fiscal Year 2012: \$27 million

Foodborne illness affects 48 million Americans every year, resulting in 128,000 hospitalizations and 3,000 deaths. CDC's Food Safety program seeks to ensure food safety through surveillance and outbreak response. Local and State health departments are an essential part of the process that ensures that food is safe to eat at home, at community events, in restaurants, and in schools. NACCHO supports the administration's \$17 million increase as it will advance implementation of the Food Safety Modernization Act by enhancing and integrating disease surveillance, improving outbreak and response timeliness and helping address deficits in local capacity to prevent and stop illness. This increase will enable CDC to enhance and integrate disease surveillance, improve outbreak response timeliness and help address local deficits in capacity to prevent and stop illness. The increase also expands the number of Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCORE) sites.

Public Health Performance Improvement

Center: Center for Public Health Leadership and Support (CDC)
 Funding Line: National Public Health Improvement Initiative
 NACCHO Request: \$40.2 million
 Fiscal Year 2013 President's Budget: \$40.2 million
 Fiscal Year 2012: \$40.2 million

The National Public Health Improvement Initiative (NPHII) provides funding to 74 State, tribal, local and territorial health departments to make fundamental changes and enhancements in their organizations and practices that improve the delivery and impact of public health services. Local and State health departments currently face unprecedented financial challenges that threaten their ability to prevent disease and promote health in their communities. NPHII strengthens health departments by providing staff, training, tools, and technical/capacity building assistance dedicated to establishing performance management and evidence-based practices that drive improved service delivery and better health outcomes. NACCHO supports continuation of funding for this important quality improvement program for health departments.

317 Immunization Program

Center: National Center for Immunization and Respiratory Diseases (CDC)
 Funding Line: 317 Immunization Program
 NACCHO Request: \$720 million
 Fiscal Year 2013 President's Budget: \$562.2 million
 Fiscal Year 2012: \$620.2 million

The Section 317 Immunization Program provides funds to 50 States, six large cities and eight territories for vaccine purchase for at-need populations and immunization program operations, including support for implementing billing systems for immunization services at public health clinics to sustain high levels of vaccine coverage. Childhood immunizations are one of the most cost-effective public health interventions, saving 42,000 lives and preventing 20 million cases of disease annually with an estimated \$10.20 in savings for every \$1 invested. Increased funding would expand vaccine purchase grants to State and local health departments to cover the many new vaccines and expanded recommendations of existing vaccines. Additional funding would also strengthen State and local infrastructure to support vaccination programs and increase vaccine uptake rates.

NACCHO opposes the \$58 million cut proposed in the President's budget. While provisions in the Affordable Care Act (ACA) will expand insurance coverage of vaccines recommended by the Advisory Committee on Immunization Practices, that doesn't necessarily translate to increased vaccination by private physicians. Many private insurers do not reimburse physicians for the full cost of vaccine, nor do they cover actual administration expenses, causing physicians to stop offering immunizations. Health departments will continue to need sufficient funding for vaccinations not covered by the ACA expansions, services to the underinsured and administrative expenses not reimbursed by insurance. Additionally, the ACA expansion will not be fully implemented until 2019 while cuts are being proposed now.

As the Subcommittee drafts the fiscal year 2013 Labor-Health and Human Services-Education appropriations bill, NACCHO urges consideration of these recommendations for CDC programs critical to protecting people and improving the public's health.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

Introduction

Chairman Harkin, Ranking Member Shelby, and Distinguished Members of the Subcommittee: My name is Dan Hawkins, and I am the Senior Vice President for Public Policy and Research at the National Association of Community Health Centers. On behalf of the American health center community, including the more than 20 million patients served nationwide by health centers, the 131,660 full-time health center staff, and countless volunteer board members who serve our centers as well as the National Association of Community Health Centers, we want to offer our deep thanks and appreciation for this Subcommittee's strong bipartisan support of health centers. I also appreciate the opportunity to submit testimony for the committee to review as you craft the fiscal year 2013 Labor-Health and Human Services-Education and Related Agencies appropriations bill.

Health Centers—General Background

Health Centers are locally owned nonprofit entities that provide primary medical, dental, and behavioral healthcare, along with pharmacy and a variety of enabling and support services to more than 20 million patients today. Currently, there are more than 1,200 health centers serving as medical homes at more than 8,000 sites in rural and urban underserved communities nationwide, including as you know, in the States represented by the members of this Subcommittee.

By statute and mission, health centers are located in a medically underserved area or serve a medically underserved population and provide comprehensive primary care services to all community residents regardless of insurance status or ability to pay, while offering care on a sliding fee scale. This has enabled health centers to become healthcare homes to the medically underserved and our Nation's most vulnerable populations.

Health centers also have a unique connection to the health needs of their communities as they are directed by patient-majority boards, ensuring that care is locally controlled and responsive to each individual community.

Health centers specialize in providing high-quality, cost-effective primary and preventive healthcare to their patients. Utilizing the unique health center model, health centers are able to save the entire health system, including the Government and taxpayers, approximately \$24 billion annually by keeping patients out of costlier healthcare settings, such as emergency departments. Indeed, countless published studies over many decades have demonstrated that health centers are a proven cost saver. Studies have also proven that health centers improve the health status in communities, reduce emergency room use, and eliminate health disparities amongst their patients. Additionally, health centers serve as small businesses and economic drivers in their communities creating 200,000 jobs in just 2009.

Fiscal Year 2012 Funding Background

Thanks to the tireless efforts of this Subcommittee, in fiscal year 2012 health centers received \$2.8 billion in total program funding. This includes \$1.6 billion in discretionary funding and \$1.2 billion in mandatory funding for health centers through the Affordable Care Act for a total increase of \$200 million above fiscal year 2011.

A portion of this increase will go toward funding some of the more than 1,800 applications for health center expansion currently pending at HRSA. We anticipate this will mean health centers opening in more than 200 communities where primary care is currently scarce or non-existent. We want to again thank the Subcommittee for their support which is now being translated into real healthcare for many of our fellow Americans who currently go without access to even basic healthcare.

Overwhelming Demand for Accessible Primary Care

And yet, even with this tremendous new investment, there is still a pressing need for access to primary care services in communities across the country. As we recently documented in a new report entitled: *Health Wanted, the State of Unmet Need for Primary Health Care in America* ("Health Wanted"), the demand for primary care far exceeds supply all across our Nation. *Health Wanted* documents the principal barriers to care: affordability, accessibility, and availability. Within these three categories, specific hurdles to accessing primary care include lack or type of insurance, limited income, distance, and other factors that leave individuals, or whole communities, without care. As *Health Wanted* demonstrates, when health centers locate in underserved areas, they overcome these barriers using the unique health center model, improving health and producing documented health system savings. The report also highlights the multiple indicators, including health outcomes, that make the case that many more communities still need a health center, and that many of those communities with a health center have greater needs than the health center can meet with existing funding levels.

Recent application cycles bear out the research and show that health centers are striving to meet this demand for primary care. Right now, more than 1,800 health center expansion applications are pending at HRSA, including:

- More than 700 new health center applications that remain unfunded. These are communities with no health center and a documented shortage of primary care access.
- More than 1,100 applications from existing Health Centers for expanded medical, oral and behavioral health, pharmacy, and vision service capacity based on identified unmet need in their communities remain unfunded.
- 129 communities without a Health Center but with documented need have received funding for planning grants, and most will soon be ready to apply to be funded for a new Health Center in their community.

Health centers are clearly ready to do more to ensure all Americans have access to primary and preventive healthcare services. We look forward to working with this Subcommittee to translate this readiness into a reality.

Fiscal Year 2013 Request

The President's proposed fiscal year 2013 Health Resources and Services Administration (HRSA) fiscal year 2013 budget proposal provides \$1.58 billion in discretionary funding for the Health Centers program. Together with the \$1.5 billion in fiscal year 2013 mandatory funding available for health centers, health centers could receive a net increase of \$300 million in total programmatic funding for fiscal year 2013 equaling total funding of \$3.1 billion.

We strongly support the President's proposed funding level of \$3.1 billion for health centers, but we are very concerned about the administration's proposal to hold back \$280 million of the total proposed increase of \$300 million and instead spread out health center growth over a longer period of time. This proposal does not recognize the great need outlined above for access to the very primary care services provided in health centers. In addition, health centers are looking ahead to 2014, when the demand for primary care is expected to soar as millions receive health coverage for the first time, many of them living in the very communities we serve. The experience of health centers in Massachusetts tells us that health centers will become the healthcare home for many of these new patients. We must begin to create the capacity to serve these patients now. If primary care is not available in the communities where the newly insured live, they will access care elsewhere, most likely the emergency room or hospital, when they are sicker. This will mean poorer health for these patients and much higher costs for the system.

Health centers do, however, share the concern of the administration, and many members of this Subcommittee, over the funding cliff facing the Health Centers program in fiscal year 2016 when the mandatory funding from ACA is slated to end. If not remedied, health centers and the thousands of communities and millions of patients they serve could face a serious threat. We want to work with members of this Subcommittee to forge a bipartisan solution that averts this scenario.

Health Centers are respectfully requesting a total of no less than \$3.1 billion in funding for the Health Center program. However, instead of holding back funding, we propose that the entire increase be used immediately to provide for the expansion of care to 2.5 million new patients. We also urge the Subcommittee to consider the long-term stability and viability of the program, and the coming cliff in funding, while ensuring its continued growth which is so desperately needed.

Conclusion

We understand this Subcommittee will have to make many difficult budgetary decisions as you work within the funding limits set for the fiscal year 2013 Labor-Health and Human Services-Education appropriations bill. We understand that will be no easy task, but we ask you to keep in mind that health centers have continually proven to be a worthwhile investment by delivering affordable healthcare to those who need it most, while generating savings to our health system. We are deeply grateful for your longstanding leadership and ask for the Subcommittee's continued support for the Health Center program.

Thank you for your consideration.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF CLINICAL NURSE
SPECIALISTS

The National Association of Clinical Nurse Specialists (NACNS) is a national organization that exists to enhance and promote the unique, high value contribution of the clinical nurse specialist to the health and well-being of individuals, families, groups, and communities, and to promote and advance the practice of nursing. There are an estimated 72,000 registered nurses that have the education and credentials to practice as a clinical nurse specialist. NACNS supports funding for nursing education and training provided through the Nursing Workforce Development programs, authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.). NACNS also supports funding for research initiatives at the National Institute of Nursing Research (NINR) under the National Institutes of Health (NIH), and investment in the Nurse-Managed Health Clinics, authorized under Title III of the Public Health Service Act (42 U.S.C. 254c-1a.)

Clinical Nurse Specialists (CNSs) are licensed registered nurses who have graduate preparation (Master's or Doctorate) in nursing as a Clinical Nurse Specialist. They are Advanced Practice Registered Nurses (APRNs) in a specialized area of nursing practice in many areas, including but not limited to: primary care, pediat-

rics, geriatrics, women's health, critical care, emergency room, specific conditions, such as diabetes or oncology, psychiatry and rehabilitation. In addition to providing direct patient care, Clinical Nurse Specialists influence care outcomes by providing expert consultation for nurses, physicians, hospital administrators and other colleagues to implement improvements in healthcare delivery systems. Their leadership has led to reduced costs and increased quality of care, such as:

- Reduced Hospital Costs and Length of Stay;
- Reduced Frequency of Emergency Room Visits;
- Shortened Hospital Stays;
- Improved Pain Management Practices;
- Increased Patient Satisfaction with Nursing Care; and
- Reduced Medical Complications in Hospitalized Patients.

NURSING WORKFORCE DEVELOPMENT PROGRAMS

The Nursing Workforce Development programs have supported the supply and distribution of qualified nurses to meet our Nation's healthcare needs since 1964. Since its inception, Title VIII programs have supported over hundreds of thousands of nurses from entry-level preparation through graduate study, and provide support for institutions that educate nurses for practice in rural and medically underserved communities. Between fiscal year 2005 and fiscal year 2010 alone, Title VIII programs have supported more than 400,000 nurses and nursing students as well as numerous academic nursing institutions and healthcare facilities. Today, the Title VIII programs are essential to solving the looming national nursing shortage.

The National Association of Clinical Nurse Specialists respectfully request \$251 million for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act in fiscal year 2013. Last year, your Subcommittee provided a significant funding boost for Title VIII that helped support the Loan Repayment program and Scholarship and Nurse Faculty Loan program. These increases will bolster the pipeline of nurses and nurse faculty, which is so critical to reversing the nursing shortage. We feel it is extremely important to fund these critical programs. This funding not only increases the much needed number of nurses but allows individuals to pursue a career in nursing, contribute to the healthcare needs of their community and build a career to support them and their families in the future.

The Advanced Education Nursing, Nursing Workforce Diversity, Nurse Education, Practice, and Retention, and Comprehensive Geriatric Education programs expand nursing school capacity and increase patient access to care. Below is a description of these four critical programs.

- Advanced Education Nursing (AEN) Grants (Sec. 811) support the preparation of RNs in master's and doctoral nursing programs. The AEN grants help to prepare our Nation's nurse practitioners, clinical nurse specialists, nurse midwives, nurse anesthetists, nurse educators, nurse administrators, public health nurses, and other nurse specialists requiring advanced education. In fiscal year 2008 (most current data available), these grants supported the education of 5,649 students.
 - AEN Traineeships assist graduate nursing students by providing full or partial reimbursement for the costs of tuition, books, program fees and reasonable living expenses. In fiscal year 2008, this funding helped support 6,675 graduate nurses and APRNs.
 - Nurse Anesthetist Traineeships (NAT) support the education of students in nurse anesthetist programs. In some States, Certified Registered Nurse Anesthetists (CRNAs) are the sole anesthesia providers in almost 100 percent of rural hospitals. Much like the AEN Traineeships, the NAT provides full or partial support for the costs of tuition, books, program fees, and reasonable living expenses. In fiscal year 2008, the program supported 2,145 future CRNAs.
- Workforce Diversity Grants (Sec. 821) prepare disadvantaged students to become nurses. This program awards grants and contract opportunities to schools of nursing, nurse managed health centers, academic health centers, State or local governments, and nonprofit entities looking to increase access to nursing education for disadvantaged students, including racial and ethnic minorities under-represented among RNs. In fiscal year 2008, the program supported 11,638 students.
- Nurse Education, Practice, and Retention Grants (Sec. 831) help schools of nursing, academic health centers, nurse-managed health centers, State and local governments, and healthcare facilities strengthen programs that provide nursing education. In fiscal year 2008, the priority areas under this program

supported 42,761 with an additional 455 students supported by the Integrated Nurse Education Technology program.

- Comprehensive Geriatric Education Grants (Sec. 855) are awarded to schools of nursing or healthcare facilities to better provide nursing services for the elderly. These grants are used to educate RNs who will provide direct care to older Americans, develop and disseminate geriatric curriculum, prepare faculty members, and provide continuing education. In fiscal year 2008, this program supported 6,514 nurses and nursing students.

NATIONAL INSTITUTE OF NURSING RESEARCH

The National Association of Clinical Nurse Specialists respectfully requests \$150 million for the National Institute of Nursing Research in fiscal year 2013. The NINR funds research that lays the groundwork for evidence-based nursing practice. Nurse-scientists at NINR examine ways to improve models of care to deliver safe, high quality, and cost-effective health services to the Nation. It is critical that we look toward the prevention aspect of healthcare as the vehicle for saving our system from further financial burden, and the work of NINR supports this through research related to care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life for those with chronic illness, and care for individuals at the end of life.

NURSE-MANAGED HEALTH CLINICS: EXPANDING ACCESS TO CARE

The National Association of Clinical Nurse Specialists respectfully requests \$20 million for the Nurse-Managed Health Clinics authorized under Title III of the Public Health Service Act in fiscal year 2013. NMHCs are healthcare delivery sites managed by APRNs and are staffed by an interdisciplinary health provider team that may include physicians, social workers, public health nurses, and therapists. These clinics are often associated with a school, college, university, department of nursing, federally qualified health center, or independent nonprofit healthcare agency. NMHCs serve as critical access points to keep patients out of the emergency room, saving the healthcare system millions of dollars annually. The NMHCs provide care to patients in medically underserved regions of the country, including rural communities, Native American reservations, senior citizen centers, elementary schools, and urban housing developments.

Without an adequate supply of nurses to care for our Nation, including our growing aging population, the healthcare system is not sustainable. The NACNS requests \$251 million in fiscal year 2013 for the HRSA Nursing Workforce Development programs, \$150 million for NINR and \$20 million for the Nurse-Managed Health Clinics authorized under Title III of the Public Health Service Act in fiscal year 2013 to ensure access to quality care provided by America's nursing workforce

PREPARED STATEMENT OF THE NATIONAL ALLIANCE FOR EYE AND VISION RESEARCH

The National Alliance for Eye and Vision Research (NAEVR) requests fiscal year 2013 NIH funding of at least \$32 billion, which reflects a \$1.38 billion, or 4.5 percent increase over fiscal year 2012, which consists of biomedical inflation of 2.8 percent plus modest growth, and is necessary since:

- After nearly a decade of budgets below biomedical inflation, NIH's inflation-adjusted funding is close to 20 percent lower than fiscal year 2003.
 - Even before adjusting for inflation, enacted spending bills in recent years have cut the NIH budget. The looming sequestration mandated by the Budget Control Act threatens further cuts, estimated by the Congressional Budget Office (CBO) at 8 percent in fiscal year 2013 alone.
- NIH, our Nation's biomedical research enterprise, is unique in that:
- Its basic and clinical research has helped to understand the basis of disease, thereby resulting in innovations in healthcare to save and improve lives.
 - Its research serves an irreplaceable role that the private sector could not duplicate.
 - It has been shown through several studies to be a major force in the economic health of communities across the Nation. The latest United for Medical Research report estimates that NIH funding supported more than 432,000 jobs in 2011, directly or indirectly, and generated more than \$62.1 billion in economic activity.

NAEVR requests National Eye Institute (NEI) funding at \$730 million, commensurate with the overall NIH funding increase, especially since:

—Proposed fiscal year 2013 NEI funding of \$693 million reflects little more than 1 percent of the \$68 billion annual cost of eye disease/vision impairment in the United States.

—The proposed \$693 million level is a \$14 million cut since fiscal year 2010, translating into 40 research project grants—any one of which could have cured blindness.

—In 2009, the Congress spoke volumes in passing S. Res. 209 and H. Res. 366, which designated 2010–2020 as The Decade of Vision, in which the majority of 78 million Loomers will turn 65 years of age and face greatest risk of aging eye disease. A cut, level funding, or even an inflationary increase is not sufficient for NEI to meet the vision challenges presented by the “Silver Tsunami.”

Congress must improve upon the President’s fiscal year 2013 request, since it cuts NEI funding by \$8.86 million, or 1.2 percent below fiscal year 2012, which results in funding close to the base fiscal year 2009 level.

Although the President’s budget request level-funds NIH, it proposes to cut NEI by \$8.8 million. Although most of this cut reflects the NIH Office of AIDS Research pulling its funding from the NEI’s Studies of Ocular Implications of AIDS (SOCA) clinical trials, which established the efficacy of combination antiviral drug therapy in treating cytomegalovirus (CMV) retinitis, the resulting total NEI funding of \$693 million reflects a level just slightly higher than that in fiscal year 2009, prior to the addition of American Recovery and Reinvestment Act (ARRA) funding. Although the NEI’s congressional justification (CJ) notes that this funding level will still enable NEI to increase Research Project Grant (RPG) funding by \$3 million, it will still cut training programs and Research and Development contracts.

The fiscal year 2013 level also results in a net \$14 million loss of NEI funding since its highest level in fiscal year 2010, which translates into about 40 research grants—any one of which could hold the promise of curing a blinding eye disease. NEI is already facing enormous challenges in this Decade of Vision 2010–2020. Each day, from 2011 to 2029, 10,000 citizens will turn 65 and be at greatest risk for eye disease, the fast growing African-American and Hispanic populations will experience a disproportionately higher incidence of eye disease, and the epidemic of obesity will significantly increase the incidence of diabetic retinopathy.

NAEVR requests NEI funding at \$730 million, reflecting biomedical inflation plus modest growth commensurate with that of NIH overall, since our Nation’s investment in vision health is an investment in overall health. NEI’s breakthrough research is a cost-effective investment, since it is leading to treatments and therapies that can ultimately delay, save, and prevent health expenditures, especially those associated with the Medicare and Medicaid programs. It can also increase productivity, help individuals to maintain their independence, and generally improve the quality of life, especially since vision loss is associated with increased depression and accelerated mortality.

The very health of the vision research community is also at stake with a decrease in NEI funding. Not only will funding for new investigators be at risk, but also that of seasoned investigators, which threatens the continuity of research and the retention of trained staff, while making institutions more reliant on bridge and philanthropic funding. If an institution needs to let staff go, that usually means a highly-trained person is lost to another area of research or an institution in another State, or even another country.

Fiscal year 2013 NIH funding of at least \$32 billion, NEI at \$730 million lets NEI build upon its past record of basic and translational research.

In late June 2010, NIH Director Francis Collins, M.D., Ph.D. recognized NEI’s leadership in translational research at an NEI-sponsored Translational Research and Vision Conference. Just 2 weeks earlier, Dr. Collins testified before the House Energy and Commerce Committee, stating that:

“Twenty years ago we could do little to prevent or treat AMD. Today, because of new treatments and procedures based on NIH/NEI research, 1.3 million Americans at risk for severe vision loss from AMD over the next 5 years can receive potentially sight-saving therapies.”

With fiscal year 2013 funding at \$730 million, NEI can build upon its past research, including:

—*Genetic Basis of Eye Disease.*—As NEI Director Paul Sieving, M.D., Ph.D. has stated, of the more than 2,000 genes identified to date, more than 500, or one-quarter, are associated with both common and rare eye diseases. By further understanding the genetic basis of eye disease, NEI can study underlying disease mechanisms and develop appropriate diagnostic and therapeutic applications for such blinding eye diseases as AMD, glaucoma, and retinitis pigmentosa (RP).

- NEI's AMD Gene Consortium, which consolidates 15 international Genome Wide Association Studies (GWAS) representing more than 8,000 patients, has validated 8 previously known gene variants and identified 19 new variants.
- NEI's Glaucoma Human Genetics Collaboration (NEIGHBOR) has identified the first risk variant in a gene thought to play a role in the development of the optic nerve head, the degeneration of which leads to glaucoma and loss of peripheral vision, and then ultimately blindness.
- The NEI-led human gene therapy clinical trial for neurodegenerative eye disease Leber Congenital Amaurosis (LCA) has resulted to date in 15 patients being treated and experiencing visual improvement. NEI's pioneering work, as well as subsequent refinement of gene therapy techniques, is enabling further research into ocular gene therapy through the launch of NEI-funded clinical trials for AMD, choroideremia, Stargardt disease, and Usher Syndrome. The latter three neurodegenerative diseases occur in early childhood and progressively destroy the retina, leading to vision loss and blindness and resulting in a lifetime of direct medical and indirect support costs. NEI is also funding pre-clinical safety trials for human gene therapy for RP, juvenile retinoschisis ("splitting" of the retina, resulting in vision loss), and achromatopsia (affecting color perception and visual acuity).
- Diabetic Eye Disease.*—NEI's Diabetic Retinopathy Clinical Research (DRCR) Network found that laser treatment for diabetic macular edema, when combined with anti-angiogenic drug treatment, is more effective than laser treatment alone and will revolutionize the standard of care in place the past 25 years. With the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) leading a new NIH strategic plan to combat diabetes, NEI's research through its various diabetic eye disease networks over the past 40 years—in partnership with NIDDK—will be more important than ever.

Blindness and vision loss is a growing public health problem that individuals fear and would trade years of life to avoid.

The NEI estimates that more than 38 million Americans age 40 and older experience blindness, low vision, or an age-related eye disease such as AMD, glaucoma, diabetic retinopathy, or cataracts. This is expected to grow to more than 50 million Americans by year 2020. Although the NEI estimates that the current annual cost of vision impairment and eye disease to the United States is \$68 billion, this number does not fully quantify the impact of indirect healthcare costs, lost productivity, reduced independence, diminished quality of life, increased depression, and accelerated mortality. NEI's proposed fiscal year 2013 funding of \$693 million reflects just a little more than 1 percent of this annual costs of eye disease. The continuum of vision loss presents a major public health problem, as well as a significant financial challenge to the public and private sectors.

Vision loss also presents a real fear to most citizens:

- In public opinion polls over the past 40 years, Americans have consistently identified fear of vision loss as second only to fear of cancer.
- NEI's "Survey of Public Knowledge, Attitudes, and Practices Related to Eye Health and Disease" reported that 71 percent of respondents indicated that a loss of their eyesight would rate as a "10" on a scale of 1 to 10, meaning that it would have the greatest impact on their day-to-day life.
- In patients with diabetes, going blind or experiencing other vision loss rank among the top four concerns about the disease. These patients are so concerned about vision loss diminishing their quality of life that those with nearly perfect vision (20/20 to 20/25) would be willing to trade 15 percent of their remaining life for "perfect vision," while those with moderate impairment (20/30 to 20/100) would be willing to trade 22 percent of their remaining life for perfect vision. Patients who are legally blind from diabetes (20/200 to 20/400) would be willing to trade 36 percent of their remaining life to regain perfect vision.

NAEVR urges the Congress to fund NIH and NEI at funding levels of at least \$32 billion and \$730 million, respectively, which ensures the momentum of research and retention of trained personnel.

ABOUT NAEVR

The National Alliance for Eye and Vision Research (NAEVR), which serves as the "Friends of the NEI," is a 501(c)4 nonprofit advocacy coalition comprised of 55 professional (ophthalmology and optometry), patient and consumer, and industry organizations involved in eye and vision research. Visit NAEVR's Web site at www.eyereseearch.org.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF NUTRITION AND AGING SERVICES PROGRAMS

On behalf of the National Association of Nutrition and Aging Services Programs (NANASP), we thank you for providing an opportunity to submit testimony as you consider an fiscal year 2013 Labor, Health and Human Services, Education, and Related Agencies appropriations bill. NANASP is a national membership organization of nearly 1,000 members working to provide older adults healthful food and nutrition through community-based services. We have 5 members from Montana and about 30 members in Connecticut who in turn serve hundreds of older adults every day.

We are writing today to urge you to provide a much needed increase in funding for the senior nutrition programs in the Older Americans Act. These programs consist of the congregate and home-delivered (Meals on Wheels) nutrition programs along with the Nutrition Services Incentive Program. Together, these programs are known as the Elderly Nutrition Programs and all three keep millions of vulnerable older adults healthy and independent in their homes and communities by providing nutritious meals and needed socialization.

These programs were forced to endure level funding in fiscal year 2012 and if the President's budget was to be adopted, the same fate would occur in fiscal year 2013. Level funding is fine if costs associated with a program and the need for a program stay level as well. That is not the case with the Elderly Nutrition Programs. USDA has estimated that food costs are expected to increase by 3 percent. In addition, the price of gasoline has risen dramatically (up 12 percent since last year) as well as related energy costs which go to the heart of the nutrition programs that operate in congregate sites and who provide home-delivered meals on a daily basis. These costs have also reduced the ranks of volunteers for our programs. On the need side, many of our programs continue to have waiting lists or unmet needs.

We would also proudly point out that the Elderly Nutrition Programs represent a sound and solid investment of the Federal dollar. Our programs keep seniors at home and in the community and out of nursing homes and hospitals because they help prevent hunger and malnutrition. In the congregate and home-delivered meal programs, a senior can be fed for 1 year for about \$1,300. This \$1,300 is the same as the cost of 6 days in a nursing home or 1 day of hospitalization. In addition, for every \$1 spent on home-delivered meals, an additional \$3.35 is contributed from State, local, and private funds.

The Elderly Nutrition Programs celebrate their 40th anniversary this year. They have more than proven their value. It is not time to pull back on the commitment of the Older Americans Act. We urge you to provide the nutrition programs with a modest increase of at least 3 percent to allow them to keep up with inflation. Level funding in reality is a reduction. Only if there is absolutely no other choice then do we urge level funding be maintained for fiscal year 2013.

In closing, another important priority for NANASP is the Senior Community Service Employment Program SCSEP. The President's fiscal year 2013 budget once again proposes funding SCSEP at \$448 million, which represents a 45 percent cut which was first enacted in fiscal year 2011. The SCSEP program, also authorized by the Older Americans Act, is the only Federal job training program targeted for older adults seeking employment and training assistance. Many SCSEP participants work in programs that serve older adults, including the Elderly Nutrition Programs. We urge you to restore funding for the SCSEP program to \$600.4 million, the pre-American Recovery and Reinvestment Act funding level.

Thank you for the opportunity to submit this testimony. Please feel free to contact us with any questions or if you need additional information.

PREPARED STATEMENT OF THE NATIONAL AHEC ORGANIZATION

The members of the National AHEC Organization (NAO) are pleased to submit this statement for the record recommending \$33.145 million in fiscal year 2013 for the Area Health Education Center (AHEC) program authorized under Titles VII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA). The NAO is the professional organization representing AHECs. The AHEC Program is an established and effective national primary care training network built on committed partnerships of 53 medical schools and academic centers. Additionally, 253 AHEC centers within 48 States and tens of thousands of community practitioners are affiliated with the AHEC's national clinical training network.

AHEC is one of the Title VII Health Professions Training programs, originally authorized at the same time as the National Health Service Corps (NHSC) to create

a complete mechanism to provide primary care providers for Community Health Centers (CHCs) and other direct providers of healthcare services for underserved areas and populations. The plan envisioned by creators of the legislation was that the CHCs would provide direct service. The NHSC would be the mechanism to fund the education of providers and supply providers for underserved areas through scholarship and loan repayment commitments. The AHEC program would be the mechanism to recruit providers into primary health careers, diversify the workforce, and develop a passion for service to the underserved in these future providers, i.e. Area Health Education Centers are the workforce development, training and education machine for the Nation's healthcare safety-net programs. The AHEC program is focused on improving the quality, geographic distribution and diversity of the primary care healthcare workforce and eliminating the disparities in our Nation's healthcare system.

AHECs develop and support the community based training of health professions students, particularly in rural and underserved areas. They recruit a diverse and broad range of students into health careers, and provide continuing education, library and other learning resources that improve the quality of community-based healthcare for underserved populations and areas.

The Area Health Education Center program is effective and provides vital services and national infrastructure. Nationwide, more than 379,000 students have been introduced to health career opportunities, and more than 33,000 mostly minority and disadvantaged high school students received more than 20 hours each of health career exposure. More than 44,000 health professions students received training at 17,530 community-based sites, and furthermore; more than 482,000 health professionals received continuing education through AHECs. AHECs perform these education and training services through collaborative partnerships with Community Health Centers (CHCs) and the National Health Service Corps (NHSC), in addition to Rural Health Clinics (RHCs), Critical Access Hospitals, (CAHs), Tribal clinics and Public Health Departments.

Justification for Recommendations

The AHEC network is an economic engine that fuels the recruitment, training, distribution, and retention of a national health workforce. AHEC stands for JOBS.

—Primary Care services improve the health of the population, and therefore increase productivity of the U.S. workforce, while at the same time, contain costs within the U.S. healthcare system. Primary care practitioners are the front-line in prevention of disease, providing cost savings in the United States healthcare system.

—AHECs are critical in the recruitment, training, and retention of the primary care workforce.

—Research has demonstrated that the community-training network is the most effective recruitment tool for the health professions and those who teach remain longer in underserved areas and communities.

—AHECs are in almost every county in the United States.

—With the aging and growing population, the demand for primary care workforce is far outpacing the supply.

—AHECs continue to educate and train current workforce, as well as recruiting and preparing future workforce

—In 2010, AHECs trained 476,585 Health Professionals in 48 States in 13,842 Health Professions Shortage Areas (HPSAs)—26.4 percent of those trained were physicians (125,818).

The AHEC network's outcomes are the backbone of the Nation's community-based health professions training, with a focus on training primary care workforce.

—HRSA has encouraged functional linkage between Bureau of Primary Care and Bureau of Health Professions Programs. AHECs have partnerships with more than 1,000 Community Health Centers nationally to recruit, train, and retain health professionals who have the cultural and linguistic skills to serve in HRSA designated underserved areas.

—AHECs via a cooperative agreement with HRSA are training 10,000 primary care providers throughout the county to address OIF/OEF/OND Veteran's mental health, substance abuse, traumatic brain injury and post-traumatic stress for those not utilizing the VA system

PREPARED STATEMENT OF THE NATIONAL ASSEMBLY ON SCHOOL BASED HEALTH CARE

I am grateful for this opportunity to submit written testimony on behalf of the National Assembly on School Based Health Care (NASBHC), an organization representing the interests of school-based health centers and the children and adolescents who depend upon them.

More than 1,900 school-based health centers provide comprehensive primary healthcare for nearly 2 million students—regardless of their ability to pay—and in a location that meets children and adolescents where they are: at school. School-based health centers are a common-sense solution to address the severe gaps in educational achievement, healthcare access, and future employment potential among children and adolescents. School-based health centers are on the frontlines tackling challenging and expensive health crises like diabetes, asthma, mental health and oral health. School-based health centers keep students healthy and learning.

The Patient Protection and Affordable Care Act (Public Law 111-148; section 4101(b)), includes a Federal authorization for school-based health center operations. The success of a Federal school-based health center authorization was a huge and historical victory for vulnerable children and adolescents; now, the Nation's school-based health centers need funds to be appropriated in order to continue providing critical health services to our Nation's children and adolescents.

The National Assembly on School Based Health Care respectfully asks the Subcommittee to provide \$50 million in funding for school-based health centers for fiscal year 2013.

At school-based health centers, developmentally appropriate health services are provided by qualified health professionals, incorporating the principles and practices of pediatric and adolescent healthcare recommended by the American Medical Association, the American Academy of Pediatrics, and the American Association of Family Physicians.

School-based health centers are first-hand witnesses to factors that impact student health and academic achievement—including bullying, school violence, depression, stress, and poor eating habits—circumstances often missed by outside health providers. Working within the school building, school-based health center staff members are uniquely poised to address the many challenges students bring to the classroom. Access to competent and appropriate healthcare leads to positive academic outcomes as shown in a recent study proving that school-based health centers have positive impacts on student achievement—particularly increasing grade point averages and attendance.

Sadly, many school-based health centers are struggling to keep their doors open. Diminished public and private support, layoffs, and hiring freezes have reduced the number of providers on site to deliver care. Additionally, school-based health centers have historically faced limited patient revenue streams despite decades of providing services to Medicaid and CHIP-covered children: the gap between cost and actual revenue paid by Medicaid is quite steep in some communities. Average payment rates for SBHC visits by Medicaid enrollees range widely. In addition, many developmentally appropriate services—mental health, health education, and behavioral risk reduction counseling—are oftentimes either not reimbursed or, if so, at a fraction of the cost of actual care.

Restricted and diminishing revenue to support the delivery of health services to kids through school-based health centers jeopardizes the health and well-being of our Nation's children. Examples of funding limitations include:

—*New York*.—Suffolk County Department of Health Services suffered reduction in funding and needed to reduce operations. Eastern BOCES School Based Health Center, supported by the county, closed on July 1, 2011. Even worse, UHS Chenango Memorial Hospital decided to close 10 comprehensive school-based health centers which include 5 dental programs prior to the start of this school year.

—*Illinois*.—A survey taken by the Illinois Coalition for School Health Centers found that seven school-based health centers in that State have cut programs or staff over the last 4 years due to financial constraints.

—*Arizona*.—In January 2009, 10 rural school-based health care centers were shut down because of lack of funding support at the following schools: Aquila Elementary, Arlington Elementary, Buckeye High School, Harquahala Valley community, Liberty Elementary, Paloma Elementary, Palo Verde Elementary, Ruth Fisher Elementary, Rainbow Valley Elementary, and Tolleson High School.

School-based health centers need direct Federal financial support for operations to continue delivering quality comprehensive services to our Nation's children and adolescents.

Thanks to the school-based health center authorization and the path it creates toward future reform, if funded, fewer school-based health centers will be forced to shut their doors because of State and local budget cuts, and more communities that desire to open a health clinic at their school will have the critical resources to do so. In her statement at the Coalition for Community School's national forum, Secretary Sebelius agreed: "We are thrilled that part of the [health reform] legislation calls for an expanded foot print of school-based health clinics . . . I can't think of a better way to deliver primary care and preventive care to not only students but their families than through school-based clinics."

We are pleased that school-based health centers are, at last, a federally authorized program. Until funds are appropriated, however, there remains no Federal support for their operations. We ask that funds be allocated this year to enable school-based health centers to keep their doors open, and to give critical resources to communities that desire to open health clinics at their schools.

We recognize that there has been some confusion about capital money allocated to school-based health centers in the Affordable Care Act under section 4101(a). These funds, although important, are limited to capital improvements, land acquisition, and equipment purchases. Expenditures for care and personnel are specifically excluded.

We respectfully request that a \$50 million appropriation be provided for the school-based health center authorization for fiscal year 2013.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE COMPREHENSIVE
HEALTH INSURANCE PLANS

The National Association of State Comprehensive Health Insurance Plans (NASCHIP) submits this testimony to urge your support for a fiscal year 2013 appropriation of \$55 million for the State High Risk Pool Funding Extension Act of 2006.

This funding level would be what our programs received in fiscal year 2011. Our programs which operate in 35 States (including Iowa and Alabama) and serve more than 200,000 persons with pre-existing conditions have been growing consistently year over year. Even with the advent of the Pre-Existing Condition Insurance Plans (PCIP) authorized under the Patient Protection and Affordable Care Act to serve individuals with pre-existing conditions, State pool enrollment continues to grow across the country. This is in part due to continued erosion of employer-sponsored coverage.

Fiscal year 2012 funding to support the 35 State high risk pools was cut by \$11 million or 25 percent. These cuts resulted in higher premiums and some of our most vulnerable citizens finding themselves unable to afford the healthcare services they need. Nearly half of all State high risk pools depend on the funding to directly buy-down premiums and other cost shares for low income pool members. Continuing with such dramatic cuts to this critical funding will ensure that more low income plan members may have to drop coverage altogether as premiums will be unaffordable.

Contrast this to the lagging enrollment numbers for the totally separate PCIP program under the Affordable Care Act (with \$5 billion in funding). The simple fact is not only do our State high risk pool programs predate the PCIP program but they are also distinct from PCIP because of the subsidy we provide in one-third of our States to low-income individuals offering discounts of between 18 and 67 percent.

The administration's budget proposal for fiscal year 2013 slashes funding to \$22 million, another 50 percent reduction. The administration's justification for this draconian cut is based on the patently false premise that only 6 months of funding is needed for this program in fiscal year 2013 because State exchanges will be fully operational and there will no need for the State high risk pool program. That is a misreading on the reality of the situation. Individuals covered by high risk pools will not be able to access insurance in the Exchange marketplace until January 1, 2014 at the earliest. Therefore, our State high risk pools will require funding for the entire fiscal year 2013 as they will be operational until at least December 31, 2013. State exchanges will not be ready to insure State high-risk pools members until after the close of fiscal year 2013. Funding must be provided to ensure continuation of coverage through 2013 and a safe transition for these needy individuals in 2014.

The funding level we seek is to simply allow us to continue our important work for the duration of fiscal year 2013; therefore, our request is a funding level of \$55 million. We suggest as an offset to support this funding level come with the authority to allow PCIP funds to be used to support State operational grants and low-income subsidies for those with preexisting conditions in the 35 States we serve.

Thank you for your consideration and the opportunity to submit this testimony.

PREPARED STATEMENT OF THE NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS

The National Alliance of State and Territorial AIDS Directors (NASTAD) represents the Nation's chief State health agency staff who have programmatic responsibility for administering HIV/AIDS and viral hepatitis healthcare, prevention, education, and supportive service programs funded by State and Federal governments. On behalf of NASTAD, we urge your support for increased funding for Federal HIV/AIDS and viral hepatitis programs in the fiscal year 2013 Labor-Health-Education appropriations bill, and thank you for your consideration of the following critical funding needs for HIV/AIDS, viral hepatitis and STD programs in fiscal year 2013. These funding needs support activities aligned with the goals set forth in the National HIV/AIDS Strategy (NHAS)—a game-changing blueprint for tackling the Nation's HIV/AIDS epidemic.

As we are 30 years into the HIV/AIDS epidemic, we must be mindful that HIV/AIDS is still a crisis in the United States, not just abroad. HIV/AIDS is an emergency and while there are life-saving medications that did not exist 20 years ago, there is still no cure, and approximately 50,000 new infections occur annually. The Nation's prevention efforts must match our commitment to the care and treatment of infected individuals. First and foremost we must address the devastating impact on racial and ethnic minority communities, particularly African-Americans and Latinos, as well as gay men and other men who have sex with men of all races and ethnicities, substance users, women and youth. To be successful, we must expand outreach, scale-up and consider new and innovative approaches to arrest the epidemic here at home.

HIV/AIDS CARE AND TREATMENT PROGRAMS

The Health Resources and Services Administration (HRSA) administers the \$2.4 billion Ryan White Program that provides health and support services to more than 500,000 Persons Living with HIV/AIDS (PLWHA). NASTAD requests a minimum increase of \$270.1 million in fiscal year 2013 for State Ryan White Part B grants, including an increase of \$79.9 million for the Part B base and \$190.2 million for AIDS Drug Assistance Programs (ADAPs). With these funds States and territories provide care, treatment and support services to PLWHA, who need access to HIV clinicians, life-saving and life-extending therapies, and a full range of wrap-around support services to ensure adherence to complex treatment regimens. All States have reported to NASTAD a significant increase in the number of individuals seeking Part B base and ADAP services.

State ADAPs provide medications to low-income uninsured or underinsured PLWHA. In fiscal year 2010, more than 226,000 clients were enrolled in ADAPs nationwide. Due to many factors such as unemployment, economic challenges, increased HIV testing and linkages to care, and new HIV treatment guidelines calling for earlier therapeutic treatments, program demand has increased dramatically. Due to emergency funding for ADAPs throughout fiscal year 2012, the waitlists have decreased; however, to eliminate waitlists and other cost containment measures completely, there is still a need for additional funding. As of April 19, 2012, there are 3,079 individuals are on waiting lists in 10 States to receive their life-sustaining medications through ADAP:

- Florida: 427 individuals;
- Georgia: 1,058 individuals;
- Idaho: 8 individuals;
- Louisiana: 356 individuals;
- Montana: 4 individuals;
- Nebraska: 222 individuals;
- North Carolina: 140 individuals;
- South Carolina: 0 individuals;
- Utah: 0 individuals; and
- Virginia: 864 individuals.

HIV/AIDS PREVENTION AND SURVEILLANCE PROGRAMS

One of the major goals of the NHAS is to lower the annual number of new infections by 25 percent from 56,300 to 42,225 by 2015. In order to meet this ambitious goal, NASTAD requests an increase of \$100 million above fiscal year 2012 funding levels for State and local health department HIV prevention and surveillance coop-

erative agreements in order to provide comprehensive prevention programs. By providing adequate resources to State and local health departments to scale up HIV prevention and surveillance programs, we will be closer to meeting the NHAS goal of reducing new HIV infections by 25 percent by 2015.

NASTAD is gravely concerned about the unraveling of State public health HIV prevention infrastructure in an era where averting new HIV infections is paramount. NASTAD requests that of these funds, \$41 million (\$27 million for core health department prevention programs and \$14 million for expanded HIV testing) be used to restore funding to health departments who lost resources through PS12–1201: Comprehensive Human Immunodeficiency Virus (HIV) Prevention Programs for Health Departments to fiscal year 2010 levels. The funding should reinstate Category A: HIV Prevention Programs for Health Departments losses and Category B: Expanded HIV Testing for Disproportionately Affected Populations. NASTAD's analysis indicates that 40 jurisdictions (including 34 States, the District of Columbia, three cities and two territories) experienced decreases in their core HIV prevention awards between fiscal year 2011 and fiscal year 2012. In terms of expanded HIV testing 24 jurisdictions (including 20 States, the District of Columbia and three cities) experienced a decrease in their awards between fiscal year 2010 and fiscal year 2012.

NASTAD supports targeting resources to where they are most needed and innovation in HIV prevention programming. However, since the funding levels were lower than the previous year and because funds were shifted to some jurisdictions as a result of a new formula based on reported HIV cases, dramatic decreases in resources have occurred for the majority of States. Unfortunately, cuts of this magnitude erode the capacity of many of States to drive down HIV incidence and link newly diagnosed individuals to care, both critical goals of the National HIV/AIDS Strategy. Many health departments are experiencing significant challenges as they restructure existing programs in reaction to these funding shifts.

NASTAD also recommends that all jurisdictions be eligible for expanded testing resources. Additional analyses indicate that approximately \$18 million in additional funds are needed for Category B, expanded HIV testing, to bring currently funded programs to their fiscal year 2010 levels (including the MAI and PPHF resources) and fund the remaining programs at tiered levels based on prevalence. If the NHAS is to be truly "national," all jurisdictions should receive resources under Category B. Currently, expanded HIV testing activities serve disproportionately impacted populations: African-Americans, Latinos, gay and bisexual men of all races and ethnicities and persons who inject drugs. Moreover, the program has been an effective way to implement routine HIV testing in clinical settings—increasing the number of people who know their HIV status and linking those with HIV to care and treatment. During the first 3 years of the program approximately 2.6 million tests were conducted with an estimated 28,000 being confirmed HIV positive. Reducing new HIV infections relies heavily on "knowing your status." This program should be expanded with adequate funding to ensure that more individuals learn their HIV status and are linked to care.

In addition, NASTAD believes an increase of \$40 million should be directed toward critical HIV surveillance efforts. HIV surveillance has been chronically underfunded in most jurisdictions for over a decade. As a result, many States cobble together their HIV surveillance programs with resources leveraged from other programs. With the significant reallocation of resources to State and local health departments through FOA PS12–1201 Comprehensive HIV Prevention Programs for Health Departments, the ability of these health departments to continue supporting surveillance activities will be greatly diminished. Additional resources will allow improvements in core surveillance and expand surveillance for HIV incidence, behavioral risk, and receipt of care information including CD4 and viral load reporting. HIV surveillance data are the mechanism through which the success at achieving the goals of the NHAS will be measured. The completeness of national HIV surveillance activities is critical to monitor the HIV/AIDS epidemic and to provide data for targeting with greater precision the delivery of HIV prevention, care, and treatment services.

VIRAL HEPATITIS PREVENTION PROGRAMS

NASTAD requests an increase of \$40 million for a total of \$59.3 million in fiscal year 2013 for the CDC's Division of Viral Hepatitis (DVH) for a national testing, education and surveillance initiative as outlined in the Division's professional judgment budget submitted to the Congress last year. We believe that testing to identify more than 3 million people or 65–75 percent of chronic hepatitis B and C patients who do not know they are infected is the highest priority for reducing illness and

death related to viral hepatitis. Testing must accompany education efforts to reach those already infected and at high risk of death and of spreading the disease. DVH received an increase of \$10 million from the Prevention and Public Health Fund in fiscal year 2012 for the development of a national screening initiative. NASTAD requests funding to continue to support the viral hepatitis screening and testing initiative and encourages the Division to make all currently funded health departments eligible for funding. Due to the lack of strong surveillance data for viral hepatitis, it would be impossible to adequately determine which jurisdictions have the highest incidence or prevalence of viral hepatitis. Developing a national surveillance system is the Division's second highest priority. Surveillance is needed to monitor disease trends and evaluate evidence-based interventions. Unlike other infectious diseases, viral hepatitis lacks a national surveillance system. NASTAD requests funding to State adult viral hepatitis prevention coordinators be increased from \$5 to \$10 million. Adult Viral Hepatitis Prevention Coordinators are based in State health departments and implement and integrate testing, education and surveillance into the existing public health infrastructure. States and cities receive an average funding award from DVH of \$90,000, which supports a single staff position and is not sufficient for the provision of core prevention services.

HHS' Viral Hepatitis Action Plan will improve the collaboration and coordination of the Federal Government's response and implement the Institute of Medicine's (IOM) expert recommendations on controlling and preventing viral hepatitis. Funding is needed to support increased capacity at the HHS Office of the Assistant Secretary for Health (ASH) for supporting the implementation of the HHS Viral Hepatitis Action Plan.

SYRINGE EXCHANGE PROGRAMS

NASTAD supports the lifting of the ban on the use of Federal funds for syringe exchange programs and opposes any Federal actions which ban or increase the bureaucratic, regulatory and reporting requirements on syringe access beyond those already in place at the State and local level. Syringe exchange programs are a crucial aspect of comprehensive HIV and viral hepatitis prevention services. Sharing used syringes is the primary reason IDUs become infected with HIV and hepatitis C and morbidity and mortality rates among IDUs remain disproportionately high. People who inject drugs bear the highest burden of hepatitis C (HCV) infection and in some communities as many as 90 percent of IDUs are infected with chronic HCV. Research has provided overwhelming evidence that access to sterile syringes is effective in reducing transmission of HIV, without increasing drug use. The 21-year-old ban on the use of Federal funds for syringe exchange programs was lifted in December 2009 when the fiscal year 2010 appropriations bill was signed into law without this restriction. However, in the fiscal year 2012 Consolidated Appropriations Act, the Federal ban on syringe exchange programs was reinstated in the Labor-HHS appropriations and Financial Services appropriations, barring the use of Federal funds for syringe exchange in the United States and the District of Columbia.

STD PREVENTION PROGRAMS

NASTAD supports an increase of \$26.2 million for a total of \$180 million in fiscal year 2013 for STD prevention, treatment and surveillance activities undertaken by State and local health departments. CDC's Division of STD Prevention has prioritized four disease prevention goals—Prevention of STD-related infertility, STD-related adverse pregnancy outcomes, STD-related cancers and STD-related HIV transmission. CDC estimates that 19 million new infections occur each year, almost half of them among young people ages 15 to 24. In 1 year, the United States spends more than \$8 billion to treat the symptoms and consequences of STDs. Untreated STDs contribute to infant mortality, infertility, and cervical cancer. Additional Federal resources are needed to reverse these alarming trends and reduce the Nation's health spending. The teen pregnancy prevention initiative, administered through the Office of Adolescent Health should be expanded to include prevention of HIV and STDs and funded at \$130 million.

PREVENTION AND PUBLIC HEALTH FUND

The Prevention and Public Health Fund (PPHF) tackles critical epidemics, such as HIV/AIDS and viral hepatitis. The fund is a unique opportunity to decrease healthcare spending related to HIV/AIDS treatment and care, and invest in viral hepatitis prevention and screening efforts. We encourage you to utilize the PPHF to support a broad testing and screening initiative that would include neglected diseases such as viral hepatitis in order to capture patients before they progress in

their liver disease and increase costs to public healthcare systems, as well as HIV/AIDS prevention initiatives.

PPHF is urgently needed to address the many emerging health threats our country faces through a coordinated, comprehensive, sustainable and accountable approach to improving health outcomes and curbing costs. It is essential to the health of Americans that we capitalize on the opportunity to invest in prevention programs and transform our public health system. In order to accomplish this, we must maintain the PPHF. The PPHF was used to offset costs for the Middle Class Tax Relief and Job Creation Act of 2012, which cut approximately \$6.25 billion from PPHF over the next 10 years. It is imperative that the Prevention and Public Health Fund is not cut further or used again as an offset for other programs.

As you contemplate the fiscal year 2013 Labor, HHS and Education appropriations bill, we ask that you consider all of these critical funding needs. We thank the Chairman, Ranking Member and members of the Subcommittee, for their thoughtful consideration of our recommendations. Our response to the HIV, viral hepatitis and STD epidemics in the United States defines us as a society, as public health agencies, and as individuals living in this country. There is no time to waste in our Nation's fight against these infectious and often chronic diseases. The Nation's prevention efforts must match our commitment to the care and treatment of infected individuals.

PREPARED STATEMENT OF THE NURSING COMMUNITY

The Nursing Community is a forum comprised of 59 national professional nursing membership associations that builds consensus and advocates on a wide spectrum of healthcare and nursing issues surrounding practice, education, and research. These 59 organizations are committed to promoting America's health through the advancement of the nursing profession. Collectively, the Nursing Community represents nearly 1 million Registered Nurses (RNs), Advanced Practice Registered Nurses (APRNs—including certified nurse-midwives, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists), nurse executives, nursing students, nursing faculty, and nurse researchers. Together, our organizations work collaboratively to support a robust investment in the Nursing Workforce Development programs (authorized under Title VIII of the Public Health Service Act [42 U.S.C. 296 et seq.]), support research initiatives at the National Institute of Nursing Research (NINR), and secure authorized funding for Nurse-Managed Health Clinics (Title III of the Public Health Service Act) so that our Nation's population receives the highest-quality nursing services possible.

Demand for Nurses Continues to Grow

According to the Bureau of Labor Statistics' Employment Projections for 2010–2020, the expected number of practicing nurses will grow from 2.74 million in 2010 to 3.45 million in 2020, an increase of 712,000 or 26 percent. The projections further explain the need for 495,500 replacements in the nursing workforce, bringing the total number of job openings for nurses due to growth and replacements to 1.2 million by 2020.

Two primary factors contribute to this overwhelming projection. First, America's nursing workforce is aging. According to the 2008 National Sample Survey of Registered Nurses, more than 1 million of the Nation's 2.6 million practicing RNs are over the age of 50. Within this population, more than 275,000 nurses are over the age of 60. As the economy continues to rebound, many of these nurses will seek retirement, leaving behind a significant deficit in the number of experienced nurses in the workforce. Second, America's baby boomer population is aging. It is estimated that more than 80 million baby boomers reached age 65 last year. This population will require a vast influx of nursing services, particularly in areas of primary care and chronic illness management. A significant investment must be made in the education of new nurses to provide the Nation with the nursing services it demands.

Addressing the Demand: Title VIII Nursing Workforce Development Programs

For nearly 50 years, the Nursing Workforce Development programs, authorized under Title VIII of the Public Health Service Act, have helped build the supply and distribution of qualified nurses to meet our Nation's healthcare needs. The Title VIII programs bolster nursing education at all levels, from entry-level preparation through graduate study, and provide support for institutions that educate nurses for practice in rural and medically underserved communities. Today, the Title VIII programs are essential to ensure the demand for nursing care is met. Between fiscal year 2005 and 2010 alone, the Title VIII programs supported more than 400,000

nurses and nursing students as well as numerous academic nursing institutions, and healthcare facilities.

The American Association of Colleges of Nursing's (AACN) Title VIII Student Recipient Survey gathers information about Title VIII dollars and its impact on nursing students. The 2011–2012 survey, which included responses from more than 1,600 students, stated that the Title VIII programs played a critical role in funding their nursing education. The survey showed that 68 percent of the students receiving Title VIII funding are attending school full time. By supporting full-time students, the Title VIII programs are helping to ensure that new nurses enter the workforce without delay. The programs also address the current demand for primary care providers. Over one-half of respondents reported that their career goal is to become a nurse practitioner. Approximately 80 percent of nurse practitioners provide primary care services throughout the United States. Additionally, several respondents identified working in rural and underserved areas as future goals, with becoming a nurse faculty member, a nurse practitioner, or a nurse researcher as the top three nursing positions for their career aspirations.

The Title VIII programs also address the need for more nurse faculty. Data from AACN's 2011–2012 enrollment and graduations survey show that nursing schools were forced to turn away 75,587 qualified applications from entry-level baccalaureate and graduate nursing programs in 2011, citing faculty vacancy as a primary reason. The Title VIII Nurse Faculty Loan Program aids in increasing nursing school enrollment capacity by supporting students pursuing graduate education provided they serve as faculty for 4 years after graduation.

The Nursing Community respectfully requests \$251 million for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act in fiscal year 2013.

National Institute of Nursing Research: Foundation for Evidence-Based Care

As 1 of the 27 Institutes and Centers at the National Institutes of Health (NIH), the NINR funds research that lays the groundwork for evidence-based nursing practice. Nurse-scientists funded by NINR examine ways to improve care models to deliver safe, high-quality, and cost-effective health services to the Nation. Our country must look toward the prevention aspect of healthcare as the vehicle for saving our system from further financial burden, and the work of NINR embraces this endeavor through research related to care management of patients during illness and recovery, reduction of risks for disease and disability, promotion of healthy lifestyles, enhancement of quality of life for those with chronic illness, and care for individuals at the end of life. Moreover, NINR helps to provide needed faculty to support the education of future generations of nurses. Training programs at NINR develop future nurse-researchers, many of whom also serve as faculty in our Nation's nursing school.

The Nursing Community respectfully requests \$150 million for the NINR in fiscal year 2013. This level of funding is on par with the Ad Hoc Group for Medical Research's \$32 billion request for the total NIH budget in fiscal year 2013.

Nurse-Managed Health Clinics: Expanding Access to Care

NMHCs are healthcare delivery sites managed by APRNs and are staffed by an interdisciplinary team that may include physicians, social workers, public health nurses, and therapists. These clinics are often associated with a school, college, university, department of nursing, federally qualified health center, or independent nonprofit healthcare agency. NMHCs serve as critical access points to keep patients out of the emergency room, saving the healthcare system millions of dollars annually.

NMHCs provide care to patients in medically underserved regions of the country, including rural communities, Native American reservations, senior citizen centers, elementary schools, and urban housing developments. The populations within these communities are the most vulnerable to chronic illnesses that create heavy financial burden on patients and the healthcare system. NMHCs aim to reduce the prevalence of disease and create healthier communities by providing primary care services and educating patients on health promotion practices. Furthermore, NMHCs serve as clinical education training sites for nursing students and other health professionals, a crucial aspect of NMHCs given that a lack of training sites is commonly identified as a barrier to nursing school enrollment.

The Nursing Community respectfully requests \$20 million for the Nurse-Managed Health Clinics authorized under Title III of the Public Health Service Act in fiscal year 2013.

Without a workforce of well-educated nurses providing evidence-based care to those who need it most, including our growing aging population, the healthcare sys-

tem is not sustainable. The Nursing Community's request of \$251 million for the Title VIII Nursing Workforce Development programs, \$150 million for the National Institute of Nursing Research, and \$20 million for Nurse-Managed Health Clinics in fiscal year 2013 will help ensure access to quality care provided by America's nursing workforce.

MEMBERS OF THE NURSING COMMUNITY SUBMITTING THIS TESTIMONY

Academy of Medical-Surgical Nurses	Hospice and Palliative Nurses Association
American Academy of Nurse Practitioners	Infusion Nurses Society
American Academy of Nursing	International Association of Forensic Nurses
American Association of Colleges of Nursing	International Nurses Society on Addictions
American Association of Nurse Anesthetists	International Society of Nurses in Genetics
American Association of Nurse Assessment Coordination	International Society of Psychiatric Nursing
American College of Nurse Practitioners	National American Arab Nurses Association
American College of Nurse-Midwives	National Association of Clinical Nurse Specialists
American Nephrology Nurses' Association	National Association of Nurse Practitioners in Women's Health
American Nurses Association	National Association of Pediatric Nurse Practitioners
American Organization of Nurse Executives	National Black Nurses Association
American Psychiatric Nurses Association	National Gerontological Nursing Association
American Society for Pain Management Nursing	National Nursing Centers Consortium
American Society of PeriAnesthesia Nurses	National Organization for Associate Degree Nurses
Asian American and Pacific Islander Nurses Association	National Organization of Nurse Practitioner Faculties
Association of Community Health Nursing Educators	Nurses Organization of Veterans Affairs
Association of Nurses in AIDS Care	Oncology Nursing Society
Association of periOperative Registered Nurses	Pediatric Endocrinology Nursing Society
Association of Rehabilitation Nurses	Preventive Cardiovascular Nurses Association
Association of State and Territorial Directors of Nursing	Public Health Nursing Section, American Public Health Association
Association of Women's Health, Obstetric and Neonatal Nurses	Society of Urologic Nurses and Associates
Commissioned Officers Association of the U.S. Public Health Service	Wound, Ostomy and Continence Nurses Society
Dermatology Nurses' Association	
Gerontological Advanced Practice Nurses Association	

PREPARED STATEMENT OF THE NATIONAL CONGRESS OF AMERICAN INDIANS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

The National Congress of American Indians (NCAI) is the oldest and largest American Indian organization in the United States. In 1944, tribal leaders created NCAI as a response to termination and assimilation policies that threatened the existence of American Indian and Alaska Native tribes. Since then, NCAI has fought to preserve the treaty rights and sovereign status of tribal governments, while ensuring that Indian people may fully participate in the political system. As the most representative organization of American Indian tribes, NCAI serves the broad interests of tribal governments across the Nation.

Tribal nations in the United States are vastly diverse—as are the citizens that comprise them—but in the modern era, the common element responsible for revitalizing tribal homelands is tribal sovereignty at work. Effective self-rule requires that the United States respect tribes' inherent rights of self-government and self-determination and that the Federal Government honor its trust obligations to Native peoples in the Federal budget. Addressing the healthcare needs of American Indians

and Alaska Natives is one of the most important cornerstones of this Federal trust responsibility. The budget for the Department of Health and Human Services should carry forward the trust responsibility and support tribal self-determination as a key element of healthcare reform while continuing the Government's partnership with tribes to improve Indian health.

The foregoing fiscal year 2013 tribal budget program requests have been compiled in collaboration with tribal leaders, Native organizations, and tribal budget consultation bodies. Tribes respectfully request that these recommendations be included in the Labor, Health and Human Services, Education, and related agencies appropriations process.

Administration on Aging

Older Americans Act—Title VI

Provide \$30 million for Parts A (Grants for Native Americans) and B (Grants for Native Hawaiians) of the Act.

Provide \$8.3 million for the Native American Caregiver Support Program, and create a line item for training for tribal recipients.

Programs under Title VI of the Older Americans Act are the primary vehicle for providing nutrition and other direct supportive services to American Indian, Alaska Native, and Native Hawaiian elders and their caregivers. However, these programs cannot be effective if not adequately funded.

Older Americans Act—Title VII

Create a tribal set-aside of \$2 million under Subtitle B of Title VII.

Subtitle B of Title VII of the Older Americans Act authorizes a program for tribes, public agencies, or nonprofit organizations serving Native elders to assist in prioritizing issues concerning elder rights and to carry out related activities. A \$2 million tribal set-aside should be created under Subtitle B to ensure that tribes have access to funds at a comparable level to States.

Older Americans Act—Title IV

Provide \$3 million for national minority aging organizations to build the capacity of community-based organizations to better serve American Indian and Alaska Native seniors.

Language and cultural barriers severely restrict Native elder access to Federal programs for which they are eligible, such as Social Security, Medicare, and Medicaid. Funding is needed to build capacity for tribal, minority, and other community-based aging organizations to serve Native elders and enroll them in programs to which they are entitled.

Administration for Children and Families

Head Start

Exempt Head Start from budget-related reductions.

The Indian Head Start program comprehensively integrates education, health, and family services in a manner that closely mirrors a traditional Indian education model, making Indian Head Start one of the most successful Federal programs operating in Indian Country. Despite these successes, inflation-adjusted Head Start funding has significantly declined in the past decade and as a result, less than 20 percent of age-eligible Indian children are enrolled in Indian Head Start. Recognizing that achieving a significant funding increase in fiscal year 2013 will be difficult, Head Start should at least be held harmless from any reductions, just as other low-income programs are held harmless in the Budget Control Act of 2011.

Language Preservation Programs

Provide \$12 million for Native language preservation, with \$4 million designated to fund the Esther Martinez Language Programs through the Administration for Native Americans.

Nationwide, tribes are combating the loss of traditional languages through culture and language programs. Tribal students in immersion programs often perform substantially better academically than Native students who have not participated in such programs.¹ As such, in 2013, the Federal budget should include \$12 million as part of the appropriation to the Administration for Native Americans for Native

¹See for example the cases profiled in Pease-Pretty on Top, J. (2003). *Native American Language Immersion: Innovative Native Education for Children & Families*. Denver, Colorado: American Indian College Fund.

language preservation activities, with \$4 million designated to support Esther Martinez Language Programs' Native language immersion initiatives.

Foster Care Initiative

Provide \$20 million to fund Children's Bureau foster care demonstration grants and track tribal awards.

The goal of this Obama administration initiative is to identify innovative strategies that improve outcomes for children in long-term foster care. Twenty million dollars in demonstration grants should be provided to tribes, States, and localities to test new, innovative strategies for improving outcomes for foster care children.

Child Welfare Services

Increase the tribal allocation of Title IV-B, Subpart 1 by creating a 3 percent set-aside of the total appropriation.

Provide \$200 million for Title IV-B, Subpart 2—the full amount authorized for the discretionary component of the program that will benefit tribes and States.

The bare minimum needed to establish a child abuse and neglect prevention program in any tribal community is approximately \$80,000. Title IV-B, Subpart 1 supports a significant portion of this amount, yet tribes are hindered in their ability to effectively administer a program as the majority of them are only eligible for small grants (less than \$10,000, in most cases). No other consistent, stable source of funding is available to tribal governments to provide basic, preventive child welfare services. A 3 percent tribal set-aside of Title IV-B, Subpart 1 funding (within a total appropriation of \$281.7 million for this capped entitlement program) will allow for larger tribal grants to provide basic child welfare services to support Native families and protect Native children.

In order for tribal courts to advance new practices and improve outcomes with children under their jurisdiction, they need access to funding that will support capacity building and innovative practices. Currently, the Title IV-B, Subpart 1 program allows the use of funds for family preservation purposes, but Title IV-B, Subpart 2 (the larger of the two programs) does not focus on family preservation. Title IV-B, Subpart 2 should be funded at \$200 million—the full amount authorized under the Act for the discretionary component of the program—so tribes will receive increased resources from the 3 percent set-aside.

Child Abuse Prevention and Treatment Act (CAPTA)

Provide a separate line item for tribal Title II grants and set-aside 3 percent of total funding for tribes and tribal consortia.

Currently, tribes and migrant programs must compete with each other for a 1 percent set-aside of the total funding appropriated under Title II of CAPTA. Tribes and States have a governmental responsibility to ensure that foster care protections are provided to every child that is in an out-of-home placement under their jurisdiction and care. A 3 percent tribal set-aside, listed as a separate line item in the budget, will provide a base level of funding for every tribe, regardless of size, and give every tribal community an opportunity to establish a quality child abuse and neglect prevention program.

Low-Income Home Energy Assistance Program (LIHEAP)

Maintain full funding levels for LIHEAP (\$4.5 billion), with \$51 million to tribes. LIHEAP prevents families from having to make the choice between food and heat. With high unemployment and barriers to economic development, much of Indian Country cannot afford to pay for the rising costs of heat and power. Full funding of LIHEAP is crucial to address the extreme need for heating assistance in Indian Country.

Substance Abuse and Mental Health Services Administration

Behavioral Health

Provide \$40 million to fund the Behavioral Health—Tribal Prevention Grant (BH-TPG).

This proposed SAMHSA grant program has been authorized to award grants to tribes to evidence-based prevention practices in tribal communities. Funded through the prevention fund (authorized by the Affordable Care Act), the BH-TPG will be used to implement comprehensive prevention strategies to address the most serious mental health and substance abuse issues in tribal communities.

Suicide Prevention

Provide a \$6 million tribal set-aside for American Indian and Alaska Native suicide prevention programs under the Garrett Lee Smith Act.

Suicide has reached epidemic proportions in some tribal communities. The Garrett Lee Smith Memorial Act of 2004 is the first Federal law to provide specific funding for youth suicide prevention programs, authorizing \$82 million in grants over 3 years through SAMHSA. Currently, tribes must compete with other institutions to access these funds. To assist tribal communities in accessing these funds, a line-item for tribal-specific resources is necessary.

DEPARTMENT OF LABOR

Tribal nations in the United States are vastly diverse—as are the citizens that comprise them—but in the modern era, the common element responsible for revitalizing tribal homelands is tribal sovereignty at work. Effective self-rule requires that the United States respect tribes' inherent rights of self-government and self-determination and that the Federal Government honor its trust obligations to Native peoples in the Federal budget. Investing in the education of American Indian and Alaska Native students is not only one of the most important cornerstones of this Federal trust responsibility, but is also critical to economic revitalization for both Indian Country and the Nation as a whole.

Research repeatedly demonstrates that investments in education contribute to economic growth while also expanding opportunities for individual advancement. Unfortunately, when faced with tough budgetary decisions, policymakers and elected officials often target education and other social welfare budgets that require more long-term investments. Even worse, Native youth and families are often the hardest hit by these cuts. As a result, schools in Indian Country face inadequate Federal support, which leads to a shortage of staff, lack of support services, dilapidated facilities, and, ultimately, lower student achievement and limited educational opportunities. The Federal Government must live up to its commitment to providing a quality education for American Indian and Alaska Native students and for all of the Nation's students.

The foregoing fiscal year 2013 tribal budget program requests have been compiled in collaboration with tribal leaders, Native organizations, and tribal budget consultation bodies. Tribes respectfully request that these recommendations be included in the Labor, Health and Human Services, Education, and related agencies appropriations process.

DEPARTMENT OF EDUCATION

Culturally Based Education

Provide \$198.4 million for Title VII funding under the Elementary and Secondary Education Act.

Title VII of the Elementary and Secondary Education Act, which provides essential support for culturally based education approaches for American Indian and Alaska Native students and addresses the unique educational and cultural needs of Native students, is severely underfunded. It is well-documented that Native students are more likely to thrive in environments that support their cultural identities.² Title VII has produced many success stories, but increased funding is needed in this area to close the achievement gap for Native students and to ensure continued support for Native cultures and language education.

Impact Aid Funding

Provide \$1.395 billion for Impact Aid, Title VIII funding under the Elementary and Secondary Education Act.

Impact Aid provides resources to public schools whose tax bases are reduced because of Federal activities, including the presence of an Indian reservation. Thousands of American Indian and Alaska Native youth are served by reservation and other schools eligible for Impact Aid, including those located on or near tribal lands and those living on military bases.³ Yet, Impact Aid funding has not kept pace with inflation. Past budgets have also failed to provide appropriate allocations for facilities construction, causing a tremendous backlog in new construction and leaving many public schools on reservations in desperate need of repair.

Tribal Education Departments

Provide \$5 million to fund Tribal Education Departments (TEDs).

²Demmert, W.G. & Towner, J.C. (2003). *A Review of the Research Literature on the Influences of Culturally Based Education on the Academic Performance of Native American Students*. Portland, Oregon: Northwest Regional Educational Laboratory.

³DeVoe, J. & Darling-Churchill, K. (2008). *Status and Trends in the Education of American Indians and Alaska Natives*. Washington, DC: U.S. Department of Education, National Center for Education Statistics (Publication Number NCES 2008-084).

Five million dollars should be appropriated to the Department of Education to support Tribal Education Departments (TEDs). The Elementary and Secondary Education Act of 2001 authorizes this appropriation. Congress provided the first appropriation of \$2 million in the Department of Education's Indian Education National Activities line for TEDs in the fiscal year 2012 Consolidated Appropriations Act. With continued funding, the impact on Indian education would be significant.

Currently, most tribes fund TEDs with non-Federal sources of funding, Federal funding from Johnson O'Malley, and sometimes limited Title VII Indian education formula grants from the Elementary and Secondary Education Act. TEDs have a wide range of budgets depending upon the tribe's overall budget and priorities. TEDs serve thousands of American Indian and Alaska Native students nationwide in Bureau of Indian Education, tribal, and public schools. TEDs must have adequate financial support so they can serve the educational needs of these students at a comparable level to the students served by State education departments and agencies.

Tribal Colleges and Universities

Provide \$36 million for Title III-A grants under the Higher Education Act.

Titles III and V of the Higher Education Act, known as Aid for Institutional Development programs, support institutions with a large proportion of financially disadvantaged students and low cost-per-student expenditures. Tribal Colleges and Universities (TCUs) clearly fit this definition. The Nation's 36 TCUs serve Native and non-Native students in some of the most impoverished areas in the Nation, yet they are the country's most poorly funded postsecondary institutions. Congress recognized the TCUs as emergent institutions, and as such, authorized a separate section of Title III (Part A, Sec. 316) specifically to address their needs. Additionally, a separate section (Sec. 317) was created to address similar needs of Alaska Native and Native Hawaiian institutions. Section 316 is divided into two competitive grants programs: formula-funded basic development grants and competitive single-year facilities construction grants. Thirty-six million dollars should be provided in fiscal year 2013 to fund these two competitive grant programs.

Vocational Rehabilitation Services Projects for American Indians with Disabilities

Increase Vocational Rehabilitation Services Projects to \$67 million and create a line item of \$5 million for providing outreach to tribal recipients.

According to the U.S. census, 24 percent of American Indians and Alaska Natives have a disability. High rates of diabetes, heart disease, and preventable accidents are among the issues that contribute to this troubling reality. This creates an extraordinary need for tribes to support their disabled citizens in becoming self-sufficient. Further, tribes have had limited access to funding for vocational rehabilitation and job training—such as funds made available under the American Recovery and Reinvestment Act (ARRA)—compared to States. An increase to \$67 million would begin to put tribes on par with State governments.

DEPARTMENT OF LABOR

YouthBuild

Restore the rural and tribal set-aside in the YouthBuild program and create a dedicated 5 percent tribal set aside of at least \$4 million.

The YouthBuild program assists disadvantaged, low-income youth ages 16–24 in obtaining education and work skills to be competitive candidates in the job market. When the program was transferred to Department of Labor in September 2006, the 10 percent set-aside for rural and tribal programs was eliminated. Given significant unemployment challenges and the growing Native youth population, it is essential that the 10 percent tribal and rural set-aside be restored, including a dedicated set-aside of 5 percent. Based on fiscal year 2011 and fiscal year 2012 appropriations, we request a set-aside of at least 5 percent (\$4 million) for tribal programs.

CONCLUSION

Thank you for your consideration of this testimony. For more information, please contact Ahniwake Rose, NCAI Director of Human Service Policy, at arose@ncai.org and Amber Ebarb, NCAI Legislative Associate, at aearb@ncai.org.

PREPARED STATEMENT OF THE NATIONAL COUNCIL FOR DIVERSITY IN THE HEALTH PROFESSIONS

Mr. Chairman and members of the subcommittee, thank you for the opportunity to present my views before you today. I am Dr. Wanda Lipscomb, President of the National Council for Diversity in the Health Professions (NCDHP) and the Director of the Center of Excellence for Culture Diversity in Medical Education at Michigan State University. NCDHP, established in 2006, is a consortium of our Nation's majority and minority institutions that once house the Health Resources and Services (HRSA) Minority Centers of Excellence (COE) and Health Careers Opportunities Programs (HCOP) when there was more funding. These institutions are committed to diversity in the health professions. In my professional life, I have seen firsthand the importance of health professions institutions promoting diversity and the Title VII Health Professions Training programs.

Mr. Chairman, time and time again, you have encouraged your colleagues and the rest of us to take a look at our Nation and evaluate our needs over the next 10 years. I want to say that minority health professional institutions and the Title VII Health Professions Training programs address a critical national need. Persistent and severe staffing shortages exist in a number of the health professions, and chronic shortages exist for all of the health professions in our Nation's most medically underserved communities. Furthermore, our Nation's health professions workforce does not accurately reflect the racial composition of our population. For example while blacks represent approximately 15 percent of the U.S. population, only 2-3 percent of the Nation's health professions workforce is black. Mr. Chairman, I would like to share with you how your committee can help NCDHP continue our efforts to help provide quality health professionals and close our Nation's health disparity gap.

There is a well established link between health disparities and a lack of access to competent healthcare in medically underserved areas. As a result, it is imperative that the Federal Government continue its commitment to minority health profession institutions and minority health professional training programs to continue to produce healthcare professionals committed to addressing this unmet need.

An October 2006 study by the Health Resources and Services Administration (HRSA), entitled "The Rationale for Diversity in the Health Professions: A Review of the Evidence" found that minority health professionals serve minority and other medically underserved populations at higher rates than non-minority professionals. The report also showed that; minority populations tend to receive better care from practitioners who represent their own race or ethnicity, and non-English speaking patients experience better care, greater comprehension, and greater likelihood of keeping follow-up appointments when they see a practitioner who speaks their language. Studies have also demonstrated that when minorities are trained in minority health profession institutions, they are significantly more likely to: (1) serve in rural and urban medically underserved areas, (2) provide care for minorities and (3) treat low-income patients.

As you are aware, Title VII Health Professions Training programs are focused on improving the quality, geographic distribution and diversity of the healthcare workforce in order to continue eliminating disparities in our Nation's healthcare system. These programs provide training for students to practice in underserved areas, cultivate interactions with faculty role models who serve in underserved areas, and provide placement and recruitment services to encourage students to work in these areas. Health professionals who spend part of their training providing care for the underserved are up to 10 times more likely to practice in underserved areas after graduation or program completion.

Institutions that cultivate minority health professionals, like the NCDHP members, have been particularly hard-hit as a result of the cuts to the Title VII Health Profession Training programs in fiscal year 2006, fiscal year 2007, and fiscal year 2008. Given their historic mission to provide academic opportunities for minority and financially disadvantaged students, and healthcare to minority and financially disadvantaged patients, minority health professions institutions operate on narrow margins. The cuts to the Title VII Health Professions Training programs amount to a loss of core funding at these institutions and have been financially devastating. We have been pleased to see efforts to revitalize both COE and HCOP in recent fiscal years, but it is important to fully fund the programs at least at the fiscal year 2004 level so that more diversity is achieved in our health professions.

Earlier this year with the passage of health reform, the Congress showed the importance of the many of the Title VII programs, including the Minority Centers of Excellence (COE) and Health Careers Opportunities Program (HCOP), by reauthorizing the programs.

Minority Centers of Excellence.—COEs focus on improving student recruitment and performance, improving curricula in cultural competence, facilitating research on minority health issues and training students to provide health services to minority individuals. COEs were first established in recognition of the contribution made by four historically black health professions institutions (the Medical and Dental Institutions at Meharry Medical College; The College of Pharmacy at Xavier University; and the School of Veterinary Medicine at Tuskegee University) to the training of minorities in the health professions. Congress later went on to authorize the establishment of “Hispanic”, “Native American” and “Other” Historically black COEs. For fiscal year 2013, I recommend a funding level of \$24 million for COEs.

Health Careers Opportunity Program (HCOP).—HCOPs provide grants for minority and non-minority health profession institutions to support pipeline, preparatory and recruiting activities that encourage minority and economically disadvantaged students to pursue careers in the health professions. Many HCOPs partner with colleges, high schools, and even elementary schools in order to identify and nurture promising students who demonstrate that they have the talent and potential to become a health professional.

Collectively, the absence of HCOPs will substantially erode the number of minority students who enter the health professions. Over the last three decades, HCOPs have trained approximately 30,000 health professionals including 20,000 doctors, 5,000 dentists and 3,000 public health workers. For fiscal year 2013, I recommend a funding level of \$23 million for HCOPs.

Mr. Chairman, please allow me to express my appreciation to you and the members of this subcommittee. With your continued help and support, NCDHP member institutions and the Title VII Health Professions Training programs can help this country to overcome health and healthcare disparities. Congress must be careful not to eliminate, paralyze or stifle the institutions and programs that have been proven to work. NCDHP seeks to close the ever widening health disparity gap. If this subcommittee will give us the tools, we will continue to work towards the goal of eliminating that disparity everyday.

Thank you, Mr. Chairman, and I welcome every opportunity to answer questions for your records.

PREPARED STATEMENT OF THE NATIONAL CONSUMER LAW CENTER

The Federal Low Income Home Energy Assistance Program (LIHEAP)¹ is the cornerstone of Government efforts to help needy seniors and families stay warm and avoid hypothermia in the winter, as well as stay cool and avoid heat stress (even death) in the summer. LIHEAP is an important safety net program for low-income, unemployed and underemployed families struggling in this economy. The demand for LIHEAP assistance remains at record high levels. In fiscal year 2011, the program helped an estimated 9 million low-income households afford their energy bills.

One of the fastest growing segments of LIHEAP recipients is veterans. The number of LIHEAP recipient households with a veteran increased from 12 percent of all households served in fiscal year 2008 to 20 percent of all LIHEAP households in fiscal year 2011.²

Unemployment and poverty forecasts for 2013 indicate that the number of struggling households will remain at record high levels. In light of the crucial safety net function of this program in protecting the health and well-being of low-income seniors, the disabled, and families with very young children, we respectfully request that LIHEAP be fully funded at its authorized level of \$5.1 billion for fiscal year 2013.

Low Income Home Energy Assistance Program Provides Critical Help With Home Energy Bills for the Large Number of Low-Income Households Struggling to Move Forward in These Difficult Economic Times

Funding LIHEAP at \$5.1 billion for the regular program in fiscal year 2013 is essential in light of the sharp increase in poverty and unemployment. It is telling that even with unusually warm winter temperatures, the size of home heating bills still remains beyond the ability to pay for struggling households.³ Ohio was hard hit by

¹ 42 U.S.C. §§ 8621 et seq.

² *LIHEAP Recipients by Veteran Status*, NEADA (Dec. 8, 2011). Available at www.neada.org.

³ See e.g., Steve Gravelle, *Thousands of Iowans Facing Utility Shutoff Despite Mild Winter*, *The Gazette*, Mar. 22, 2012. Available at <http://thegazette.com/2012/03/22/thousands-of-iowans-facing-utility-shutoff-despite-mild-winter/>.

the great recession, losing 430,500 jobs.⁴ In that State, the total number of disconnections for gas and electric service for the year ending December 31, 2011 was 454,445. While the number of disconnections in 2011 represents a modest increase over 2010 disconnections, this growth is cause for concern. Ohio strengthened its Percentage of Income Payment Program (PIPP) and other payment plans designed to help struggling low-income households afford their energy bills,⁵ yet the State faced a 30 percent reduction in LIHEAP funding from fiscal year 2011. LIHEAP assistance is critical for helping these struggling families afford their heating bills.

Despite milder winter temperatures this winter and lower natural gas bills in Iowa, a record number of low-income households have fallen behind on their energy bills. In February 2012, the number of low-income households with past due energy accounts was the second highest on record for this time of year since these data have been tracked. The Iowa LIHEAP program estimates that demand for assistance will remain strong and that it will be serving close to last year's number of applicants, about 95,000 households. However, the size of the energy assistance has been cut back 25 percent due to the substantial cuts to the LIHEAP funding in fiscal year 2012. Thus, as the data shows, the need for LIHEAP remains strong in this sluggish economy despite the milder temperatures and the mitigation in natural gas prices.⁶

Data from Pennsylvania also demonstrate that an unusually mild winter cannot make up for cuts to vital energy assistance. Pennsylvania experienced a steady increase in enrollment for the regular LIHEAP program from fiscal year 2008 to fiscal year 2010, with 371,000 households served in 2008, 547,000 in fiscal year 2009, and 587,000 in fiscal year 2010. However, due to the decreased LIHEAP funds, the projection for fiscal year 2012 is down to 425,000. Utilities in Pennsylvania that are regulated by the Pennsylvania Public Utility Commission (PA PUC) have established universal service programs that assist utility customers in paying bills and reducing energy usage. Even with these programs, electric and natural gas utility customers find it difficult to keep pace with their energy burdens. The PA PUC estimates that more than 20,034 households entered the current heating season without heat-related utility service. This number includes about 2,559 households who are heating with potentially unsafe heating sources such as kerosene or electric space heaters and kitchen ovens. One harmful impact of unaffordable home energy is the abandonment of property that is no longer habitable. In mid-December 2011, an additional 13,136 residences where electric service was previously terminated were vacant and more than 5,977 residences where natural gas service was terminated were vacant. In 2011, the number of terminations increased 60 percent compared with terminations in 2004. As of December 2011, preliminary data shows that 19.4 percent of residential electric customers and 15.8 percent of natural gas customers were overdue on their energy bills.⁷

Unfortunately, the number of households around the country that are struggling to make ends meet remains very high due to the slow recovery from the great recession. According a Pew Fiscal Analysis Initiative report, as of December 2011, 4 million jobless workers (which is more than the population of Oregon) have been unemployed for a year or longer.⁸ While long-term unemployment has affected all age groups, older workers have been hit particularly hard by this downturn.⁹ CBO's budget and economic outlook report projects that unemployment will average 9.1 percent in 2013,¹⁰ far from the 5.3 percent that CBO estimates is the natural rate of unemployment.¹¹ The U.S. Census reports the largest number in poverty in 52 years, 46.2 million people in 2010.¹²

⁴*The State of Poverty in Ohio: A Path to Recovery*, Ohio Association of Community Action Agencies (May 2011) at p. iv.

⁵Office of the Ohio Consumers' Counsel.

⁶Iowa Bureau of Energy Assistance.

⁷Pennsylvania Public Utilities Commission.

⁸Pew Economic Policy Group Fiscal Analysis Initiative, *Five Long-Term Unemployment Questions*, February 1, 2012 at Question 1.

⁹Id at Question 3. ("However, among people without jobs, unemployed older workers were the most likely to have been jobless for a year or more. For example, in the fourth quarter of 2011, more than 42 percent of unemployed workers older than 55 had been out of work for at least a year, a higher percentage than any other age category.")

¹⁰CBO, *The Budget and Economic Outlook: Fiscal Years 2012 to 2022*, Chpt. 2 The Economic Outlook Table 2-1. CBO's Economic Projections for Calendar Years 2012 to 2022 (Jan. 2012) at p.27.

¹¹CBO, *The Budget and Economic Outlook: Fiscal Years 2011 to 2021*, Summary (Jan. 2011) at Summary Table 2.

¹²U.S. Census, *Income, Poverty, and Health Insurance Coverage in the United States: 2010* (Sept. 2011) at p.14.

Thus indications are that the demand for LIHEAP in fiscal year 2013 will remain very strong as this program helps struggling households in a number of ways. LIHEAP protects the health and safety of the frail elderly, the very young and those with chronic health conditions, such as diabetes, that increase susceptibility to temperature extremes. LIHEAP assistance also helps keep families together by keeping homes habitable during the bitter cold winter and sweltering summers.

Low Income Home Energy Assistance Program Is a Critical Safety Net Program for the Elderly, the Disabled and Households With Young Children

Dire Choices and Dire Consequences.—Recent national studies have documented the dire choices low-income households face when energy bills are unaffordable. Because adequate heating and cooling are tied to the habitability of the home, low-income families will go to great lengths to pay their energy bills. Low-income households faced with unaffordable energy bills cut back on necessities such as food, medicine and medical care.¹³ The U.S. Department of Agriculture has released a study that shows that low-income households, especially those with elderly persons, experience very low food security during heating and cooling seasons when energy bills are high.¹⁴ A pediatric study in Boston documented an increase in the number of extremely low weight children, age 6 to 24 months, in the 3 months following the coldest months, when compared to the rest of the year.¹⁵ Clearly, families are going without food during the winter to pay their heating bills, and their children fail to thrive and grow. A 2007 Colorado study found that the second leading cause of homelessness for families with children is the inability to pay for home energy.¹⁶

When people are unable to afford paying their home energy bills, dangerous and even fatal results occur. In the winter, families resort to using unsafe heating sources, such as space heaters, ovens and burners, all of which are fire hazards. Space heaters pose 3 to 4 times more risk for fire and 18 to 25 times more risk for death than central heating. In 2007, space heaters accounted for 17 percent of home fires and 20 percent of home fire deaths.¹⁷ In the summer, the inability to keep the home cool can be lethal, especially to seniors. According to the CDC, older adults, young children and persons with chronic medical conditions are particularly susceptible to heat-related illness and are at a high risk of heat-related death. The CDC reports that 3,442 deaths resulted from exposure to extreme heat during 1999–2003.¹⁸ The CDC also notes that air-conditioning is the number one protective factor against heat-related illness and death.¹⁹ LIHEAP assistance helps these vulnerable seniors, young children and medically vulnerable persons keep their homes at safe temperatures during the winter and summer and also funds low-income weatherization work to make homes more energy efficient.

LIHEAP is an administratively efficient²⁰ and effective targeted health and safety program that works to bring fuel costs within a manageable range for vulnerable low-income seniors, the disabled and families with young children. LIHEAP must be fully funded at its authorized level of \$5.1 billion in fiscal year 2013 in light of unaffordable, but essential heating and cooling needs of millions of struggling house-

¹³ See e.g., National Energy Assistance Directors' Association, 2011 National Energy Assistance Survey (Nov. 2011) (to pay their energy bills, 24 percent of LIHEAP recipients went without food, 37 percent went without medical or dental care, 34 percent did not fill or took less than the full dose of a prescribed medicine). Available at <http://www.neada.org/news/nov012011.html>.

¹⁴ Mark Nord and Linda S. Kantor, *Seasonal Variation in Food Insecurity Is Associated with Heating and Cooling Costs Among Low-Income Elderly Americans*, *The Journal of Nutrition*, 136 (Nov. 2006) 2939–2944.

¹⁵ Deborah A. Frank, MD et al., *Heat or Eat: The Low Income Home Energy Assistance Program and Nutritional and Health Risks Among Children Less Than 3 years of Age*, *AAP Pediatrics* v.118, no.5 (Nov. 2006) e1293–e1302. See also, Child Health Impact Working Group, *Unhealthy Consequences: Energy Costs and Child Health: A Child Health Impact Assessment Of Energy Costs And The Low Income Home Energy Assistance Program* (Boston: Nov. 2006) and the Testimony of Dr. Frank Before the Senate Committee on Health, Education, Labor and Pensions Subcommittee on Children and Families (March 5, 2008).

¹⁶ Colorado Interagency Council on Homelessness, *Colorado Statewide Homeless Count Summer, 2006*, research conducted by University of Colorado at Denver and Health Sciences Center (Feb. 2007).

¹⁷ John R. Hall, Jr., *Home Fires Involving Heating Equipment* (Jan. 2010) at ix and 33. Also, 40 percent of home space heater fires involve devices coded as stoves.

¹⁸ CDC, "Heat-Related Deaths—United States, 1999–2003" *MMWR Weekly*, July 28, 2006.

¹⁹ CDC, "Extreme Heat: A Prevention Guide to Promote Your Personal Health and Safety" available at http://emergency.cdc.gov/disasters/extremeheat/heat_guide.asp.

²⁰ States can only spend 10 percent or less of their LIHEAP grant in administrative and planning costs. 42 U.S.C. § 8624(b)(9).

holds due to the record high unemployment levels during the slow recovery from the great recession.²¹

PREPARED STATEMENT OF THE NATIONAL COUNCIL OF SOCIAL SECURITY
MANAGEMENT ASSOCIATIONS

On behalf of the National Council of Social Security Management Associations (NCSSMA), thank you for the opportunity to submit our written testimony on the fiscal year 2013 funding for the Social Security Administration (SSA). We respectfully request your support of full funding of the President's fiscal year 2013 budget request on behalf of SSA and the American public we serve.

NCSSMA is a membership organization of more than 3,500 SSA managers and supervisors who provide leadership in nearly 1,300 community-based Field Offices and Teleservice Centers throughout the country. We are the front-line service providers for SSA in communities throughout the Nation. We are also the Federal employees who work with many of your staff members to resolve problems and issues for constituents who receive Social Security benefits. For over 42 years, NCSSMA has considered a strong and stable Social Security Administration that delivers quality and prompt locally delivered service to the American public a top priority. We also consider it a top priority to be good stewards of the taxpayers' monies.

SSA is cost-efficient and appropriations to the agency are an excellent investment and return on taxpayer dollars. We are very appreciative of the support for SSA that the Subcommittee has provided in recent years. The additional funding SSA received in fiscal years 2008–2010 helped significantly to prevent workloads from spiraling out of control and assisted with improving service to the American public. However, budgetary constraints in fiscal years 2011–2012 have resulted in vital service reductions and many public service repercussions.

NCSSMA strongly supports the President's fiscal year 2013 budget request for SSA, which includes \$11.760 billion for the agency's administrative expenses through the Limitation on Administrative Expenses (LAE) account. We respectfully request the Subcommittee provides no less than the President's full SSA budget request in fiscal year 2013. Full funding for SSA is critical to maintain staffing in front-line components, cover inflationary increases, continue efforts to reduce hearings and disability backlogs, and increase deficit-reducing program integrity work.

Current State of Social Security Administration Operations

NCSSMA has significant concerns about the dramatic growth in SSA workloads. We strongly believe that SSA must receive adequate funding to maintain service levels vital to 60 million Americans. Despite agency strategic planning, expansion of online services, significant productivity gains, and the best efforts of management and employees, SSA is still faced with many challenges to providing the service that the American public has earned and deserves.

Over the last 8 years, SSA has experienced a dramatic increase in Retirement, Survivor, Dependent, Disability, and Supplementary Security Income (SSI) claims. The additional claims receipts are driven by the ongoing wave of the nearly 80 million baby boomers who will be filing for Social Security benefits by 2030—an average of 10,000 per day! By fiscal year 2013, retirement and survivor claims will have increased by more than 30 percent and disability claims will have increased by nearly 25 percent since fiscal year 2007.

The need for resources in SSA Field Offices is critical to process these additional claims and provide other vital services to the American public. Field Offices are responsible for processing 2.6 million SSI redeterminations in fiscal year 2012, an increase of more than 100 percent from fiscal year 2008. Nationally, visitors to Field Offices increased from 41.9 million in fiscal year 2007 to 44.9 million in fiscal year 2011. SSA continues to experience unprecedented telephone call volumes. In fiscal year 2011, SSA completed 62 million transactions over the 800 Number network. NCSSMA estimates Field Office telephone contacts to be more than 32 million during the same time period. The result is a combined total of more than 92 million telephone contacts annually for SSA.

Social Security Administration Funding for Fiscal Year 2012

NCSSMA strongly supported the President's fiscal year 2012 budget request of \$12.522 billion for SSA's administrative expenses. Much of this increase was needed

²¹“A large portion of the economic and human costs of the recession and slow recovery remain ahead . . . Those costs fall disproportionately on people who lose their jobs, who are displaced from their homes, or who own businesses that fail.” CBO, *The Budget and Economic Outlook: Fiscal Years 2012 to 2022*, Chpt. 2 The Economic Outlook at p.26.

to cover inflationary costs for fixed expenses. Funding at this level would have ensured that SSA could meet its public service obligations. Despite SSA's enormous challenges, with the Federal deficit concerns, attaining this level of funding was not possible. SSA's fiscal year 2012 appropriation for administrative funding through the LAE account was \$11.446 billion, only \$22 million above the fiscal year 2011 enacted level.

Inadequate funding of SSA in fiscal year 2013 would have major repercussions for SSA, including a continued hiring freeze, reduction of overtime, and postponement of initiatives to improve efficiency. Reducing resources at the same time SSA workloads are dramatically increasing is a prescription for significant service deterioration and workload backlogs. In addition, inadequate fiscal year 2013 funding levels will have a collateral negative impact on fiscal year 2014.

Field Office Service Delivery Challenges

SSA Field Offices are experiencing tremendous stress because of ever-increasing workloads and additional customer contacts. The fiscal year 2011 and fiscal year 2012 enacted funding levels exacerbated the situation and the impact on local Field Offices around the country is significant.

- Frontline feedback from our busiest urban offices indicates that some are seeing their visitor traffic explode with overflowing reception areas and increased waiting times.
- Most of SSA has been under a hiring freeze because of the current budget constraints. The agency expects to lose 3,000 employees in fiscal year 2012 and 2,000 more in fiscal year 2013. This is in addition to 4,000 lost in fiscal year 2011 resulting in a total loss of 9,000 employees in just 3 years. SSA will have approximately the same number of employees in fiscal year 2013 as it did in fiscal year 2007, even though workloads have increased dramatically.
- SSA projects 45 percent of its employees, including 60 percent of supervisors, will be eligible to retire by fiscal year 2020. Serious concerns exist about SSA's ability to sustain service levels with the tremendous loss of institutional knowledge from front-line personnel.
- Geographical staffing disparities have occurred with uneven attrition leaving some offices significantly understaffed. This is especially problematic for rural SSA Field Offices, whose customers often live vast distances away, may have no Internet service, and lack access to public transportation.

Social Security Administration Online eServices Assist with Service Delivery Challenges

Expansion of services available to the American public via the Internet has helped to alleviate the number of visitors and telephone calls to SSA. However, Internet services are not keeping pace with the increasing demand for service. High-volume transactions, such as requests for Social Security cards and benefit verifications are not yet available on the Internet, or are only being used to a limited degree. Requests for Social Security cards and benefit verifications represent about 35 percent of all transactions completed in SSA Field Offices in fiscal year 2011.

NCSSMA believes that SSA must be appropriately funded in fiscal year 2013 and beyond for continued investment in improved, user-friendly Internet services allowing for more online transactions. If individuals were able to successfully conduct SSA business online, the results would include fewer contacts with Field Offices and the 800 Number network, improved efficiencies, and enhanced public service.

Disability Workload Processes

Nationwide, more than 3.3 million new disability claims were processed and sent to State Disability Determination Services in fiscal year 2011, the highest in our history. This surge of increased claims has created backlogs. We expect that pending initial disability claims will rise to nearly 861,000 in fiscal year 2012 and to more than 1.1 million in fiscal year 2013. SSA's largest backlogs are hearings appealing initial disability decisions processed by the Office of Disability Adjudication and Review. Hearing receipts continue to rise, and through March 2012, 822,757 hearings were pending, which is 117,390 more than at the end of fiscal year 2010, and a new all-time high.

Despite these unprecedented challenges, SSA continues to make progress. In fiscal year 2012 (through March), the average processing time for a hearing was 350 days, the lowest average time since fiscal year 2003. Unfortunately, the number of claims and hearings pending is still not acceptable to Americans who need Social Security to support their families. Budget constraints in fiscal year 2011 and fiscal year 2012 impeded progress and prevented SSA from opening eight planned Hearing Offices. This significantly threatens to prevent SSA from achieving its goal of eliminating the hearings backlog by fiscal year 2013.

It is important to understand that annual appropriated funding levels for SSA have a critical impact on the hearings backlog. One of the most significant reasons for the increase in the hearings backlog was the significant underfunding of SSA from fiscal years 2004 through 2007.

President's Fiscal Year 2013 Budget Request for Social Security Administration

NCSSMA strongly supports the President's fiscal year 2013 budget request for SSA and requests that the Congress provide full funding to maintain public service levels and to allow the agency to:

- Cover fixed cost increases of \$300 million (rent, guards, postage, and employee compensation).
- Replace about one out of four employees lost in our Field Offices and Processing Centers.
- Process more than 3 million disability and SSI claims along with 5 million retirement, survivor, and Medicare claims.
- Eliminate the disability hearings backlog by conducting hearings for 960,000 cases, 75 percent more than in fiscal year 2007, and reduce processing time for a hearing to 270 days.
- Complete additional program integrity workloads yielding billions in savings—650,000 medical Continuing Disability Reviews (CDRs) and 2.622 million SSI redeterminations.

SSA issues more than \$60 billion in monthly benefit payments to more than 60 million people and the agency takes its stewardship responsibilities seriously. The fiscal year 2013 budget request includes \$1.024 billion dedicated to program integrity. Investment in program integrity reviews saves taxpayer dollars and is fiscally prudent in reducing the Federal budget and deficit.

- CDRs determine whether disability benefits should be ceased because of medical improvement. SSA medical CDRs yield \$9 in lifetime program savings for every \$1 spent.
- SSI redeterminations review nonmedical factors of eligibility, such as income and resources, to identify payment errors. SSI redeterminations yield a return on investment of \$6 in program savings over 10 years for each \$1 spent, including Medicaid savings accruals.

NCSSMA recommends consideration of legislative proposals included in the fiscal year 2013 budget request, which can improve the effective administration of the Social Security program, with minimal effect on program dollars. We believe these proposals have the potential to reduce operational costs and increase administrative efficiency. This includes enacting the Work Incentives Simplification Pilot (WISP), quarterly Federal wage reporting, workers compensation automatic reporting, and development of an automated system to report State and local pensions.

Conclusion

NCSSMA recognizes in the current budget environment that it may be difficult to provide adequate funding for SSA. However, Social Security is one of the most successful Government programs in the world and touches the lives of nearly every American family. We are a very productive agency and a key component of the Nation's economic safety net for the aged and disabled. A strong Social Security program equates to a strong America and it must be maintained as such for future generations.

NCSSMA sincerely appreciates the Subcommittee's interest in the vital services Social Security provides, and your ongoing support to ensure SSA has the resources necessary to serve the American public. We respectfully request your support of full funding of the President's fiscal year 2013 budget request on behalf of our agency and the American public we serve. We would appreciate any assistance you can provide in ensuring the American public receives the critical and necessary service they deserve from the Social Security Administration.

On behalf of NCSSMA members nationwide, thank you for the opportunity to submit this written testimony.

PREPARED STATEMENT OF THE NATIONAL ENERGY ASSISTANCE DIRECTORS'
ASSOCIATION

The members of National Energy Assistance Directors' Association (NEADA), representing the State directors of the Low Income Home Energy Assistance Program (LIHEAP) would like to first take this opportunity to thank the members of the subcommittee for considering our funding request for fiscal year 2013. The program is facing key challenges this year as we address the high level of demand for program

services as a result of continuing weakness in the Nation's economy and high unemployment rates.

LIHEAP is the primary source of heating and cooling assistance for some of the poorest families in the United States. In fiscal year 2012, the number of households receiving heating assistance remained at record levels of about 8.9 million. In addition, close to 600,000 are expected to receive cooling assistance. Of these households, approximately 20 percent contain at least one member who served in the military, a major increase from about 12 percent in 2008.

Veteran households in fact accounted for almost 35 percent of total growth in the program between fiscal year 2008 and 2011. Of specific interest, 12 percent of all veterans receiving LIHEAP have served in Iraq or Afghanistan. Seven percent of military families are currently serving in the military. The increase in veterans' families mirrors the overall increase in LIHEAP across the country. It also clearly demonstrates that LIHEAP is reaching some of the Nation's poorest families—including those who have served their Nation in times of peace as well as war.

Federal funding was decreased in fiscal year 2012 by 25 percent from the comparable appropriation level in fiscal year 2011. During this period, the average cost of home heating declined by 9.4 percent, considerably less than the reduction in funding. The purchasing power of the average home heating benefit declined from 42.1 percent to 34.7 percent. The President's request would further decrease the purchasing power of LIHEAP, reducing the average grant to about 30 percent of the cost of home heating.

ESTIMATE AVERAGE PERCENT OF HOME HEATING PURCHASED WITH LIHEAP (FISCAL YEAR 2008–FISCAL YEAR 2012)

[Percentage]

Fiscal year	Heating oil	Natural gas	Propane	Electricity	All fuels
2008	15.6	38.6	17.5	38.7	32.5
2009	27.4	55.5	27.5	52.6	47.8
2010	26.2	64.0	28.7	50.5	49.7
2011	18.1	57.6	22.9	43.4	42.1
2012	13.8	49.0	18.6	33.8	34.7

FISCAL YEAR 2013 FUNDING REQUEST AND FISCAL YEAR 2014 ADVANCED FUNDING REQUEST

For fiscal year 2013 we are requesting that the subcommittee restore funding for LIHEAP to the authorized level of \$5.1 billion to maintain services for the 8.8 million households that received heating assistance and the 600,000 expected to receive cooling assistance, and provide \$600 million in emergency funding authority. The additional funds would allow States to restore the average benefit to about 42 percent of home heating costs plus provide sufficient flexibility in the event that heating oil prices remain at record levels and other fuel prices increase as a result of the continuing recovery in the Nation's economy.

In addition, to these funding requests, we are concerned that States will be hampered in their ability to administer their programs efficiently due to the lack of advanced funding. The lack of a final program appropriation prior to the beginning of the fiscal year creates significant administrative problems for States in setting their program eligibility guidelines. In order to address this concern, we are requesting advance appropriations of \$5.1 billion for fiscal year 2014 and \$600 million in emergency contingency fund authority.

LIHEAP FAMILIES ARE AMONG THE NATION'S POOREST AND MOST VULNERABLE.

In order to obtain a comprehensive demographic picture of LIHEAP recipients and the characteristics of those who are helped as well as who would be hurt by the program cuts, NEADA conducted a survey of approximately 1,800 households that received LIHEAP benefits in fiscal year 2011. The results show that LIHEAP households are among the vulnerable in the country.

- 40 percent have someone age 60 or older;
- 72 percent have a family member with a serious medical condition;
- 26 percent use medical equipment that requires electricity;
- 37 percent went without medical or dental care;
- 34 percent did not fill a prescription or took less than their full dose of prescribed medication;
- 19 percent became sick because the home was too cold; and

- 85 percent of people with a medical condition are seniors.
- Many LIHEAP recipients were unable to pay their energy bills:
- 49 percent skipped paying or paid less than their entire home energy bill;
- 37 percent received a notice or threat to disconnect or discontinue their electricity or home heating fuel;
- 11 percent had their electric or natural gas service shut off in the past year due to nonpayment, 24 percent were unable to use their main source of heat in the past year because their fuel was shut off, they could not pay for fuel delivery, or their heating system was broken and they could not afford to fix it; and
- 17 percent were unable to use their air conditioner in the past year because their electricity was shut off or their air conditioner was broken and they could not afford to fix it.

LIHEAP's impact in many cases goes beyond providing bill payment assistance by playing a crucial role in maintaining family stability. It enables elderly citizens to live independently and ensures that young children have safe, warm homes to live in. Although the circumstances that lead each client to seek LIHEAP assistance are different, LIHEAP links these stories by enabling people to cope with difficult circumstances with dignity.

THE FACES OF LIHEAP

Households of all varieties receive LIHEAP assistance. However, the positive impact on the most vulnerable members of society, including the elderly, disabled, and very young children, is striking. LIHEAP agencies in every State have continued to receive new requests for assistance from families struggling in the most difficult economy we have seen in decades. Finally, as many of these examples demonstrate, LIHEAP is administered in many places by Community Actions Agencies with deep ties to the people that they serve. Through their knowledge and connection to their communities, in many cases they are able to assist people in need at multiple levels, creating backward and forward linkages that enable people to regain their footing and start fresh.

Help for the Elderly and Disabled

The elderly and disabled constitute some of the most vulnerable members of society and a large number of those receiving energy assistance. Many elderly and disabled clients are in poor health and most live on small, fixed incomes. One such recipient, living in Oklahoma, relies on LIHEAP throughout the year in order to prevent utility shutoff, even planning her expenses around her small benefit. After her rent, she is left with approximately \$165/month to pay electric, phone, natural gas, and water. This \$165 must also be used to pay for medications not covered by Medicare or Medicaid, and other household expenses. She also knows she is eligible for winter heating assistance in December, which although it does not cover the entire bill, does cover enough to keep her utilities on until the next small payment is made in January or February. She is unable to pay all of her utilities and purchase medications each month so she alternates the utilities she pays. LIHEAP is her lifeline for keeping her utilities connected. Without it, she would likely go without medications in order to keep her heat and electricity connected.

Back in December, the Illinois LIHEAP program received a request for assistance from an 84 years old woman with no heat. She hadn't had a working furnace for more than 2 years. Her daughter brought her in to apply for LIHEAP. As her story unfolded the program staff learned that she was heating her home with her cook stove and oven. She lives on \$612 a month social security, and relies on food pantries and LIHEAP to make ends meet. Through LIHEAP, she was able to receive a new 90-percent efficient furnace in December and a payment toward her utilities. Representatives from the local community action agency went to her home on the final inspection of the furnace and she met both with a smile and a hug. She said that she was warm and doing well and looking forward to having her house weatherized.

In Minnesota, an elderly couple was living on only social security benefits, totaling \$998 a month. They had prided themselves on being self-sufficient for many years by keeping their thermostat set at 57 degrees and dressing in many layers. However, after they were referred to the Minnesota Energy Assistance Program, they were able to heat their home to a safer temperature, and afford better food. They thanked the agency for giving them "one of the best winters in many years."

Those living with disabilities often face seriously challenges in affording basic home necessities. One terminally ill 50-year old man from Utah who applied for assistance had been hospitalized and released several times for his severe health condition and had already had his power shut off when he contacted the LIHEAP agency. His utility bill had been transferred to his apartment complex's name, which

they were charging him for, and he was also in danger of eviction. He was living on a fixed and limited social security income and a pension. Although his income was higher than many LIHEAP recipients, he too was faced with making the difficult choice between utility bills, doctor bills, food, or medication. His local agency was able to see him through this emergency and restore his utility connections, which were vital to providing him heat during the cold winter months. LIHEAP allowed him to afford the medications he needs without sacrificing heat in his home.

This past heating season also highlighted how dangerous it can be for people living with disabilities to go without heat. In Maine, a disabled woman was running out of heating oil. To conserve supplies she was forced to turn her heat down extremely low. Her poorly insulated home leaked warm air and moisture, eventually resulting in her door freezing over completely. Her disability prevented her from removing the ice and she became trapped inside her home. Through LIHEAP assistance and Maine's Weatherization program, contractors were sent to her home to melt the ice from around her door, seal the leaks that contributed to her high energy bills, and provide her with fuel to heat her home.

Finally, LIHEAP has been instrumental in improving the lives of those faced with challenging health conditions. One Minnesota woman, a longtime nurse in St. Paul, Minnesota, was diagnosed with degenerative blindness in 2004. She was an avid jogger who completed marathons with friends and enjoyed her career as a nurse. As her condition deteriorated however, she found it dangerous to drive and nursing became too difficult. She was devastated and worried about how she would make ends meet without her job. She lived off her retirement savings until they were almost exhausted, finally moving into an assisted living apartment for low-income residents. Although she had always prided herself on being frugal, conserving energy, keeping bills low, and maintaining her credit score, she could no longer make it without help. With the help of a health assistant, she applied for energy assistance. She still lives in her small apartment, still prides herself on being frugal and conserving energy.

Children

LIHEAP is critical for many families with small children and new babies. A warm home is a pre-requisite for hospitals to release babies and mothers after birth. The following family reached out for energy assistance when their child was born during the winter and they could not afford to heat their home. The mother had been employed as a full-time nurse in a nursing home but had been let go when her doctor ordered her to rest because her blood pressure was too high. Her husband worked in the remodeling business, which was hit hard in the recession.

The family was not able to pay their gas bill and by the time their child was born the house was down to 40 degrees. Although they were reluctant to ask for help, they contacted the Green Hills Community Action Agency. Their energy assistance application was processed within a day and the gas was turned back on. In their letter to the agency, the family notes how helpful the staff was during a difficult time. The mother has since gone back to work and they no longer need energy assistance, but they said they would never forget how desperate they felt and how much it meant to them to be able to bring their new child home to a safe and warm house.

Older children are also impacted by shut-off notices. One mother from Wisconsin had two school age children at home and was facing electricity shut-off. The Wisconsin Crisis Assistance payment stopped her impending disconnection. The mother's primary concern was the effect the disconnection would have on children, who would not be able to do their school work at home.

Illinois was also able to help a single mother of two to restore her heat after her gas and electricity were shut off. This recipient was forced to send her children to live with family members because the home was too cold for them. After she received assistance from LIHEAP both of the utilities were restored and her children were able to come home. She was so thankful that she even sent the agency a thank you card. In it she stated, "I appreciate your role in helping to turn my electricity and gas back on so my kids could come back home. For that there are simply not enough ways to say thank you."

Economic Conditions

Many families have found themselves in shut-off situations as a result of the recession, including many that have never before sought energy assistance. One such family in Georgia was living on \$330 a week in unemployment benefits. A single mother of two children, she was not receiving child support and did not have close family members who could assist her with bills. Her Georgia Power bill for 2 months was \$651, and it was scheduled for disconnection when she reached out for

energy assistance. The amount she owed was clearly unmanageable considering her income. The help she received through LIHEAP allowed her to keep her power on.

Another story from Iowa highlights how complicated it can be to provide assistance to families whose assets have been completely diminished. A single father of two children had been out of liquid petroleum for a substantial amount of time. He had tried to deal with the situation by shutting off the entire house to just two rooms and using space heaters to heat those rooms. His hot water heater was fueled by propane, so the family also did not have hot water. They were boiling water on the stove for hot water for cleaning and bathing. His kids were making the best of the situation and had draped blankets over the furnishings to make tents and keep the heat in the enclosed areas. Despite these difficult circumstances, he did not reach out for assistance until his pipes froze and burst.

The father was employed, and was working long hours through a temp agency but was not making enough to afford the \$500 minimum fill for his propane company. Although he was qualified for LIHEAP assistance, the propane vendor told the agency that because the family was completely out of fuel, they would have to have to pay for a leak test, and pay a fee for same day delivery. If they did not order a full 250 gallons, there would be an additional "under the minimum" fee. Because they were only eligible for \$500 of assistance, the fees would not allow them to fill to 250 gallons. However, the agency stepped in to negotiate with the vendor, and was able to have some of the fees removed. Although the family did not receive a full fill, they were able to get substantial help, and have their heat and hot water restored.

THE NEED FOR LIHEAP

Households reported enormous challenges despite the fact that they received LIHEAP. However, they reported that LIHEAP was extremely important. About 64 percent reported that they would have kept their home at unsafe or unhealthy temperatures and/or had their electricity or home heating fuel discontinued if it had not been for LIHEAP. Almost 98 percent said that LIHEAP was very or somewhat important in helping them to meet their needs. In addition, 53 percent of those who did not have their electricity or home heating fuel discontinued said that they would have if it had not been for LIHEAP.

The members of NEADA recognize the difficult budget decisions that you face as you consider funding levels for LIHEAP for fiscal year 2013 and advance funding for fiscal year 2014. We appreciate your interest and continued support for LIHEAP. Please feel free to call upon us if we can provide you with additional information.

PREPARED STATEMENT OF NEMOURS

Nemours thanks Chairman Harkin, Ranking Member Shelby and members of the subcommittee for the opportunity to submit written testimony on the fiscal year 2013 Labor, Health and Human Services, Education, and Related Agencies appropriations bill. Nemours, one of the Nation's leading child health systems, is dedicated to improving children's health and well-being by offering a spectrum of clinical treatment, research, advocacy, educational health, and prevention services extending to families in the communities it serves.

ABOUT NEMOURS

Nemours is an internationally recognized children's health system that owns and operates the Nemours/Alfred I. duPont Hospital for Children in Wilmington, Delaware, along with major pediatric specialty clinics in Delaware, Florida, Pennsylvania, and New Jersey. In 2012, it will open the full-service Nemours Children's Hospital in Orlando, Florida. Established as The Nemours Foundation through the legacy and philanthropy of Alfred I. du Pont, Nemours offers pediatric clinical care, research, education, advocacy, and prevention programs to all families in the communities it serves.

In addition to its investments in clinical care, education and treatment, Nemours has made significant investments in community-based prevention programs, policies and practices to reach all children in the community, not just those who cross our doors. Nemours Health and Prevention Services, an operating division in Newark, Delaware, as well as the Florida Prevention Initiative, lead Nemours' prevention work.

Community-Based Prevention

As an integrated health system that is very engaged with the community, Nemours sees first-hand the impact of chronic disease on our Nation's children. We

treat obese young children at our clinics, and we know that unhealthy habits that contribute to obesity are starting at a very young age. More than 20 percent of preschoolers are obese or overweight, an alarming statistic. We know that much of what influences their health is outside the realm of the healthcare system, which is why we have made and will continue to make significant investments in community-based prevention. We believe that investing in clinical and community-based prevention is an important way to ensure that children grow up to be healthy adults. We are supportive of the Prevention and Public Health Fund (Fund) and the potential it holds to address obesity and chronic disease. We are disappointed that to help finance the Sustainable Growth Rate (SGR), the Congress made significant cuts to the fund. Physician reimbursement and prevention should not be pitted against one another. Instead, physicians must be enlisted in the fight to prevent disease and should be working closely with other community-based partners to help families and children lead healthy, active lifestyles, as is the case with Nemours-employed physicians. We urge the subcommittee to utilize the resources provided from the Fund to support the integration of clinical and community-based prevention and to evaluate the outcomes associated with those investments. In particular, we are supportive of Community Transformation Grants.

Community Transformation Grants (CDC)

Community Transformation Grants (CTGs) draw upon the best of what we know works: strong coalitions, multi-sector, public-private partnerships, evidence-based approaches, and evaluation. In Delaware, Nemours has successfully used this combination of approaches to stem the rising childhood obesity curve between 2006 and 2008. CTGs allow us to build upon this foundation and spread what works to other communities. The purpose of the grants is to support the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming. We urge the subcommittee to provide \$226 million for CTGs in fiscal year 2013, the level of support provided in fiscal year 2012.

Children's Hospital Graduate Medical Education (HRSA)

Another important priority for Nemours is the healthcare workforce, particularly the pediatric workforce. Children's hospitals care for large numbers of children with complex health conditions. In order to achieve high-quality clinical care and outcomes, these specialty hospitals need to have well-trained residents and physicians. The Children's Hospital Graduate Medical Education (CHGME) provides support for Graduate Medical Education (GME) to freestanding children's hospitals that train resident physicians. The program was created to correct an unintended inequity in the level of Federal Graduate Medical Education funding for pediatric teaching hospitals, as opposed to other types of hospitals that are tied to the number of Medicare beneficiaries being treated at the hospital. Free-standing children's hospitals generally do not provide care to Medicare-eligible patients, and were largely left out of the GME financing system. While CHGME has helped address this inequity, support for children's hospitals still lags behind Medicare support for adult teaching hospitals.

CHGME supports 55 free-standing children's hospitals in 30 States. Of the 8,111 general pediatric residents in this country, approximately 45 percent of them train at a CHGME institution. Of the 4,883 pediatric subspecialist residents in the country, 51 percent of them train at a CHGME institution. In 2010, CHGME supported the training of almost 6,000 pediatric resident physicians. Upon completion of their training, pediatric resident physicians become the primary care, specialty, and subspecialty physicians that care for our children in the community. This is a very important contribution to training our pediatric workforce, which continues to experience shortages, particularly in pediatric specialty care. A 2009 survey by the National Association of Children's Hospitals and Related Institutions (NACHRI), now Children's Hospital Association, found that national shortages contribute to vacancies in children's hospitals that commonly last 12 months or longer for a number of pediatric specialties. These vacancies often result in longer wait times for children to see pediatric specialists.

More than 300 residents are trained each year at the Alfred I. duPont Hospital for Children (AIDHC). They are on the front line for families at our hospital, caring for patients 24 hours a day. They are also training to become future clinicians who will practice independently in general pediatrics specialties and subspecialties. In the outpatient department, they become the primary care physicians (under attending supervision) for numerous children. These trainees are also learning to become researchers to advance pediatric medicine in the future.

The residents at AIDHC engage in many learning and volunteer opportunities. During daily conferences, medical students, residents, and attending physicians all come together to share knowledge and discuss complex cases. Residents participate in retreats where our attending physicians teach them about important topics such as patient safety, reducing medical errors, end of life care, and communicating with families. Along with an attending physician, residents volunteer on Wednesday evenings to provide care at homeless shelters in Wilmington. Some volunteer internationally, providing health education, medical care and immunizations in Haiti and Guatemala. These training components require the active participation of and close oversight by the attending physician.

Unfortunately, the President's budget proposes reducing funding for this program to \$88 million in fiscal year 2013. We urge the Congress to reject this short-sighted cut and to continue to provide support for training the next generation of pediatricians, pediatric specialists and pediatric researchers. In fiscal year 2013, Nemours urges the subcommittee to provide flat funding for the CHGME program (\$265 million), at a minimum.

Child Care and Development Block Grant—Child Care Quality Initiative (ACF)

From high obesity rates to poor literacy levels, children in the United States face a host of obstacles to achieving the goal of living healthy, happy, and productive lives. It is alarming that more than 20 percent of pre-school aged children are obese or overweight, and reading failure affects 30 percent of our Nation's children. In order to ensure the healthy development of our children, we must reach them in as many settings as possible, including the places where they live, learn, and play. Approximately 12 million children in the United States spend time in child care outside their homes, making it a critical setting affecting the health and development of our Nation's children. To that end, we must ensure that we are providing the highest quality early care and education possible.

The President's budget proposal includes \$300 million for a Child Care Quality Initiative within the Child Care and Development Block Grant (CCDBG) to help ensure that children enter kindergarten ready to succeed. This initiative seeks to build on the progress of the Race to the Top—Early Learning Challenge (RTT-ELC). Nemours supports investments in improving the quality of child care programs by ensuring that child care providers have the training to help them meet higher-quality standards. Nemours supports funding the President's request for a Child Care Quality Initiative to improve the quality of early childhood programs in the United States, promote positive child outcomes, and ensure that our children enter kindergarten healthy and ready to learn.

CONCLUSION

Nemours appreciates the opportunity to submit written testimony. As an integrated child health system, we have prioritized investments in clinical and community-based prevention and our workforce because we believe that in the long-run these investments will bend the health curve and the cost curve. We recognize that the Nation's fiscal situation requires a close examination of the programs and priorities that the Federal Government funds. As you make these critical funding decisions, we hope that prevention, quality and the healthcare workforce will remain priorities of the subcommittee in fiscal year 2013.

PREPARED STATEMENT OF THE NEPHCURE FOUNDATION

Summary of recommendations for fiscal year 2013:

- \$32 billion for the National Institutes of Health (NIH) and a corresponding increase to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- Continue to support the Nephrotic Syndrome Rare Disease Clinical Research Network at the Office of Rare Diseases Research (ORDR).
- Support continued expansion of the FSGS/NS research portfolio at NIDDK and the National Institute on Minority Health and Health Disparities (NIMHD) by funding more research proposals for glomerular disease.

Nephrotic syndrome (NS) is a collection of signs and symptoms caused by diseases that attack the kidney's filtering system. These diseases include focal segmental glomerulosclerosis (FSGS), Minimal Change Disease (MCD) and Membranous Nephropathy (MN). When affected, the kidney filters leak protein from the blood into the urine and often cause kidney failure which requires dialysis or kidney transplantation. According to a Harvard University report, 73,000 people in the

United States have lost their kidneys as a result of FSGS. Unfortunately, the causes of FSGS and other filter diseases are very poorly understood.

FSGS is the second leading cause of NS and is especially difficult to treat. There is no known cure for FSGS and current treatments are difficult for patients to endure. These treatments include the use of steroids and other dangerous substances which lower the immune system and contribute to severe bacterial infections, high blood pressure and other problems in patients, particularly child patients. In addition, children with NS often experience growth retardation and heart disease. Finally, NS caused by FSGS, MCD or MN is idiopathic and can often reoccur, even after a kidney transplant.

FSGS disproportionately affects minority populations and is five times more prevalent in the African-American community. In a groundbreaking study funded by NIH, researchers found that FSGS is associated with two APOL1 gene variants. These variants developed as an evolutionary response to African sleeping sickness and are common in African-Americans.

FSGS has a large social impact in the United States. FSGS leads to end-stage renal disease (ESRD) which is one of the most costly chronic diseases to manage. In 2007, the Medicare program alone spent \$24 billion, 6 percent of its entire budget, on ESRD. In 2005, FSGS accounted for 12 percent of ESRD cases in the United States, at an annual cost of \$3 billion. It is estimated that there are currently approximately 20,000 Americans living with ESRD due to FSGS.

Research on FSGS could achieve tremendous savings in Federal healthcare costs and reduce health status disparities. For this reason, and on behalf of the thousands of families that are significantly affected by this disease, we recommend the following:

- \$32 billion for the National Institutes of Health (NIH) and a corresponding increase to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
- Continue to support the Nephrotic Syndrome Rare Disease Clinical Research Network (NEPTUNE) at the Office of Rare Diseases Research (ORDR).
- Support continued expansion of the FSGS/NS research portfolio at NIDDK and the National Institute on Minority Health and Health Disparities (NIMHD) by funding more research proposals for glomerular disease.

Encourage FSGS/NS Research at NIH

There is no known cause or cure for FSGS and scientists tell us that much more research needs to be done on the basic science behind FSGS/NS. More research could lead to fewer patients undergoing ESRD and tremendous savings in healthcare costs in the United States.

With collaboration from other Institutes and Centers, ORDR established the Rare Disease Clinical Research Network. This network provided an opportunity for the NephCure Foundation, the University of Michigan, and other university research health centers to come together to form the Nephrotic Syndrome Study Network (NEPTUNE). NEPTUNE is developing a database of NS patients who are interested in participating in clinical trials which would alleviate the problem faced by many rare disease groups of not having access to enough patients for research. We urge the subcommittee to continue its support for RDCRN and for NEPTUNE, which has tremendous potential to make significant advancements in NS and FSGS research.

The NephCure Foundation is also grateful to the NIDDK for issuing a program announcement (PA) that serves to initiate grant proposals on glomerular disease. This PA was issued in March 2007 and utilizes the R01 mechanism to award funding to glomerular disease researchers. In February 2010 the PA was re-released and is now scheduled to expire in 2013. We ask the subcommittee to encourage NIDDK to continue to issue glomerular disease PAs.

Due to the disproportionate burden of FSGS on minority populations, the NephCure Foundation feels that it is appropriate for NIMHD to develop an interest in this research. We ask the subcommittee to encourage ORDR, NIDDK, and NIMHD to collaborate on research that studies the incidence and cause of this disease among minority populations. We also ask the Subcommittee to urge NIDDK and the NIMHD to undertake culturally appropriate efforts aimed at educating minority populations about glomerular disease.

PREPARED STATEMENT OF THE NATIONAL HISPANIC COUNCIL ON AGING

The National Hispanic Council on Aging (NHCOA)—the leading national organization working to improve the lives of Hispanic older adults, their families, and caregivers—thanks you for the opportunity to submit written testimony. Wisely in-

vesting in the future and implementing programs that will strengthen our country is a particularly daunting task given the limited resources and constraints at hand. Therefore, NHCOA recognizes the difficult decisions that lie ahead for your committee. We write to you today to express our support for the fiscally sensible programs created by the Older Americans Act, and to request they be appropriated sufficient funds to ameliorate the impending cuts of the Budget Control Act of 2011.

For more than 30 years, NHCOA has been a strong voice dedicated to ensuring our Nation's Hispanic seniors—the fastest growing segment of the United States' rapidly expanding aging population—can age healthily and with dignity. Alongside its Hispanic Aging Network of nearly 40 community-based organizations across the country, NHCOA reaches 10 million Hispanics each year. NHCOA integrates research, policy, and practice to tackle the unique challenges Latino seniors face as they age, and by educating and empowering them to be better advocates for themselves. As an integral part of this mission, NHCOA incorporates a special focus on families and caregivers of Hispanic older adults in all its programmatic priorities, recognizing the paramount importance of family in the Latino community.

Older Americans Act programs, implemented by the Administration on Aging, effectively serve older adults across the country, while also providing a wide variety of services that are flexible enough to meet the needs of every community. The Older Americans Act authorizes programs that train families to support their loved ones, put people back to work, put food on the table, eliminate elder abuse, and help communities develop the policies they need to help their older adults age with dignity. Because of programs that provide basic necessities like Meals on Wheels, there are fewer older adults having to choose between putting food on the table and filling their prescription. As appropriators, your support is critical for the continued success of these lifesaving programs.

The population of Hispanic older adults, as well as the population of older adults in general, is growing rapidly. Every 7 seconds, today, and for the next 20 years, someone in the United States will turn 60. In terms of the Hispanic community, we have about 3 million Latino elders. By 2050, that number will increase to 17 million. Moreover, the Hispanic community as a whole is projected to grow to 30 percent of the entire U.S. population by 2050. That means nearly 1 in 3 people will be Hispanic. By 2019, the Latino senior population will become the largest non-White elder population in the United States.

Funding for the programs of the Older Americans Act has not grown to match this population increase. Therefore, the impending cuts of the Budget Control Act of 2011 will decrease its ability to keep pace with the growth of the U.S. aging population. A reduction in these services will mean that fewer people will have access to home delivered meals, communities will have less funding to operate senior centers, and families will have less support in caring for their loved ones. These programs make a vital difference in communities across the country, but to keep effectively serving the growing population, an adequate level of funding is imperative.

Hispanics face a variety of challenges that make aging particularly difficult. Many Hispanic older adults have spent their lives in jobs that have not helped them prepare for their later years. Low-wage, physically demanding jobs are all too common in the Latino community, and these jobs offer little in the way of healthcare and pension benefits. As a result, many Hispanics enter their golden years with little money saved and little or no previous access to health insurance. Cultural and linguistic differences are additional barriers to accessing needed services. All of these economic, physical, and social factors combined result in Hispanic older adults earning below average Social Security benefits, enduring chronic health problems at disparate rates, and having a harder time gaining access to needed services.

Last year, an organization called Hispanics in Philanthropy released a study about the programs of the Older Americans Act and the difficulties those programs faced in serving Hispanic communities. The study found that many communities were unable to deliver the services and information necessary to help Hispanic older adults, despite being readily available. Many communities lack the financial resources to hire and train new workers to serve the rapidly aging Hispanic population. Appropriating more money for Older Americans Act programs will allow communities to better serve their older adults and also to embrace their growing diversity.

NHCOA has worked and spoken with Hispanic older adults and their families across the country, and though the needs and concerns of the population are diverse, they were unified in their support for the Older Americans Act as a main vehicle to address the struggles of simply making ends meet in their community. Every day, Hispanic older adults must decide what to sacrifice—food on the table, rent and utilities, or medications. Family members juggle multiple jobs to care for older adults in their families and are unaware of existing opportunities for caregiver

training. Incidents of elder abuse are not reported because older adults do not know where to turn. Hispanic older adults also suffer disproportionately from chronic medical conditions like diabetes, are less likely to manage hypertension, and are significantly more likely to suffer from HIV/AIDS. With sufficient funding, however, the Older Americans Act is unequipped to adequately address these problems.

Funding Older Americans Act programs is a wise investment in the future. Nutrition and health management programs, which are proven effective at reaching Hispanic older adults, can keep minor health problems from becoming chronic, or even life threatening conditions. The National Family Caregiver Support Program offers trainings and services that are flexible enough to meet the needs of every community. Elder abuse prevention programs have the potential to save lives. Through small investments that help older adults age in dignity, we can achieve real savings in more costly programs, such as Medicare and Medicaid. Furthermore, making an investment to train service providers on how to effectively work with a diversifying older adult population is a necessary preemptive measure and cannot happen at a better time.

NHCOA respectfully asks that your committee provide increased funding to Older Americans Act programs to help them withstand the impending cuts from the Budget Control Act of 2011. This increased appropriation will not only allow communities to maintain the services and supports they already offer, but it will also improve their capacity to serve the rapidly growing diverse older adult population in the United States.

PREPARED STATEMENT OF THE NATIONAL HEAD START ASSOCIATION

Chairman Harkin, Ranking Member Shelby, thank you for allowing the National Head Start Association (NHSA) submit testimony in support of funding for Head Start and Early Head Start in fiscal year 2013. Head Start is a national commitment to provide critical early education, health, nutrition, child care, parent involvement and family support services in return for a lifelong measurable impact on the low-income children and families. Today, as our Nation's children face greater obstacles than ever, there is a significant need to prepare the next generation for success in school and later in life, and Head Start has a proven track record of accomplishing this. NHSA is grateful that the Congress and the President made a solid commitment to quality early childhood education in fiscal year 2012 by providing funding to maintain services for children currently served by Head Start and Early Head Start programs.

Quality early education prepares the Nation's youngest children for a lifetime of learning. In fact, studies show that for every \$1 invested in a Head Start child, society earns at least \$7 back through increased earnings, employment, and family stability; and decreased welfare dependency, crime costs, grade repetition, and special education. But the economy has taken a toll on the program as well. During this most recent recession, Head Start and Early Head Start directors have experienced rapidly rising operating costs that may eventually affect their ability to maintain program size.

NHSA hopes that this Subcommittee will support the administration's drive to improve accountability, as well as account for the rising cost of maintaining programs. Though we appreciate the President's request for an \$85 million increase over the fiscal year 2012 enacted level, after extensive conversations and input from the field we recognize that it is not enough. The Head Start community is proposing an increase of \$325 million over fiscal year 2012 to provide the funding necessary to ensure that Head Start centers can meet the rising costs of service for an additional school year, improve access for vulnerable infants, and meet the requirements of the 2007 Head Start Reauthorization Act.

Head Start Fixed Costs Rising

Though funding for Head Start has increased significantly in recent budget years, the cost of serving families has risen at a much faster pace. When surveyed, a full 83 percent of Head Start centers reported that their costs have increased just over the past year—in fact, 25 percent of those who responded report that their fixed costs, including maintenance, transportation, and insurance, have increased by more than 11 percent over the last 12 months. In some areas, rent on facilities alone has gone up between 5–10 percent. It is an enormous task to keep costs low for what is a very comprehensive model.

Though center directors have some flexibility to streamline and try to be more efficient, there are limits to how far they can go. Most centers have already laid off staff, closed facilities and consolidated programs to save costs, and are leaning more

than ever on other community partners to help provide health, employment, and other services that are required by the model. The Head Start community is reaching its limit on how far it can take this practice, given statutory quality standards. The only logical next step for many programs may in fact be to change their service delivery method which can result in moving from full-day to part-day service, or worse, reducing the number of children it can enroll.

Energy costs have gone up significantly, and an overwhelming majority of programs are finding it difficult to keep up with fuel costs for the transportation of kids to and from the center. This is particularly challenging in rural areas. One Idaho Tribal Head Start program spends an astonishing \$1,000 per month on gasoline. They believe that they must continue to provide transportation because, as the director says, “Many of our families can barely afford gas for work, let alone transport their child to Head Start.”

Deferred maintenance of Head Start centers poses its challenges as well. At one Western Iowa Head Start, they spent \$53,000 on one bus that only holds 16 kids—to replace one of their buses among a fleet that is nearly 20 years old. Many other centers, operating in older facilities, hope the roof will hold out one more year, or that the playground equipment will remain solid and safe. Most programs must wait until the end of a program year to decide what can be fixed within the budget. Regardless, the centers are judged by frequent monitors who have the ability to demand change when they see a potential hazard—with the additional funds being requested, Head Start directors could do more to prevent potential safety hazards.

Head Start programs also need to adapt to changing regulations. The Consumer Product Safety Commission released new rules regarding crib safety and Early Head Start programs must now replace all their cribs. Head Start centers also must implement new data systems that will track more nuanced child outcomes data. Even the smallest programs report costs upwards of \$5,000 just for the tracking software. The City of Chicago Head Start program is spending an unexpected \$12,000 on new cribs this year, and has spent a staggering \$3,000,000 on new data collection systems.

Finally, Head Start centers must provide health insurance for staff. These costs have increased rapidly. In Louisiana, the Iberville Parish Council Head Start, which serves 360 children and employs 61 teachers and staff at 6 centers, has struggled to make ends meet because of rising health insurance and other costs. Ultimately, the Parish Council voted to relinquish control of the program entirely and turn it over to the Federal Government rather than tell families they could not serve their children because it, as a local entity, could not afford to continue subsidizing the increasing costs. The director said of the decision, “The Federal Government wants you to run a Cadillac program on Chevrolet prices.”

Head Start Salaries Are Noncompetitive

Another pressing cost concern that is directly related to a child’s progress is the quality of teachers. Five years ago, a bipartisan Congress passed, and President George W. Bush signed, the Improving Head Start for School Readiness Act of 2007 (Public Law 110–134). Included in this reauthorization were a number of welcomed quality improvement measures for Head Start and Early Head Start programs; particularly, requirements for more-qualified teachers.

Specifically, by September 30, 2013, at least 50 percent of Head Start teachers nationally are required to have a Bachelor’s Degree, an Advanced Degree, or an equivalent degree in a field related to early childhood education. I am pleased to share that the Head Start community has already met this requirement.

In order to achieve compliance, Head Start directors encouraged their staff to obtain degrees. When possible they helped supplement tuition and costs in order to ensure that staff would stay on once the degree was obtained. But the market for early childhood teachers with college degrees is very competitive and it has become extremely difficult to keep these credentialed employees in place. Qualified staff comes at a price, a price the Head Start budget does not easily afford.

According to data collected by the PIR, in 2010, a Head Start teacher with a CDA made on average \$22,329 per year; a teacher with a graduate degree \$35,194. The average across all Head Start teachers is \$27,880. This is, according to the Center for Law and Social Policy, considerably less than the average salary for a preschool teacher in elementary in secondary schools, which was \$42,150 in 2010. Young graduates of education schools, moreover, are not choosing early education as a viable career path.

A Bachelor’s degree qualifies them for any number of jobs outside of early education. Some employees leave to work for the local bank or another business, where the salaries and benefits much more competitive and better for their families. After all, many of these newly credentialed individuals were once Head Start parents

themselves, due to the early focus on “parents as teachers.” We cannot and do not fault them for rising out of poverty to make a better life for themselves and their families.

This constant turnover is disruptive to Head Start children and families, and is another burden on center directors who must find qualified individuals to take their place, complete background checks and have them fully oriented to the complicated expectations of the program. With noncompetitive salaries, this is very difficult. In rural areas, it is nearly impossible—the labor pool is limited, and relatively unchanging.

Designation Renewal System

One of the most anticipated provisions of the 2007 Head Start Act will require Head Start grantees designated as low-performing to compete for the continuation of their grant. Different from the Head Start grant termination process, this additional accountability measure, the Designation Renewal System, is an enormous undertaking for the Office of Head Start (OHS) and will certainly require additional funds to execute. NHSA supports the Administration for Children and Families’ request for additional staff to ensure that the renewal competitions are executed in a fair, transparent, and effective manner.

Last December, OHS began the first stages of the DRS by informing an initial 132 grantees that would re compete for their funding. We are very concerned with the potential impacts of transitioning a Head Start program from one organization to another, in particular the impact on children and families.

We therefore appreciate the administration’s request for \$40 million as a “rainy day fund” and understand these funds may indeed be necessary. However, we hope that if any of these funds are not utilized that they will be reinvested in the training and technical assistance activity funds available to grantees. During this time of change in the program, especially as new organizations may become Head Start grantees; it will be helpful to assist everyone in our continued drive to sustain excellence and remain compliant with all of the more than 1,700 separate Head Start regulations.

The Gap Between Early Head Start and Head Start

When NHSA talks to the dedicated Head Start directors across the country about how they could better serve their communities, so many of them say they wish they could get to more children earlier. Across all Head Start programs, centers are only able to serve less than 3 percent of eligible infants.

The waiting lists are increasingly long, especially as the economy continues to present significant challenges to the poor. Today, one in five children are born into poverty—and eligible for Early Head Start. In one center in Burien, Washington, the Early Head Start program serves 30 infants, 10 of which are homeless, and 7 of which are “special needs” children. There are currently more than 50 families on the waitlist. Knowing all we know about the effectiveness of intervention in these early years, NHSA strongly supports even a small investment in increasing access to Early Head Start.

Centers of Excellence

Last, the National Head Start Association supports continued investment in the now 20 Centers of Excellence in Early Childhood that were named, but only partially funded, over the last 2 years—in the following localities: Greensburg, Pennsylvania; Baltimore, Maryland; Mount Vernon, Ohio; Houghton, Michigan; Owensboro, Kentucky; Morganton, North Carolina; Birmingham, Alabama; Denver, Colorado; Albuquerque, New Mexico; Dunkirk, New York; Laguna, New Mexico; Rock Island, Illinois; Reno, Nevada; Modesto, California; Marshalltown, Iowa; Elmsford, New York; Tulsa, Oklahoma; Hugo, Oklahoma; Mayaguez, Puerto Rico; and Chattanooga, Tennessee. The resources and tools these Centers have designed and provided to the Head Start community are effective, well-designed, and serve as models for other Early/Head Start programs to emulate. Their innovative practices and peer-learning approaches will be much more in demand as practitioners adjust to the requirements of the 2007 law.

Head Start Works

Since 1965, Head Start (and now Early Head Start as well) has been providing a proven, evidence-based comprehensive program to prepare at-risk children and families for a stable, successful life. Head Start improves the odds and the options for at-risk kids for a lifetime. Research shows that Head Start has genuine cost ben-

efits—conservatively, it is estimated to yield a benefit-cost ratio as large as \$7 to \$1.¹

Head Start saves hard-earned tax dollars by decreasing the need for children to receive special education services in elementary schools.² Data analysis of a recent Montgomery County Public Schools evaluation found that a MCPS child receiving full-day Head Start services when in Kindergarten requires 62 percent fewer special education services and saves taxpayers \$10,100 per child annually.³ States can save \$29,000 per year for each person that they don't need to incarcerate because Head Start children are 12 percent less likely to have been charged with a crime.⁴

A study released by the National Bureau of Economic Research shows that Head Start parents are more actively engaged in their children's academic careers long after the child has entered kindergarten, a key ingredient of a learning environment that leads to future success.⁵ The Baltimore Education Research Consortium (BERC) released findings in March 2012 related to chronic absenteeism in Kindergarten—which studies have shown to relate to poorer overall academic achievement as late as 5th grade. BERC's research shows that students who had attended Head Start showed the highest attendance rates in kindergarten and the lowest level of chronic absence in first through third grades.⁶ These non-test-score findings help illustrate the long-term viability of the program—today, the more than 27 million Head Start graduates are working every day in our communities to make our country and our economy strong.

Head Start families with their increased health literacy also show immediate healthcare benefits, including lower Medicaid costs—on average \$232 per family. The program has also reduced mortality rates from preventable conditions for 5- to 9-year olds by as much as 50 percent.⁷ Studies have shown that the program reduces healthcare costs for employers and individuals because Head Start children are less obese,⁸ 8 percent more likely to be immunized,⁹ and 19 to 25 percent less likely to smoke as an adult.¹⁰

The Head Start community understands the budgetary pressures the Federal Government is facing and is so very grateful for the commitment shown by this the Congress and the President to keep early learning, and Head Start in particular, a priority. The research shows that the “achievement gap” is apparent as early as the age of 18 months—we will spend substantially more downstream if these same young people are not prepared to graduate high-school, attend college and lead prosperous lives. We urge the Subcommittee to fully invest in Head Start and Early Head Start to improve accountability, increase access, and ensure that we have a stable and prosperous workforce for generations to come.

PREPARED STATEMENT OF THE NATIONAL KIDNEY FOUNDATION

End Stage Renal Disease (ESRD), which requires dialysis or transplantation for survival, is the only disease-specific coverage under Medicare, regardless of age or

¹Ludwig, J. and Phillips, D. (2007). The Benefits and Costs of Head Start. Social Policy Report. 21 (3: 4); Meier, J. (2003, June 20). Interim Report. Kindergarten Readiness Study: Head Start Success. Preschool Service Department, San Bernardino County, California.

²Barnett, W. (2002, September 13). The Battle Over Head Start: What the Research Shows. Presentation at a Science and Public Policy Briefing Sponsored by the Federation of Behavioral, Psychological, and Cognitive Sciences.

³NHSA Public Policy and Research Department analysis of data from a Montgomery County Public Schools evaluation. See Zhao, H. & Modarresi, S. (2010, April). Evaluating lasting effects of full-day prekindergarten program on school readiness, academic performance, and special education services. Office of Shared Accountability, Montgomery County Public Schools.

⁴Reuters. (2009, March). Cost of locking up Americans too high: Pew study; Garces, E., Thomas, D. and Currie, J. (2002, September). Longer-term effects of Head Start. *American Economic Review*, 92 (4): 999–1012.

⁵National Bureau of Economic Research. (2011, December). Children's Schooling and Parents' Investment in Children: Evidence from the Head Start Impact Study (Working Paper No. 17704). Cambridge, MA: A. Gelber & A. Isen.

⁶Baltimore Education Research Consortium (2012, March). Early Elementary Performance and Attendance in Baltimore City Schools' Pre-Kindergarten and Kindergarten. Baltimore, Maryland: F. Connelly & Olson, L.

⁷Ludwig, J. and Phillips, D. (2007) Does Head Start improve children's life chances? Evidence from a regression discontinuity design. *The Quarterly Journal of Economics*, 122 (1): 159–208.

⁸Frisvold, D. (2006, February). Head Start participation and childhood obesity. Vanderbilt University Working Paper No. 06–WG01.

⁹Currie, J. and Thomas, D. (1995, June). Does Head Start Make a Difference? *The American Economic Review*, 85 (3): 360.

¹⁰Anderson, K.H., Foster, J.E., & Frisvold, D.E. (2009). Investing in health: The long-term impact of Head Start on smoking. *Economic Inquiry*, 48 (3), 587–602.

other disability. At the end of 2009, the number of Americans with ESRD totaled 558,239, including 113,908 new patients that year. Furthermore, CKD represented almost 8 percent of the Medicare population age 65 and over in 2009, but 22 percent of Medicare costs for this age group. Complicating the cost and human toll is the fact that CKD is a disease multiplier; patients are very likely to be diagnosed with diabetes, cardiovascular disease, or hypertension.

Despite this tremendous social and economic impact, no national public health program focusing on early detection and treatment existed until fiscal year 2006, when the Congress provided \$1.8 million to initiate a Chronic Kidney Disease Program at the Centers for Disease Control and Prevention (CDC). Congressional interest regarding kidney disease education and awareness also is found in section 152 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Public Law 110–275), which directed the Secretary to establish pilot projects to increase screening for Chronic Kidney Disease (CKD) and enhance surveillance systems to better assess the prevalence and incidence of CKD. Cost-effective treatments exist to potentially slow progression of kidney disease and prevent its complications, but only if individuals are diagnosed before the latter stages of CKD.

The CDC program is designed to identify members of populations at high risk for CKD, develop community-based approaches for improving detection and control, and educate health professionals about best practices for early detection and treatment. The National Kidney Foundation respectfully urges the Committee to maintain line-item funding in the amount of \$2.2 million for the Chronic Kidney Disease Program at CDC. Continued support will benefit kidney patients and Americans who are at risk for kidney disease, advance the objectives of Healthy People 2020 and the National Strategy for Quality Improvement in Health Care, and fulfill the mandate created by section 152 of MIPPA.

The prevalence of CKD in the United States is higher than a decade earlier. This is partly due to the increasing prevalence of the related diseases of diabetes and hypertension. It is estimated that CKD affects 26 million adult Americans¹ and that the number of individuals in this country with CKD who will have progressed to kidney failure, requiring chronic dialysis treatments or a kidney transplant to survive, will grow to 712,290 by 2015². Kidney disease is the 8th leading cause of death in the United States, after having been the 9th leading cause for many years. Furthermore, a task force of the American Heart Association noted that decreased kidney function has consistently been found to be an independent risk factor for cardiovascular disease (CVD) outcomes and all-cause mortality and that the increased risk is present with even mild reduction in kidney function.³ Therefore addressing CKD is a way to achieve one of the priorities in the National Strategy for Quality Improvement in Health Care: Promoting the Most Effective Prevention and Treatment of the Leading Causes of Mortality, Starting with Cardiovascular Disease.

CKD is often asymptomatic, especially in the early stages, and, therefore goes undetected without laboratory testing. In fact, some people remain undiagnosed until they have reached CKD Stage 5, requiring dialysis or a kidney transplant. Accordingly, Healthy People 2020 Objective CKD–2 is to “increase the proportion of persons with chronic kidney disease (CKD) who know they have impaired renal function.” Screening and early detection provides opportunity for interventions to foster awareness, adherence to medications, risk factor control, and improved outcomes. Additional data collection is required to precisely define the incremental benefits of early detection on kidney failure, cardiovascular events, hospitalization and mortality. Increasing the proportion of persons with CKD who know they are affected requires expanded public and professional education programs and screening initiatives targeted at populations who are at high risk for CKD. As a result of consistent congressional support, the National Center for Chronic Disease Prevention and Health Promotion at CDC has instituted a series of projects that could assist in attaining the Healthy People 2020 objective. However, this forward momentum will be stifled and CDC’s investment in CKD to date jeopardized if line-item funding is not continued. Congress rejected the administration’s proposal to consolidate funding for chronic disease programs for fiscal year 2012 and we urge you to oppose it for fiscal year 2013 as well.

¹Josef Coresh, et al. “Prevalence of Chronic Kidney Disease in the United States,” JAMA, November 7, 2007.

²D.T. Gilbertson, et al., *Projecting the Number of Patients with End-Stage Renal Disease in the United States to the Year 2015*. J Am Soc Nephrol 16: 3736–3741, 2005.

³Mark J. Sarnak, et al. Kidney Disease as a Risk Factor for the Development of Cardiovascular Disease: A Statement from the American Heart Association Councils on Kidney in Cardiovascular Disease, High Blood Pressure Research, Clinical Cardiology, and Epidemiology and Prevention. Circulation 2003; 108: 2154–69.

As noted in CDC's Preventing Chronic Disease: April 2006, Chronic Kidney Disease meets the criteria to be considered a public health issue: (1) the condition places a large burden on society; (2) the burden is distributed unfairly among the overall population; (3) evidence exists that preventive strategies that target economic, political, and environmental factors could reduce the burden; and (4) evidence shows such preventive strategies are not yet in place. Furthermore, CDC convened an expert panel in March 2007 to outline recommendations for a comprehensive public health strategy to prevent the development, progression, and complications of CKD in the United States.

The CDC Chronic Kidney Disease program has consisted of three projects to promote kidney health by identifying and controlling risk factors, raising awareness, and promoting early diagnosis and improved outcomes and quality of life for those living with CKD. These projects have included the following:

- Demonstrating effective approaches for identifying individuals at high risk for chronic kidney disease through State-based screening (CKD Health Evaluation and Risk Information Sharing, or CHERISH).
- Conducting an economic analysis by the Research Triangle Institute, under contract with the CDC, on the economic burden of CKD and the cost-effectiveness of CKD interventions.
- Establishing a surveillance system for Chronic Kidney Disease in the U.S. Development of a surveillance system by collecting, integrating, analyzing, and interpreting information on CKD using a systematic, comprehensive and feasible approach will be instrumental in prevention and health promotion efforts for this chronic disease. The CDC CKD surveillance project has built a basic system from a number of data sources, produced a report and beta-tested a website. The next steps include exploring State-based CKD surveillance data ideal for public health interventions through the State department of health.

We believe it is possible to distinguish between the CKD program and other categorical chronic disease initiatives at CDC, because the CKD program does not provide funds to State health departments. Instead, CDC has been making available seed money for feasibility studies in the areas of epidemiological research and health services investigation. Because the CKD program does not provide funds to State health departments, we maintain it should be exempted from the changes in the structure and budget of the National Center for Chronic Disease Prevention and Health Promotion, at least until surveillance planning, and studies of detection feasibility and economic impact are completed.

In summary, undetected Chronic Kidney Disease can lead to costly and debilitating irreversible kidney failure. However, cost-effective interventions are available if patients are identified in the early stages of CKD. With the continued expressed support of the Congress, the National Kidney Foundation is confident a feasible detection, surveillance and treatment program can be established to slow, and possibly prevent, the progression of kidney disease.

Thank you for your consideration of our testimony.

PREPARED STATEMENT OF THE NATIONAL LEAGUE FOR NURSING

The National League for Nursing (NLN) is the premiere organization dedicated to promoting excellence in nursing education to build a strong and diverse nursing workforce to advance the Nation's health. With leaders in nursing education and nurse faculty across all types of nursing programs in the United States—doctorate, master's, baccalaureate, associate degree, diploma, and licensed practical—the NLN has more than 1,200 nursing school and healthcare agency members, 36,000 individual members, and 27 regional constituent leagues.

The NLN urges the subcommittee to fund the following Health Resources and Services Administration (HRSA) nursing programs:

- The Nursing Workforce Development Programs, as authorized under Title VIII of the Public Health Service Act, at \$251.099 million in fiscal year 2013; and
- The Nurse-Managed Health Clinics, as authorized under Title III of the Public Health Service Act, at \$20 million in fiscal year 2013.

NURSING EDUCATION IS A JOBS PROGRAM

According to the U.S. Bureau of Labor Statistics (BLS), the registered nurse (RN) workforce will grow by 26 percent from 2010 to 2020, resulting in 711,900 new jobs. This growth in the RN workforce represents the largest projected numeric job increase from 2010 to 2020 for all occupations. The April 6, 2012, BLS Employment Situation Summary—March 2012 likewise reinforces the strength of the nursing workforce to the Nation's job growth. While the Nation's overall unemployment rate

was little changed at 8.2 percent for March 2012, the employment in healthcare increased in March with the addition of 26,000 jobs at ambulatory healthcare services, hospitals, and nursing and residential care facilities.

Nursing is the predominant occupation in the healthcare industry, with more than 3.854 million active, licensed RNs in the United States in 2010. BLS notes that healthcare is a critically important industrial complex in the Nation. Growing steadily even during the depths of the recession, healthcare is virtually the only sector that added jobs to the economy on a net basis since 2001. Over the last 12 months, healthcare added 365,800 jobs, or an average of 30,480 jobs per month.

The Nursing Workforce Development Programs provide training for entry-level and advanced degree nurses to improve the access to, and quality of, healthcare in underserved areas. The Title VIII nursing education programs are fundamental to the infrastructure delivering quality, cost-effective healthcare. The NLN applauds the subcommittee's bipartisan efforts to recognize that a strong nursing workforce is essential to a health policy that provides high-value care for every dollar invested in capacity building for a 21st century nurse workforce.

The current Federal funding falls short of the healthcare inequities facing our Nation. Absent consistent support, recent boosts to Title VIII will not fulfill the expectation of paying down on asset investments to generate quality health outcomes; nor will episodic increases in funding fill the gap generated by a 14-year nurse and nurse faculty shortage felt throughout the entire United States health system.

THE NURSE PIPELINE AND EDUCATION CAPACITY

Although the recession resulted in some stability in the short-term for the nurse workforce, policymakers must not lose sight of the long-term growing demand for nurses in their districts and States. The NLN's findings from its Annual Survey of Schools of Nursing—Academic Year 2009–2010 cast a wide net on all types of nursing programs, from doctoral through diploma, to determine rates of application, enrollment, and graduation. Key findings include:

- Expansion of nursing education programs impeded by shortage of faculty and clinical placements. The overall capacity of prelicensure nursing education continues to fall well short of demand. Fully 42 percent of all qualified applications to basic RN programs were met with rejection in 2010. Associate degree in nursing (ADN) programs rejected 46 percent of qualified applications, compared with 37 percent of baccalaureate of science in nursing (BSN) programs. Notably, the Nation's practical nursing (PN) programs turned away 40 percent of qualified applications. A strong correlation exists between the shortage of nurse faculty and the inability of nursing programs to keep pace with the demand for new RNs. Increasing the productivity of education programs is a high priority in most States, but faculty recruitment is a glaring problem that will grow more severe. Without faculty to educate our future nurses, the shortage cannot be resolved.
- Yield rates continued to grow. Yield rates—a classic indicator of the competitiveness of college admissions—remain extraordinarily high among pre- and post-licensure nursing programs. A stunning 94 percent of all applicants accepted into ADN programs, and 93 percent of those accepted in PN programs, went on to enroll in 2010. Yield rates among the other program types were nearly as high, averaging 89 percent for RN-to-BSN programs; 86 percent for RN diploma programs, master's in nursing (MSN) programs, and doctoral programs; and 84 percent for BSN programs.

NURSE SHORTAGE AFFECTED BY FACULTY SHORTAGE

A strong correlation exists between the shortage of nurse faculty and the inability of nursing programs to keep pace with the demand for new RNs. Increasing the productivity of education programs is a high priority in most States, but faculty recruitment is a glaring problem that likely will grow more severe. Without faculty to educate our future nurses, the shortage cannot be resolved.

The NLN's findings from the 2009 Faculty Census show that:

- Shortages of Faculty and Clinical Placements Impeded Expansion.*—A shortage of faculty continues to be cited most frequently as the main obstacle to expansion by RN-to-BSN and doctoral programs—indicated by 47 and 53 percent, respectively. By contrast, prelicensure programs are more likely to point to a lack of available clinical placement settings as the primary obstacle to expanding admissions.
- Inequities in Faculty Salaries Added to Shortage Difficulties.*—Despite a national shortage of nurse educators, in 2009 the salaries of nurse educators remained notably below those earned by similarly ranked faculty across higher

education. At the professor rank nurse educators suffer the largest deficit with salaries averaging 45 percent lower than those of their non-nurse colleagues. Associate and assistant nursing professors were also at a disadvantage, earning 19 and 15 percent less than similarly ranked faculty in other fields, respectively.

—*Faculty Staffing Deficit Expected to Intensify as Workforce Reaches Retirement Age.*—The percentage of faculty ages 30 to 45 and ages 46 to 60 both dropped by 3 percent between 2006 and 2009. At the same time the percentage of full-time educators over age 60 grew dramatically from only 9 percent in 2006 to nearly 16 percent in 2009. Overall, 57 percent of part-time educators and nearly 76 percent of full-timers were over the age of 45 in 2009.

TITLE VIII FEDERAL FUNDING REALITY

Today's undersized supply of appropriately prepared nurses and nurse faculty does not bode well for our Nation. The Title VIII Nursing Workforce Development Programs are a comprehensive system of capacity-building strategies that provide students and schools of nursing with grants to strengthen education programs, including faculty recruitment and retention efforts, facility and equipment acquisition, clinical lab enhancements, and loans, scholarships, and services that enable students to overcome obstacles to completing their nursing education programs. HRSA's Title VIII data below provide perspective on a few of the current Federal investments.

Nurse Education, Practice, Quality, and Retention Grants (NEPQR).—NEPQR funds projects addressing the critical nursing shortage via initiatives designed to expand the nursing pipeline, promote career mobility, provide continuing education, and support retention. In fiscal year 2011, NEPQR funded 106 infrastructure grants, including the Nursing Assistant and Home Health Aide program awarding grants to 10 colleges or community-based training programs.

Comprehensive Geriatric Education Program (CGEP).—CGEP funds training, curriculum development, faculty development, and continuing education for nursing personnel who care for older citizens. In academic year 2010–2011, 27 non-competing CGEP grantees provided education to 3,645 RNs, 1,238 RN students, 870 direct service workers, 569 licensed practical/vocational nurses, 264 faculty, and 5,344 allied health professionals.

Advanced Nursing Education (ANE) Program.—ANE supports infrastructure grants to schools of nursing for advanced practice programs preparing nurse-midwives, nurse anesthetists, clinical nurse specialists, nurse administrators, nurse educators, public health nurses, or other advanced level nurses. In academic year 2010–11, the ANE Program supported 151 advanced nursing education projects and enrolled 7,863 advanced nursing education students.

NURSE-MANAGED HEALTH CLINICS (NMHC)

NMHCs are defined as a nurse-practice arrangement, managed by advanced practice registered nurses, that provides primary care or wellness services to underserved or vulnerable populations. NMHCs are associated with a school, college, university, or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

NMHCs deliver comprehensive primary healthcare services, disease prevention, and health promotion in medically underserved areas for vulnerable populations. Approximately 58 percent of NMHC patients either are uninsured, Medicaid recipients, or self-pay. The complexity of care for these patients presents significant financial barriers, heavily affecting the sustainability of these clinics. While providing access points in areas where primary care providers are in short supply, expansion of NMHCs also increases the number of structured clinical teaching sites available to train nurses and other primary care providers. Appropriating \$20 million in fiscal year 2013 to NMHCs would increase access to primary care for thousands of uninsured people in rural and underserved urban communities.

The NLN can state with authority that the deepening health inequities, inflated costs, and poor quality of healthcare outcomes in this country will not be reversed until the concurrent shortages of nurses and qualified nurse educators are addressed. Your support will help ensure that nurses exist in the future who are prepared and qualified to take care of you, your family, and all those who will need our care. Without national efforts of some magnitude to match the healthcare reality facing our Nation today, a calamity in nurse education and in health care generally may not be avoided.

The NLN urges the subcommittee to strengthen the Title VIII Nursing Workforce Development Programs by funding them at a level of \$251.099 million in fiscal year

2013. We also recommend that the Nurse-Managed Health Clinics, as authorized under Title III of the Public Health Service Act, be funded at \$20 million in fiscal year 2013.

PREPARED STATEMENT OF THE NATIONAL MINORITY CONSORTIA

The National Minority Consortia (NMC)¹ submits this statement on the fiscal year 2015 advance appropriations for the Corporation for Public Broadcasting (CPB). The NMC is a coalition of five national organizations dedicated to bringing unique voices and perspectives from America's diverse communities into all aspects of public broadcasting and other media, including content transmitted digitally over the Internet. Our role has been crucial to public broadcasting's mission for over 35 years. We are unique in the services we provide minority producers for access, training and support. The NMC delivers important and timely public interest content to our communities and to public broadcasting. We ask the committee to:

- Direct CPB to increase its efforts for diverse programming with commensurate increases for minority programming and for organizations and stations located within underserved communities;
- Include report language, which recognizes the contribution of the NMC and directs that the CPB partnership with us be expanded. Specifically:

“The committee recognizes the importance of the partnership CPB has with the National Minority Public Broadcasting Consortia, which helps develop, acquire, and distribute public television programming to serve the needs of African American, Asian American, Latino, Native American, Pacific Islander, and other viewers. As communities in the Nation welcome increased numbers of citizens of diverse ethnic backgrounds, local public television stations should strive to meet these viewers' needs. With an increased focus on programming to meet local community needs, the committee encourages CPB to support and expand this critical partnership.”; and

- Provide fiscal year 2015 advance appropriation for CPB of \$445 million, in order to develop content that reaches across traditional media boundaries, such as those separating television and radio. We feel strongly that CPB should be directed to engage in transparent and fair funding practices that guarantee all applicants equal access to these public resources. In particular, we urge the Congress to direct CPB to insert language in all of its funding guidelines that encourages and rewards public media that fully represents and reaches a diverse American public.

While public broadcasting continues to uphold strong ethics of responsible journalism and thoughtful examination of American history, life and culture, it has not kept pace with our rapidly changing public as far as diversity is concerned. Members of minority groups continue to be underrepresented on programming and oversight levels within and in content production. This is unacceptable in America today, where minorities comprise over 35 percent of the population.

Public broadcasting has the potential to be particularly important for our growing minority and ethnic communities, especially as we transition to a broadband-enabled, 21st century workforce that relies on the skills and talent of all of our citizens. While there is a niche in the commercial broadcast and cable world for quality programming about our communities, it is in the public broadcasting sphere where minority communities and producers should have more access and capacity to produce diverse high-quality programming for national audiences. We therefore, urge the Congress to insert strong language in this act to ensure that this is the case and that these opportunities are made available to minorities and other underserved communities.

About the National Minority Consortia.—With primary funding from the CPB, the NMC serves as an important component of American public television as well as content delivered over the Internet. By training and mentoring the next generation of minority producers and program managers as well as brokering relationships between content makers and distributors (such as PBS, APT and NETA), we are in a perfect position to ensure the future strength and relevance of public television and radio television programming from and to our communities.

Each Consortia organization is engaged in cultivating ongoing relationships with the independent producer community by providing technical assistance and program

¹Center for Asian American Media; Latino Public Broadcasting; National Black Programming Consortium/Black Public Media; Native American Public Telecommunications; Pacific Islanders in Communications.

funding, support and distribution. Often the funding we provide is the initial seed money for a project. We also provide numerous hours of programming to individual public television and radio stations, programming that is beyond the reach of most local stations. To have a real impact, we need funding that recognizes and values the full extent of minority participation in public life.

CPB Funds for the National Minority Consortia.—The NMC receives funds from two portions of the CPB budget: organizational support funds from the Systems Support and programming funds from the Television Programming funds. The organizational support funds we receive are used for operations requirements and also for programming support activities and for outreach to our communities and system-wide within public broadcasting. The programming funds are re-granted to producers, used for purchase of broadcast rights and other related programming activities. Each organization solicits applications from our communities for these funds. A brief description of our organizations follows:

- Center for Asian American Media.*—CAAM’s mission is to present stories that convey the richness and diversity of Asian American experiences to the broadest audience possible. We do this by funding, producing, distributing and exhibiting works in film, television and digital media. Over our 32-year history we have provided funding for more than 200 projects, many of which have gone on to win Academy, Emmy and Sundance awards, examples of which are “Daughter from Danang”; “Of Civil Rights and Wrongs: The Fred Korematsu Story”; and “Maya Lin: A Strong Clear Vision”. CAAM presents the annual San Francisco International Asian American Film Festival and distributes Asian American media to schools, libraries and colleges. CAAM’s newest department, Digital Media, is becoming a respected leader in bringing innovative content and audience engagement to public media. CAAM is partnering with Pacific Islanders in Communications on a documentary about Youtube ukulele sensation Jake Shimabukuro.
- Latino Public Broadcasting.*—LPB supports the development, production and distribution of public media content that is representative of Latino people, or addresses issues of particular interest to Latino Americans. Since 1998, LPB has awarded more than \$8 million to Latino Independent Producers, and provided more than 150 hours of compelling programming to public television. LPB supports more than 300 Latino filmmakers per year through professional development initiatives. LPB also produces “Voces”, the only Latino anthology series on public television. In addition, LPB presented the PBS concert special, “In Performance at the White House: Fiesta Latina”, that was re-broadcast on Telemundo and V-me and Latin Music USA, a four part series about the history and impact of Latino music on American culture which reached 14.7 million viewers, 16 percent of whom were Hispanic households (well above the PBS average). Currently LPB is working on “The Latino Americans”, a bilingual 6 part series about the history of Latinos in the United States. This past year, LPB launched the Equal Voice Community Engagement Campaign using the documentary film “Raising Hope: The Equal Voice Story”, a film about strategies to overcome poverty. The community engagement campaign helped PBS stations demonstrate how they too can become advocates for their communities. Currently, LPB is working on a 6 hour series titled “The Latino Americans”, about the history of Latinos in the United States.
- NBPC/Black Public Media* works to increase capacity in diverse communities to create, distribute and use public media. Throughout its history, its mission has been two-fold: building capacity in new generations of creators of social issue media and broadening the pool of stakeholders in public media institutions. Over the past 5 years, in addition to supporting producers who create programming for public television and other platforms, NBPC/Black Public Media has convened and mentored more than 500 digital media professionals and created the Public Media Corps (PMC) to address an urgent need in our communities at the grassroots level. Currently entering its third year, the PMC, in partnership with K–12 schools, libraries and universities, is a framework for supporting creative, sustainable and community-initiated methods for using media and media-technology in underserved communities by deploying public media content and tools. In 2012, we presented the fourth season of its critically acclaimed series “AfroPop: the Ultimate Cultural Exchange”, which features independent perspectives from the African diaspora, including the African continent, the Caribbean and the Americas, as well as numerous hours of prime-time television programming to PBS. Currently, NBPC/Black Public Media is in production on a television special and related engagement activities that support CPB’s American Graduate initiative to combat the drop out crisis in American

public schools and two new web-exclusive content series by emerging black filmmakers.

—*Native American Public Telecommunications*.—NAPT shares Native stories with the world. We advance media that represents the experiences, values, and cultures of American Indians and Alaska Natives. Founded in 1977, through various media—public television and radio and the Internet—NAPT brings awareness of Indian and Alaska Native issues. In 2011 NAPT presented seven Native American documentaries to PBS stations nationwide and offered producers and educators numerous workshops related to media maker topics including “Media for Change: Documentary Film in Education and Social Issues” that allowed NAPT to build learning objects to teach Native American History and fit all of its curricular materials to the set of core standards. In addition, NAPT continues to target and work with stations to bring new voices into the public broadcasting system using new media civic engagement technology and support. NAPT is currently developing curriculum and community engagement strategies to support CPB’s American Graduate initiative that extends the reach of the Nebraska Educational Telecommunications’ documentary “Standing Bear’s Footsteps” through a partnership with NBPC’s Public Media Corps, Southern Ponca Tribe of Oklahoma and Northern Ponca Tribe of Nebraska.

—*Pacific Islanders in Communications*.—Since 1991, PIC has delivered programs and training that bring voice and visibility to Pacific Islander Americans. PIC produced the award winning film “One Voice” which tells the story of the Kamehameha Schools Song Contest. Other PBS broadcasts include “There Once Was an Island”, about the devastating effects of global warming on the Pacific Islands and “Polynesian Power: Islanders in Pro Football”. Currently PIC is developing a multi-part series, “Expedition: Wisdom”, in partnership with the National Geographic Society. PIC offers a wide range of development opportunities for Pacific Island producers through travel grants, seminars and media training. Producer training programs are held in the U.S. territories of Guam and American Samoa, as well as in Hawai‘i, on a regular basis. This year the PIC series *Pacific Heartbeat* premieres on American Public Television.

Thank you for your consideration of our recommendations. We see new opportunities to increase diversity in programming, production, audience, and employment in the new media environment, and we thank the Congress for support of our work on behalf of our communities.

PREPARED STATEMENT OF THE NATIONAL MARFAN FOUNDATION

National Marfan Foundation Fiscal Year 2013 LHHS Appropriations Recommendations

\$7.8 billion for CDC, an increase of \$1.7 billion over fiscal year 2012, including proportional increases for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and the National Center on Birth Defects and Developmental Disabilities (NCBDDD) to facilitate critical Marfan syndrome and related connective tissue disorders education and awareness activities.

\$32 billion for NIH, an increase of \$1.3 billion over fiscal year 2012, including proportional increases for the National Heart, Lung, and Blood Institute (NHLBI); National Center for Advancing Translational Sciences (NCATS); National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); and other NIH Institutes and Centers to facilitate adequate growth in the Marfan syndrome and related connective tissue disorders research portfolios.

Chairman Harkin, Ranking Member Shelby, and distinguished members of the Subcommittee, thank you for the opportunity to submit testimony on behalf of NMF. It is my honor to represent the estimated 200,000 Americans who are affected by Marfan syndrome or a related condition before you.

Marfan syndrome is a genetic disorder of the connective tissue that can affect many areas of the body, including the heart, eyes, skeleton, lungs and blood vessels. It is a progressive condition and can cause deterioration in each of these body systems. The most serious and life-threatening aspect of the syndrome is a weakening of the aorta. The aorta is the largest artery carrying oxygenated blood from the heart. Over time, many Marfan syndrome patients experience a dramatic weakening of the aorta which can cause the vessel to dissect and tear.

Aortic dissection is a leading killer in the United States, and 20 percent of the people it affects have a genetic predisposition, like Marfan syndrome, to developing the complication. Early surgical intervention can prevent a dissection and strengthen the aorta and the aortic valves, especially when preventive surgery is performed before a dissection occurs.

The NMF is a nonprofit voluntary health organization founded in 1981. NMF is dedicated to saving lives and improving the quality of life for individuals and families affected by the Marfan syndrome and related disorders. The Foundation has three major goals: (1) To provide accurate and timely information about the Marfan syndrome to affected individuals, family members, physicians, and other health professionals; (2) to provide a means for those with Marfan syndrome and their relatives to share in experiences, to support one another, and to improve their medical care; and (3) to support and foster research.

NMF is deeply appreciative of this Subcommittee's historic support for critical public health programs at CDC and NIH, particularly programs focused on addressing life-threatening genetic disorders such as Marfan syndrome. Under your leadership NIH through NHLBI and NIAMS has been able to expand research in this area and advance our scientific understanding of the condition. In addition, CDC through NCCDPHP and NCBDDD has the resources necessary to implement life-saving awareness and education activities that can prevent thoracic aortic aneurysms and dissections. We urge you to once again prioritize funding for public health programs in fiscal year 2013 to ensure that these activities can continue to improve the quality of life for Americans affected by Marfan syndrome and related connective tissue disorders.

To follow, please find NMF's fiscal year 2013 appropriations recommendations for CDC and NIH. Thank you for your time and your consideration of these recommendations.

Centers for Disease Control and Prevention

NMF joins the other voluntary patient and medical organizations comprising the public health community in requesting that you support CDC by providing the agency with an appropriation of \$7.8 billion in fiscal year 2013. Such a funding increase would allow CDC to undertake critical Marfan syndrome and related connective tissue disorders education and awareness activities, which would help prevent deadly thoracic aortic aneurysms and dissections.

In 2010, the American College of Cardiology and the American Heart Association issued landmark practice guidelines for the treatment of thoracic aortic aneurysms and dissections. NMF is promoting awareness of the new guidelines in collaboration with other organizations through a new Coalition known as "TAD"; the Thoracic Aortic Disease Coalition. The TAD Coalition is presently comprised of 10 organizations that are coordinating efforts to help promote the Guidelines to healthcare professionals and to raise public awareness of various aortic diseases and the associated risk factors.

The CDC would be an invaluable partner in the ongoing campaign to save lives and improve health outcomes by promoting the new Guidelines to healthcare providers and raising public awareness of risk factors. In this regard, we ask the Subcommittee encourage CDC to identify appropriate staff at the NCCDPHP and NCBDDD to participate in TAD Coalition activities. It is our hope that involving CDC in the activities of the TAD Coalition will lead to a lasting partnership and collaboration on critical outreach campaigns.

National Institutes of Health

NMF joins the other voluntary patient and medical organizations comprising the public health community in requesting that you support NIH by providing the agency with an appropriation of \$32 billion in fiscal year 2013. This modest 4 percent funding increase would ensure that biomedical research inflation does not result in a loss of purchasing power at NIH, critical new initiatives like the Cures Acceleration Network (CAN) are adequately supported, and the Marfan syndrome research portfolio can continue to progress.

National Heart, Lung, and Blood Institute.—First and foremost, NMF applauds NHLBI for its leadership in advancing a landmark clinical trial on Marfan syndrome. Under the direction of Dr. Lynn Mahoney and Dr. Gail Pearson, the Institute's Pediatric Heart Network (PHN) has spearheaded a multicenter study focused on the potential benefits of a commonly prescribed blood pressure medication (losartan) on aortic growth in Marfan syndrome patients.

Marfan syndrome patients (age 6 months to 25 years) are now enrolled in the study. Patients are randomized onto either losartan or atenolol (a beta blocker that is the current standard of care for Marfan patients with an enlarged aortic root). We anxiously await the results of this first-ever clinical trial for our patient population. It is our hope that losartan will emerge as the new standard-of-care and greatly reduce the need for surgery in at-risk patients.

NMF is proud to actively support the losartan clinical trial in partnership with PHN. Throughout the life of the trial we have provided support for patient travel

costs, coverage of select echocardiogram examinations, and funding for ancillary studies. These ancillary studies will explore the impact that losartan has on other manifestations of Marfan syndrome. The Foundation asks for your continued support to ensure this critical study continues to move forward.

Secondarily, NMF is grateful for the Subcommittee's previous recommendations encouraging NHLBI to support research on surgical options for Marfan syndrome patients.

For the past several years, the NMF has supported an innovative study looking at outcomes in Marfan syndrome patients who undergo valve-sparing surgery compared with valve replacement. Initial findings were published recently in the *Journal of Thoracic and Cardiovascular Surgery*. Some short term questions have been answered, most importantly that valve-sparing can be done safely on Marfan patients by an experienced surgeon. The consensus among the investigators however is that long-term durability questions will not be answered until patients are followed for at least 10 years.

Confirming the utility and durability of valve sparing procedures will save our patients a host of potential complications associated with valve replacement surgery. In this regard, we ask that you encourage NHLBI to consider working with the Genetically Triggered Thoracic Aortic Aneurysms and Cardiovascular Conditions Registry or GenTAC to identify ways we can partner moving forward to facilitate continuation of the aforementioned outcomes study.

Finally, in 2007, NHLBI convened a "Working Group on Research in Marfan Syndrome and Related Conditions." This panel was comprised of experts in all aspects of basic and clinical science related to the disorder. The panel was charged with identifying key recommendations for advancing the field of research in the coming decade.

In addition to laying out a roadmap for research, the working group found that, "Scientific opportunities to advance this field are conferred by technological advances in gene discovery, the ability to dissect cellular processes at the molecular level and imaging, and the establishment of multi-disciplinary teams." The barriers to progress are addressed through the research recommendations, which are also consistent with goals and challenges identified in the NHLBI Strategic Plan.

National Center for Advancing Translational Sciences.—The Foundation applauds the recent establishment of NCATS at NIH. Housing translational research activities at a single Center at NIH will allow these programs to achieve new levels of success. Initiatives like CAN are critical to overhauling the translational research process and overcoming the research "valley of death" that currently plagues treatment development. In addition, new efforts such as taking the lead on drug repurposing hold the potential to speed new treatment to patients, particularly patients who struggle with rare or neglected conditions. NMF asks that you support NCATS and provide adequate resources for the Center in fiscal year 2013.

National Institute of Arthritis and Musculoskeletal and Skin Diseases.—NMF is proud of its longstanding partnership with NIAMS. Dr. Steven Katz has been a strong proponent of basic research on Marfan syndrome during his tenure as NIAMS Director and has generously supported several "Conferences on Heritable Disorders of Connective Tissue." Moreover, the Institute has provided invaluable support for the program project entitled, "Consortium for Translational Research in Marfan Syndrome," which has enhanced our understanding of the disorder and increased the ability to stop the disease progression using a drug-based therapy. The discoveries of fibrillin-1, TGF-beta, and their role in muscle regeneration and connective tissue function were made possible in part through collaboration with NIAMS.

As the losartan trial continues to move forward, we hope to expand our partnership with NIAMS to support related studies that fall under the mission and jurisdiction of the Institute. One of the areas of great interest to researchers and patients is the role that losartan may play in strengthening muscle tissue in Marfan patients. NMF would welcome an opportunity to partner with NIAMS on this and other research. In this regard, we ask that you encourage NIAMS to expand its support for research aimed at identifying effective therapies for heritable connective tissue disorders to reduce the number of premature deaths from these chronic and complex conditions.

Thank you again for your time and your consideration of our fiscal year 2013 appropriations requests. Please contact me if you have any questions or if you would like any additional information.

PREPARED STATEMENT OF THE NATIONAL MULTIPLE SCLEROSIS SOCIETY

Mr. Chairman and members of the subcommittee, thank you for this opportunity to provide testimony regarding funding of critically important Federal programs that impact those affected by multiple sclerosis. Multiple sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system that interrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity, and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease. MS affects more than 400,000 people in the United States.

MS stops people from moving. The National MS Society exists to make sure it doesn't. The National MS Society sees itself as a partner to the Government in many critical areas. As we advocate for NIH research, we do so as an organization that funds approximately \$40 million annually in MS research through funds generated through the Society's fundraising efforts. And as we advocate for lifespan respite funding, we do so as an organization that works to provide some level of respite relief for caregivers. So while we're here to advocate for Federal funding, we do it as an organization that commits tens of millions of dollars each year to similar or complementary efforts as those being funded by the Federal Government. Through these efforts, our goal is to see a day when MS has been stopped, lost functions restored, and a cure is at hand.

The National MS Society recommends the following funding levels for agencies and programs that are of vital importance for the lives of Americans living with MS.

LIFESPAN RESPITE CARE PROGRAM

Many caregivers are family members who provide care full time because of the needs of the patient. As you can imagine, the caregivers get worn out and need a break once in a while. That's why respite care services are so important—to provide caregivers with a chance to have a break and get refreshed. These services are a critical part of ensuring quality home-based care for people living with MS. Because of the importance of these services, the National MS Society requests the inclusion of \$5 million in the fiscal year 2013 Labor-HHS-Education appropriations bill to fund lifespan respite programs. The Lifespan Respite Care Program, enacted in 2006, provides competitive grants to States to establish or enhance statewide lifespan respite programs, improve coordination, and improve respite access and quality. States provide planned and emergency respite services, train and recruit workers and volunteers, and assist caregivers in gaining access to services. Perhaps the most critical aspect of the program for people living with MS is that lifespan respite serves families regardless of special need or age—literally across the lifespan. Much existing respite care has age eligibility requirements and since MS is typically diagnosed between the ages of 20 and 50, lifespan respite programs are often the only open door to needed respite services.

Up to one-quarter of individuals living with MS require long-term care services at some point during the course of the disease. Often, a family member steps into the role of primary caregiver to be closer to the individual with MS and to be involved in care decisions. According to a 2011 AARP report, 61.6 million family caregivers provided care at some point during 2009 and the value of their uncompensated services was approximately \$450 billion per year—more than total Medicaid spending and almost as high as Medicare spending. Family caregiving, while essential, can be draining and stressful, with caregivers often reporting difficulty managing emotional and physical stress, finding time for themselves, and balancing work and family responsibilities. The impact is so great, in fact, that American businesses lose an estimated \$17.1 to \$33.36 billion each year due to lost productivity costs related to caregiving responsibilities. Providing \$5 million for Lifespan Respite in fiscal year 2013 would improve access to respite services, allowing family caregivers to take a break from the daily routine and stress of providing care, improve overall family health, and help alleviate the monstrous financial impact caregiver strain currently has on American businesses.

NATIONAL INSTITUTES OF HEALTH

We urge the Congress to continue its investment in innovative medical research that can help prevent, treat, and cure diseases such as MS by providing at least \$32 billion for the National Institutes of Health (NIH) in fiscal year 2013.

The NIH is the country's premier institution for medical research and the single largest source of biomedical research funding in the world. The NIH conducts and sponsors a majority of the MS-related research carried out in the United States. Approximately \$122 million of fiscal year 2011 and American Recovery and Reinvestment Act appropriations were directed to MS-related research. An invaluable partner, the NIH has helped make significant progress in understanding MS. NIH scientists were among the first to report the value of MRI in detecting early signs of MS, before symptoms even develop. Advancements in MRI technology allow doctors to monitor the progression of the disease and the impact of treatment.

Research during the past decade has enhanced knowledge about how the immune system works, and major gains have been made in recognizing and defining the role of this system in the development of MS lesions. These NIH discoveries are helping find the cause, alter the immune response, and develop new MS therapies that are now available to modify the disease course, treat exacerbations, and manage symptoms. Twenty years ago there were no MS therapies or medications. Now there are eight, with the first oral medication now available and other new treatments in the pipeline. The NIH provided the basic research necessary so that these therapies could be developed. Had there been no Federal investment in research, it's doubtful people living with MS would have any therapies available. The NIH also directly supports jobs in all 50 States and 17 of the 30 fastest growing occupations in the United States are related to medical research or healthcare. More than 83 percent of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at more than 3,000 universities, medical schools, and other research institutions in every State.

To continue the forward momentum in the ability to aggressively combat, treat, and one day cure diseases like MS, the National MS Society requests that the Congress provide at least \$32 billion for the NIH in fiscal year 2013.

CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicaid

The National MS Society urges the Congress to maintain funding for Medicaid and reject proposals to cap or block grant the program.

Medicaid provides comprehensive health coverage to more than 8 million persons living with disabilities and 6 million persons with disabilities who rely on Medicaid to fill Medicare's gaps. Approximately 10 percent of people living with MS rely on Medicaid.

Capping or block-granting Medicaid will merely shift costs to States, forcing States to shoulder a seemingly insurmountable financial burden or cut services on which our most vulnerable rely. Capping and block-granting could result in many more individuals becoming uninsured, compounding the current problems of lack of coverage, over flowing emergency rooms, limited access to long-term services, and increased healthcare costs in an overburdened system. By capping funds that support home- and community-based care, such proposals would also likely lead to an increased reliance on costlier institutional care that contradicts the principles laid forth in the 1999 U.S. Supreme Court decision *Olmstead* and integrating and keeping people with disabilities in their communities.

While the economic situation demands leadership and thoughtful action, the National MS Society urges the Congress to remember people with MS and all disabilities, their complex health needs, and the important strides Medicaid has made for persons living with disabilities particularly in the area of community-based care and not modify the program to their detriment.

SOCIAL SECURITY ADMINISTRATION

The National MS Society urges the Congress to provide \$13.4 billion for the Social Security Administration's (SSA) Limitations on Administrative (LAE) Expenses to fund SSA's day-to-day operational responsibilities and make key investments in addressing increasing disability and retirement workloads, in program integrity, and in SSA's Information Technology (IT) infrastructure.

Because of the unpredictable nature and sometimes serious impairment caused by the disease, SSA recognizes MS as a chronic illness or "impairment" that can cause disability severe enough to prevent an individual from working. During such periods, people living with MS are entitled to and rely on Social Security Disability Insurance (SSDI) or Supplemental Security Income (SSI) benefits to survive. People living with MS, along with millions of others with disabilities, depend on SSA to promptly and fairly adjudicate their applications for disability benefits and to handle many other actions critical to their well-being including: timely payment of their monthly benefits; accurate withholding of Medicare Parts B and D premiums; and

timely determinations on post-entitlement issues, e.g., overpayments, income issues, prompt recording of earnings.

The wave of increased disability claims—in part due to the distressed economy—continues to have a very significant impact on the Disability Determination Services (DDSs). In the 35-month period ending in August 2011, the number of claims pending for a disability medical decision rose from 556,670 to 755,058—an increase of 36 percent. SSA faces an unprecedented backlog of disability hearings. In fiscal year 2011, 859,514 hearings were filed, which is 270,065 (45.8 percent) more than in fiscal year 2008. Despite these challenges, eliminating the disability hearings backlog remains SSA's top priority and processing time has been reduced from 491 days in fiscal year 2009 to 340 days in October 2011. If SSA does not receive adequate funding for fiscal year 2013 this progress will regress. The reduced SSA funding level in fiscal year 2011 for example resulted in the suspension of opening eight planned hearing offices, which diminishes SSA's ability to eliminate the backlog by fiscal year 2013. To support continued progress to eliminate the backlog and to help ensure that persons with disabilities relying on SSDI or SSI receive entitled benefits in a timely manner, the National MS Society urges the Congress to provide \$13.4 billion for the SSA's LAE in fiscal year 2013.

FOOD AND DRUG ADMINISTRATION

The FDA is the United States' pre-eminent public health agency and its role as the regulator of the country's pharmaceutical industry provides invaluable support and encourages vital progress for people living with MS and other diseases. In its capacity as the industry's regulator, the FDA ensures that drugs and medical devices are safe and effective for public use and provides consumers with confidence in new technologies. Because of the tremendous impact the FDA has on the development and availability of drugs and devices for individuals with disabilities, the NMSS requests that the Congress provide a 6 percent increase over the fiscal year 2012 budget.

Advancements in medical technology and medical breakthroughs play a pivotal role in decreasing the societal costs of disease and disability. The FDA is responsible for approving drugs for the market and in this capacity has the ability to keep healthcare costs down. Each \$1 invested in the life-science research regulated by the FDA has the potential to save upwards of \$10 in health gains. Breakthroughs in medications and devices can reduce the potential costs of disease and disability in Medicare and Medicaid and can help support the healthier, more productive lives of people living with chronic diseases and disabilities, like MS. The approval of low-cost generic drugs saved the healthcare system \$140 billion in 2010 and nearly \$1 trillion over the past decade. However, recent funding constraints have resulted in a 2 year backlog of generic drug approval applications and could potentially cost the Federal Government and patients billions of dollars in the coming years. The potential for these cost-saving medical breakthroughs and overall healthcare savings relies on a vibrant industry and an adequately funded FDA. Entire industries are working to enhance the lives of Americans with new medical devices and pharmaceuticals with tens of billions of dollars being spent annually by the NIH and industry in pursuit of new breakthroughs. The FDA has a comparatively small budget yet is charged with ensuring the safety and efficacy of these new products. The answer to the backlog is to provide adequate funding to FDA, not, as some have suggested, to lessen the rigorous protocols in place to ensure safety. Therefore, the National MS Society urges the Congress to provide the FDA with a 6 percent increase to address this backlog.

CONCLUSION

The National MS Society thanks the subcommittee for the opportunity to provide written testimony and our recommendations for fiscal year 2013 appropriations. The agencies and programs we have discussed are of vital importance to people living with MS and we look forward to continuing to working with the subcommittee to help move us closer to a world free of MS. Please don't hesitate to contact me with any question.

PREPARED STATEMENT OF THE NEUROFIBROMATOSIS NETWORK

Thank you for the opportunity to submit testimony to the Subcommittee on the importance of continued funding at the National Institutes of Health (NIH) for research on Neurofibromatosis (NF), a genetic disorder closely linked too many common diseases widespread among the American population.

On behalf of the Neurofibromatosis (NF) Network, a national coalition of NF advocacy groups, I speak on behalf of the 100,000 Americans who suffer from NF as well as approximately 175 million Americans who suffer from diseases and conditions linked to NF such as cancer, brain tumors, heart disease, memory loss, and learning disabilities. Thanks in large measure to this Subcommittee's strong support, scientists have made enormous progress since the discovery of the NF1 gene in 1990 resulting in clinical trials now being undertaken at NIH with broad implications for the general population.

NF is a genetic disorder involving the uncontrolled growth of tumors along the nervous system which can result in terrible disfigurement, deformity, deafness, blindness, brain tumors, cancer, and even death. In addition, approximately one-half of children with NF suffer from learning disabilities. NF is the most common neurological disorder caused by a single gene and three times more common than Muscular Dystrophy and Cystic Fibrosis combined. There are three types of NF: NF1, which is more common, NF2, which primarily involves tumors causing deafness and balance problems, and schwannomatosis, the hallmark of which is severe pain.

While not all NF patients suffer from the most severe symptoms, all NF patients and their families live with the uncertainty of not knowing whether they will be seriously affected because NF is a highly variable and progressive disease.

Researchers have determined that NF is closely linked to cancer, heart disease, learning disabilities, memory loss, brain tumors, and other disorders including deafness, blindness and orthopedic disorders, primarily because NF regulates important pathways common to these disorders such as the RAS, cAMP and PAK pathways. Research on NF therefore stands to benefit millions of Americans:

Cancer.—NF is closely linked to many of the most common forms of human cancer, affecting approximately 65 million Americans. In fact, NF shares these pathways with 70 percent of human cancers. Research has demonstrated that NF's tumor suppressor protein, neurofibromin, inhibits RAS, one of the major malignancy causing growth proteins involved in 30 percent of all cancer. Accordingly, advances in NF research may well lead to treatments and cures not only for NF patients, but for all those who suffer from cancer and tumor-related disorders. Similar studies have also linked epidermal growth factor receptor (EGF-R) to malignant peripheral nerve sheath tumors (MPNSTs), a form of cancer which disproportionately strikes NF patients.

Heart Disease.—Researchers have demonstrated that mice completely lacking in NF1 have congenital heart disease that involves the endocardial cushions which form in the valves of the heart. This is because the same ras involved in cancer also causes heart valves to close. Neurofibromin, the protein produced by a normal NF1 gene, suppresses ras, thus opening up the heart valve. Promising new research has also connected NF1 to cells lining the blood vessels of the heart, with implications for other vascular disorders including hypertension, which affects approximately 50 million Americans. Researchers believe that further understanding of how an NF1 deficiency leads to heart disease may help to unravel molecular pathways involved in genetic and environmental causes of heart disease.

Learning Disabilities.—Learning disabilities are the most common neurological complication in children with NF1. Research aimed at rescuing learning deficits in children with NF could open the door to treatments affecting 35 million Americans and 5 percent of the world's population who also suffer from learning disabilities. In NF1 the neurocognitive disabilities range includes behavior, memory and planning. Recent research has shown there are clear molecular links between autism spectrum disorder and NF1; as well as with many other cognitive disabilities. Tremendous research advances have recently led to the first clinical trials of drugs in children with NF1 learning disabilities. These trials are showing promise. In addition because of the connection with other types of cognitive disorders such as autism, researchers and clinicians are actively collaborating on research and clinical studies, pooling knowledge and resources. It is anticipated that what we learn from these studies could have an enormous impact on the significant American population living with learning difficulties and could potentially save Federal, State, and local governments, as well as school districts, billions of dollars annually in special education costs resulting from a treatment for learning disabilities.

Memory Loss.—Researchers have also determined that NF is closely linked to memory loss and are now investigating conducting clinical trials with drugs that may not only cure NF's cognitive disorders but also result in treating memory loss as well with enormous implications for patients who suffer from Alzheimer's disease and other dementias.

Deafness.—NF2 accounts for approximately 5 percent of genetic forms of deafness. It is also related to other types of tumors, including schwannomas and meningiomas, as well as being a major cause of balance problems.

The enormous promise of NF research, and its potential to benefit more than 175 million Americans who suffer from diseases and conditions linked to NF, has gained increased recognition from the Congress and the NIH. This is evidenced by the fact that 11 institutes are currently supporting NF research, and NIH's total NF research portfolio has increased from \$3 million in fiscal year 1990 to an estimated \$24 million in fiscal year 2012. Given the potential offered by NF research for progress against a range of diseases, we are hopeful that the NIH will continue to build on the successes of this program by funding this promising research and thereby continuing the enormous return on the taxpayers' investment.

We respectfully request that you include the following report language on NF research at the National Institutes of Health within your fiscal year 2013 Labor, Health and Human Services, Education appropriations bill.

*“Neurofibromatosis [NF].—*The Committee supports efforts to increase funding and resources for NF research and treatment at multiple NIH Institutes. NF affected children and adults are at significant risk for the development of many forms of cancer; the Committee encourages NCI to increase its NF research portfolio in fundamental basic science, translational research and clinical trials focused on NF. The Committee also encourages the NCI to support NF centers, NF clinical trials consortia, NF preclinical mouse models consortia, and biospecimen repositories. The Committee urges NHLBI to expand its investment in NF based on the increased prevalence of hypertension and congenital heart disease in this patient population. Because NF causes brain and nerve tumors and is associated with cognitive and behavioral problems, the Committee urges NINDS to continue to aggressively fund fundamental basic science research on NF relevant to nerve damage and repair, learning disabilities and attention deficit disorders. In addition, the Committee encourages the NICHD and NIMH to expand funding of basic and clinical NF research in the area of learning and behavioral disabilities. Children with NF1 are prone to the development of severe bone deformities, including scoliosis; the Committee therefore encourages NIAMS to expand its NF1 research portfolio. Since NF2 accounts for approximately 5 percent of genetic forms of deafness, the Committee encourages NIDCD to expand its investment in NF2 basic and clinical research. Based on the increased incidence of optic gliomas, vision loss, cataracts, and retinal abnormalities in NF, the Committee urges the NEI to expand its NF research portfolio. Finally, the Committee encourages NHGRI to increase its investment in NF, given that NF represents a tractable model system to study the genomics of cancer predisposition, learning and behavior problems, and bone abnormalities translatable to individualized medicine.”

We appreciate the Subcommittee's strong support for NF research and will continue to work with you to ensure that opportunities for major advances in NF research are aggressively pursued. Thank you.

PREPARED STATEMENT OF THE NATIONAL NURSING CENTERS CONSORTIUM

The National Nursing Centers Consortium (NNCC) is a 501(c)(3) member organization of nonprofit, nurse-managed health clinics, sometimes called nurse-managed health centers or NMHCs. The Affordable Care Act defines the term “nurse-managed health clinic” as a nurse practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center (FQHC), or independent nonprofit health or social services agency. Currently there are about 200 NMHCs in operation throughout the United States. Title III of the Public Health Service Act established the Nurse Managed Health Clinic Grant Program to provide NMHCs with a stable source of Federal funding that would place them on footing similar to other safety-net providers. Although authorized, to date the Grant Program has received no appropriations.

The Value of Nurse-Managed Health Centers: Interdisciplinary Training in an Academic Setting

Many of the Nation's leading nursing schools operate NMHCs. Since the clinics are affiliated with academic institutions, they naturally become workforce development sites and can provide clinical training opportunities for health profession students. In addition to training registered nurses and advance practice registered nurses (mostly nurse practitioners), many NMHCs have interdisciplinary partnerships with other academic programs allowing them to also provide learning opportunities for medical, pharmacy, dental, social work, public health, and other health

profession students. NMHCs easily blend community healthcare with healthcare provider training and development.

In October 2010, HRSA released \$14.8 million in Prevention and Public Health Fund dollars to fund 10 NMHC grants. Since receiving funding, the NMHC grantees have provided interdisciplinary clinical training to more than 800 students of nursing, medicine, public health, and other health professions. In May 2009, the NNCC conducted a survey of its members to measure their contribution to health professions education in the United States. Forty-four NMHCs in a mix of urban, rural, and suburban communities reported providing educational opportunities for nearly 3,100 students annually. The contribution by these clinics to the healthcare workforce is undeniable.

The Value of Nurse-Managed Health Centers: Expanding Access to Care at a Lower Cost

NMHCs act as essential safety-net providers in rural, urban, and suburban communities across the country. For many patients in medically underserved areas, NMHCs and nurse practitioners are the only primary care providers in the area. These critical access points provide care to patients regardless of ability to pay and insurance status and keep patients out of the emergency room, saving the healthcare system millions of dollars annually. NMHCs also improve access by helping to build the capacity of the Nation's primary care workforce. As the number of medical students going into primary care continues to stay at an alarmingly low rate, the United States is in serious need of quickly and well-trained primary care providers. By training nurse practitioners as community-based primary care providers, NMHCs are perfectly positioned to increase the number of providers while simultaneously providing needed primary care.

By the end of 2011, the NMHC grantees that received Federal funding in October 2010 had served 27,000 patients and recorded more than 72,000 patient encounters. Additionally, the grantees are providing care in communities with unprecedented need. For instance, one of the grantees provides care to residents of Galveston, Texas, a community still recovering from a devastating natural disaster. All this indicates that any Federal funds provided to NMHCs will go to provide quality primary care in very needy communities.

Finally, having nurse practitioners provide primary care in NMHCs is cost-effective, which is critical in this time of fiscal uncertainty. In 1981, the Office of Technology Assessment first demonstrated that nurse practitioners perform comparable medical care tasks at a lower total cost than physicians.¹ Many studies have since reaffirmed that nurse practitioners provide high quality care for a lower overall cost.²

The Challenge in Sustaining Nurse-Managed Health Centers

The patient population and payor mix of NMHCs is similar to that of federally Qualified Health Centers. However, because many NMHCs are directly affiliated with academic schools of nursing, they cannot meet the governance requirements for Community Health Center funding. Without a stable source of funding to offset the cost of caring for the uninsured, several NMHCs have had to close, leaving many vulnerable patients without care.

Request

Because NMHCs are vital interdisciplinary training sites, help fill the gap in the primary care provider shortage by training primary care providers, and provide quality, affordable care to the most vulnerable people in their communities, the NNCC respectfully requests \$20 million in fiscal year 2013 for the Nurse-Managed Health Clinic Grant Program, as authorized under Title III of the Public Health Service Act.

¹LeRoy, L. & Solowitz, S. (1981). The Costs and Effectiveness of Nurse Practitioners. Office of Technology Assessment.

²Coddington J. (2010). Quality of Care and Policy Barriers to Providing Health Care at a Pediatric Nurse-Managed Clinic. *Journal of Pediatric Healthcare*, 24 (5):e9; Eibner, E et al. (2009). Controlling Health Care Spending in Massachusetts: An Analysis of Options. RAND Health; Mehrota, A. et al. (2009). Comparing Costs and Quality of Care at Retail Clinics with that of Other Medical Settings for 3 Common Illnesses. *Annals of Internal Medicine*, 151, 321–323; Chenoweth, D. et al. (2008). Nurse Practitioner Services: Three-Year Impact on Health Care Costs. *Journal of Occupational and Environmental Medicine*, 50, 1293–1298.

PREPARED STATEMENT OF THE NATIONAL POSTDOCTORAL ASSOCIATION

Mr. Chairman and Members of the Subcommittee: Thank you for this opportunity to testify in regard to the fiscal year 2013 funding for the National Institutes of Health (NIH). We are writing today in regard to support for postdoctoral researchers, specifically in support of fiscal year 2013 funding for the National Institutes of Health at the 2012 level of \$30.86 billion and in support of the 2 percent increase in the Ruth L. Kirschstein National Research Service Award (NRSA) training stipends for postdoctoral researchers, as requested in the President's proposed fiscal year 2013 budget.

Background: Postdocs are the Backbone of U.S. Science and Technology

According to estimates by the National Science Foundation (NSF) Division of Science Resource Statistics, there are approximately 89,000 postdoctoral scholars in the United States¹. The NIH and the NSF define a "postdoc" as: An individual who has received a doctoral degree (or equivalent) and is engaged in a temporary and defined period of mentored advanced training to enhance the professional skills and research independence needed to pursue his or her chosen career path. The number of postdocs has been steadily increasing. The incidence of individuals taking postdoc positions during their careers has risen, from about 31 percent of those with a pre-1972 doctorate to 46 percent of those receiving their doctorate in 2002–05². According to the 2012 Science and Engineering Indicators, an increase in those taking postdoc positions is evident across most disciplines:

"In traditionally high-postdoc fields such as the life sciences (from 46 percent to 60 percent) and the physical sciences (from 41 percent to 61 percent), most doctorate recipients now have a postdoc position as part of their career path. Similar increases were found in mathematical and computer sciences (19 percent to 31 percent), social sciences (18 percent to 30 percent), and engineering (14 percent to 38 percent). Recent engineering doctorate recipients are now almost as likely to take a postdoc position as physical sciences doctorate holders were 35 years ago."³

Postdocs are critical to the research enterprise in the United States and are responsible for the bulk of the cutting edge research performed in this country. Consider the following:

- According to the National Academy of Science (NAS), postdoctoral researchers "have become indispensable to the science and engineering enterprise, performing a substantial portion of the Nation's research in every setting."⁴
- The retention of women and under-represented groups in biomedical research depends upon their successful and appropriate completion of the postdoctoral experience.
- Postdoctoral scholars carry the potential to solve many of the world's most pressing scientific and health problems; they are the principal investigators of tomorrow.

Unfortunately, postdocs are routinely exploited. They are paid a low wage relative to their years of training and receive varying benefits depending on the institution where they work. The National Postdoctoral Association (NPA) advocates for policies that support and enhance postdoctoral training on the national level and also within the research institutions that host postdoctoral scholars. Low compensation remains one of the most serious issues faced by the postdoctoral community.

Problem: NRSA Stipends are Low and Don't Meet Cost-of-Living Standards; For Better or Worse, Postdoc Compensation is Based on NRSA Stipends

The NIH leadership has been aware that the NRSA training stipends are too low since 2001, after the publication of the results of the NAS study, *Addressing the Nation's Changing Needs for Biomedical and Behavioral Scientists*. In response, the NIH pledged (1) to increase entry-level stipends to \$45,000 by raising the stipends at least 10 percent each year and (2) to provide automatic cost-of-living increases each year thereafter to keep pace with inflation. Most recently, the 2011 NAS study, *Research Training in the Biomedical, Behavioral, and Clinical Research Sciences*, called for, among other recommendations, increased funding to support more NRSA

¹National Science Foundation Division of Science Resource Statistics. (January 2010, chapter 3, pp.44–46). *Science and engineering indicators 2010*. Arlington, Virginia: National Science Board.

²National Science Foundation National Center for Science and Engineering Statistics (NCSES). (January 2012, chapter 3, p. 39). *Science and engineering indicators 2012*. Arlington, Virginia: National Science Board.

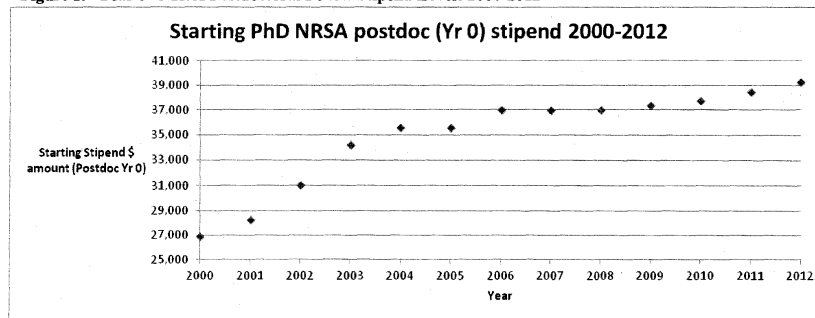
³Ibid.

⁴COSEPUP. (June 2001, p. 10). *Enhancing the postdoctoral experience for scientists and engineers*. Washington, DC: National Academy Press.

positions and to fulfill the NIH's 2001 commitment to increase pre-doctoral and postdoctoral stipends.

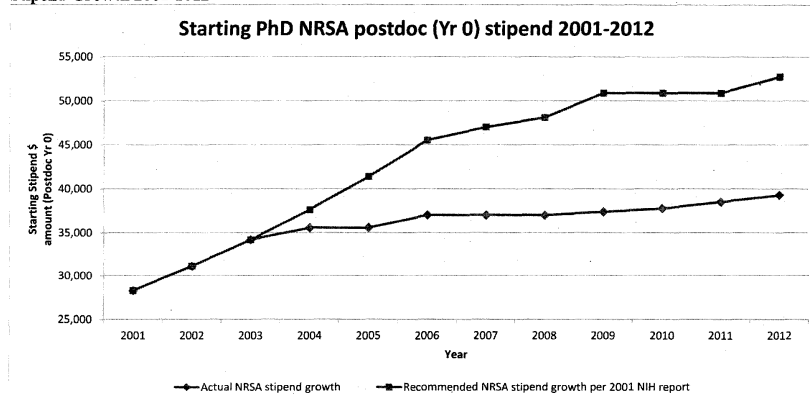
Without sufficient appropriations from the Congress, the NIH has not been able to fulfill its pledge. In 2007, the stipends were frozen at 2006 levels and since then have not been significantly increased. The stipends were increased by 1 percent each year in 2009 and 2010 and by 2 percent in 2011 and 2012. The 2012 entry-level training stipend remains low, at \$39,264, the equivalent of a GS-8 position, step 2 in the Federal Government in 2012⁵, despite the postdocs' advanced degrees and specialized technical skills and experience. Furthermore, this stipend remains far short of the promised \$45,000. Please see Figure 1 for a summary of the stipend amounts since 2000 and Figure 2 for a comparison of the actual stipend growth with the NIH recommended growth.

Figure 1. "Year 0" NRSA Postdoctoral Fellow Stipend Levels 2000-2012



Graph is based on data obtained from NIH Web site: <http://grants.nih.gov/training/nrsa.htm>

Figure 2. Comparison of the Actual "Year 0" NRSA Postdoctoral Fellow Stipend Growth with the Promised Stipend Growth 2001-2012⁶



⁶ Figure created by Lorraine Tracey, Ph.D., on behalf of the National Postdoctoral Association.

It is not only the NRSA fellows who remain undercompensated; the impact of the low stipends extends beyond the NRSA-supported postdocs. The NPA's research has strongly suggested that the NIH training stipends are used as a benchmark by research institutions across the country for establishing compensation for postdoctoral scholars.⁷ Thus, an unintended consequence is that institutions undercompensate all of their postdocs, who must then struggle to make ends meet, which in turn affects their productivity and undermines their efforts to solve the world's most critical

⁵ U.S. Office of Personnel Management Salary Tables 2012. <http://www.opm.gov/oca/12tables/html/gs.asp>.

⁷ Johnson Phillips, C. (April 2012). *National Postdoctoral Association Institutional Survey on Postdoctoral Compensation, Benefits, and Professional Development Opportunities: Highlights*. Washington, DC: National Postdoctoral Association.

problems. Additionally, the NPA is hearing from many postdocs, who say they are leaving their research careers behind because of the low compensation. In order to keep the “best and the brightest” scientists in the U.S. research enterprise, the NPA believes that it is crucial that the Congress appropriate funding for the 2-percent increase in training stipends, as a moderate yet substantial step toward reaching the recommended entry-level stipend of \$45,000.

Solution: Keep the NIH’s Original Promise to Raise the Minimum Stipends

We respectfully request that the Subcommittee appropriate funding of \$30.86 billion for the fiscal year 2013 NIH budget, which would in turn allow the NIH to appropriate \$775 million to training grants and implement a 2 percent NRSA stipend increase, as per the President’s proposed fiscal year 2013 budget:

—Support for the training mechanism would decline by 0.4 percent compared to fiscal year 2012. This reflects a 1.8 percent reduction in the number of trainees supported. Stipend rates, however, would increase at the same pace as for fiscal year 2012 at 2 percent, continuing a long-term strategy that NIH has used to try and keep stipend levels closer to salaries that could be earned in related occupations, to ensure that outstanding individuals continue to pursue biomedical research careers.”⁸

The NPA believes it is just and necessary to increase the compensation provided to these new scientists, who make significant contributions to the bulk of the research discovering cures for disease and developing new technologies to improve the quality of life for millions of people in the United States. Please do not hesitate to contact us for more information.

Thank you for your consideration.

PREPARED STATEMENT OF NATIONAL PUBLIC RADIO

Dear Chairman Harkin, Senator Shelby and Members of the Subcommittee: Thank you for this opportunity to urge the Subcommittee’s support for a Federal investment in America’s distinctive public broadcasting system. Public broadcasting’s continuing service to communities in every corner of America is dependent on a diversified revenue base, including Federal funding. For less money per American per year than a single cup of coffee, public broadcasting stations have become local community cornerstones that reflect local values and are built upon local control and local programming decisions. And this outstanding locally focused public service is widely supported by Americans from all walks of life.

As the President and CEO of NPR, I offer this testimony on behalf of the public radio system, a uniquely American public service, not-for-profit media enterprise that includes NPR, our more than 950 public radio station partners, other producers and distributors of public radio programming including American Public Media (APM), Public Radio International (PRI), the Public Radio Exchange (PRX), and many stations, both large and small, that create and distribute content through the Public Radio Satellite System (PRSS). With your continued support for an annual Federal appropriation of \$445 million to the Corporation for Public Broadcasting (CPB), every American will continue to have free access to the best in educational, news, information and cultural programming.

Funding provided by the Congress to the CPB supports the entire foundation of a system that has been one of America’s most successful models of a community-centric grant program. The revenue base provided by the Congress enables stations to raise \$6 for every Federal grant dollar. And for every \$1 that public radio stations invest in NPR programming, they are able to raise \$3 locally from audiences and local businesses. This enables local stations to invest more deeply in their own local news and cultural programming. The essential Federal investment enables the American public to receive an enduring and daily return on investment that is heard, seen, read and experienced in public radio broadcasts, apps, podcasts, and on online.

Public Radio: It’s All Local

Local is the cornerstone and watchword of public radio as stations connect with their communities and localize civil and civic discussions on reporting from across the street and around the world. Public radio stations are independently owned and operated, and are licensed to colleges, universities, community foundations, and other nonprofit organizations. Stations serve their local communities by determining

⁸Department of Health and Human Services National Institutes of Health. (pp. ES25–ES26). NIH Congressional Justification: Overview. http://officeofbudget.od.nih.gov/pdfs/FY13/FY2013_Overview.pdf.

their own schedules. They are managed locally by professionals who are accountable to community leaders and listeners who represent the diverse backgrounds of that community. Decisions about programming and services are made by people who live within the local community. That's the way it used to be throughout much of the broadcast industry, and we think it's the way it should be. Public radio stations set their own policies, make their own program decisions, and answer questions when their local listeners call or write. They respond to their listeners and respond to their needs because an actively engaged audience is public radio's calling card. Most of our system's revenue is audience-sensitive, coming either from individual local contributors or from local businesses and foundations that support the work of our stations.

Consider these recent statistics . . . Roughly 38 million Americans listen to public radio each week, more than the total combined circulation of the country's top 64 newspapers, including USA Today, The Wall Street Journal, and the New York Times. Additionally, some 20 million visitors a month find public radio's digital platforms, with some 30 million podcast downloads occurring each month. According to the Pew Research Center, NPR and public radio are the only news sources to see a meaningful increase in audience trust over the last 12 years.

As the country's largest nonprofit news organization, public radio is uniquely positioned to respond to the ever evolving nature of delivering news, music and cultural affairs programming. Our network of local public radio stations reaches diverse communities, from the largest urban areas to the smallest rural enclaves. Public radio programming is rooted in the fundamentals of accuracy, transparency, independence, balance, and fairness that foster understanding for millions of Americans seeking information, context and insight.

As a network of stations that produce local news and cultural programming and, with regional, national and international reporting capabilities that NPR, APM and others contribute, we are making a difference in the world beginning in each community you represent. On average, 44 percent of daily programming is locally produced by station staff, 28 percent is produced by NPR, and 28 percent comes from other public radio station producers and national distributors. Throughout the public radio station community, local and regional talk shows are mainstays of daily programming. Recent surveys show that the number of public radio stations carrying local news/talk programming rose from 595 to 681 stations, with hours aired each week increasing by more than 10 percent. On average, 1,400 programming segments produced by local public radio stations were included in programming distributed nationally by NPR.

Roughly 90 percent of stations produce local newscasts, airing both newscast and non-newscast content primarily in weekday drive time, especially morning drive-time. About half of all stations carry local news content during the weekends. Most stations—74 percent—are producing stories other than newscasts each week to insert into “Morning Edition” and “All Things Considered” locally; and, most news stations—88 percent—are producing and inserting stories, with a majority of these stations inserting five or more stories per week. Stations devote the most local news coverage and their reporters' specific beat assignments to State-local-politics, schools and education, arts and cultural events, and environmental, health, and business issues. News format stations provide added coverage on local politics, education, and business, whereas music stations focus on arts and cultural affairs events.

Public Radio: Music and Culture in Communities

Public radio also provides an important and growing contribution to America's music culture and America's music economy. Some 480 public radio stations offer a mixed news and music programming format, with another 180 stations engaged entirely in music. Every year, public radio stations host and broadcast more than 3,000 in-studio and community-based performances. And every year, public radio stations broadcast more than 4.8 million hours of music programming. More than a third of all public-radio listening is to music.

Classical, jazz, folk, independent, bluegrass, world and eclectic are music formats offered by public radio stations in cities large and small, and all are being eliminated as economically unsustainable in the commercial market. As a result, in dozens of communities nationwide, the local public radio station is the only free and universally available source of music from these genres. This preservation role is complemented by the important promotional role public radio stations play in music today. Local stations actively highlight in-studio performances by emerging artists and local music events spanning all music genres. Audiences increasingly are turning to their local public radio stations as trusted sources for information on new artists and events.

Public Radio: Information in Times of Crisis and Emergency

By ensuring that public radio is widely available throughout the country, Federal funding helps ensure that citizens have access to emergency and public safety information during national or local disasters. Public radio is a communications lifeline during times of emergencies, especially when the power grid is down. 98 percent of the U.S. population has access to a public radio signal. There are an estimated 800–900 million radios in the United States and more than 38 million people listen to public radio each week. Radio is the most effective medium for informing a community of weather forecasts, traffic issues, services available, evacuations, and other emergency conditions. Everyone has access to a radio; they are portable and battery operated. In Indian Country, radio stations provide essential life saving information in many Native communities that do not have available or effective 9–1–1 services and have limited or no telephone access or broadband (one-third have no telephone and less than 10 percent have Internet access).

The Federal Emergency Management Agency (FEMA) routinely advises the public to make sure that radios with batteries are on hand when major storms approach. When people are instructed to evacuate due to local crisis situations such as hurricanes, flooding, tornados, wildfires, ice storms, earthquakes and terrorist attacks, car radios become a primary instrument for receiving information about the emergency situation including evacuation routes and evacuation center locations. Effective emergency warnings allow people to take actions that save lives, reduce damage, and reduce human suffering.

Dedicated public radio personnel have worked and continued broadcasting through multiple crises such as the 9/11 attacks, Hurricanes Andrew, Hannah, Katrina, Rita and Gustav, blackouts, wildfires, ice storms, earthquakes and floods. During the 9/11 tragedy, WNYC 93.9 FM/820 AM served as a 24/7 lifeline to hundreds of thousands of people, while in the days that followed station personnel provided a calm and recognizable voice that helped survivors cope. The station kept reporting even while its FM transmitter located on the World Trade Center was destroyed in the first attack.

Public Radio: Service to Everyone

Many public radio stations also provide critical services to disabled Americans. Radio reading services in every major market in the United States provide millions of visually impaired persons the ability to function more independently in their communities. Our Nation's elderly and military veterans returning home injured or disabled from foreign combat duty depend on these broadcasts for their only access to current print-based news and information.

Everyone with a visual impairment, physical disability or learning disability has a right to equal access to all forms of information available to the general public. Audio information services provide access to printed information for individuals who cannot read conventional print because of blindness or any other visual, physical or learning disability. Many audio information services provide service to institutions as well as to individuals, such as hospital rooms, assisted living facilities, low vision clinics, senior centers and other institutional care facilities where qualified listeners may reside or frequent.

Public Radio: A Sound Investment

At a time when the Federal Government is running a large deficit, every program and function of the Government deserves to be scrutinized. A review of Federal funding to public broadcasting is fair and to be expected. But the truth remains that the Federal investment in the public radio and public broadcasting system provides one of the most effective returns of any program authorized by the Congress. For a modest Federal investment of just \$1.39 per person per year, the country is provided with exceptional journalism and culturally enriching programming that elevates the national dialogue and leads to a more informed citizenry.

In closing Chairman Harkin and Senator Shelby, I encourage you, members of the subcommittee and your staffs to visit and tour your local public radio stations to view first-hand how Federal dollars are at work locally serving your constituents.

 PREPARED STATEMENT OF THE NATIONAL PRIMATE RESEARCH CENTERS

The Directors of the eight National Primate Research Centers (NPRCs) respectfully submit this written testimony for the record to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies. The NPRCs appreciate the commitment that the Members of this Subcommittee have made to biomedical research through your support for the National Institutes

of Health (NIH) and recommend that you provide \$32 billion for NIH in fiscal year 2013, which represents a 4.2 percent increase above the fiscal year 2012 level. Within this proposed increase, the NPRCs also respectfully request that the Subcommittee provide strong support for the NIH Office of Research Infrastructure Programs (ORIP), housed within the NIH Office of the Director, which is the new administrative home of the NPRCs. This support would help to ensure that the NPRCs and other animal research resource programs continue to serve effectively in their role as a vital national resource.

The mission of the National Primate Research Centers is to use scientific discovery and nonhuman primate models to accelerate progress in understanding human diseases, leading to interventions, treatments, cures, and ultimately to overall better health of the Nation and the world. The NPRCs collaborate as a transformative and innovative network to develop and support the best science and act as a resource to the biomedical research community as efficiently as possible. There is an exceptional return on investment in the NPRC program; \$10 is leveraged for every \$1 of research support for the NPRCs. It is important to sustain funding for the NPRC program and the NIH as a whole and to continue to grow and develop the innovative plan for the future of NIH.

NPRCs' Contributions to NIH Priorities

The NPRCs' activities are closely aligned with NIH priorities. In fact, NPRC investigators conduct much of the Nation's basic and translational nonhuman primate research, facilitate additional vital nonhuman primate research that is conducted by hundreds of investigators from around the country, provide critical scientific expertise, train the next generation of scientists, and advance cutting-edge technologies.

The fiscal year 2013 NIH congressional justification underscores the vital role that the NPRCs play in NIH translational science efforts and the broader biomedical research enterprise. With the recent creation of the National Center for Advancing Translational Sciences (NCATS), the NPRCs see a great opportunity to further integrate the consortium as a trans-NIH resource on topics such as colony management, training, genetics and genome banking. The NPRC consortium will continue to engage as a resource for the Clinical and Translational Science Award (CTSA) network to help clinical researchers increase their knowledge of and access to nonhuman primates as animal models.

Outlined below are a few of the overarching goals and priorities for the NPRCs, including specifics of how the NPRCs are striving to achieve these through programs and activities across the centers.

Advance Translational Research Using Animal Models.—Nonhuman primate models bridge the divide between basic biomedical research and implementation in a clinical setting. Currently, seven of the eight NPRCs are affiliated and collaborate with an NIH CTSA program through their host institution. Specifically, the nonhuman primate models at the NPRCs often provide the critical translational link between research with small laboratory animals and studies involving humans. As the closest genetic model to humans, nonhuman primates serve in the process of developing new drugs, treatments, and vaccines to ensure safe and effective use for the Nation's public.

It is neither cost effective nor feasible to reproduce these specialized facilities and expertise at every research institution, so the NPRCs are a valuable resource to the research community. Major areas of research benefiting from the resources of the NPRCs include AIDS, avian flu, Alzheimer's disease, Parkinson's disease, autism, cardiovascular disease, diabetes, obesity, asthma, and endometriosis. To facilitate these and other studies, the NPRC have developed a resource of more than 26,000 nonhuman primates, 70 percent of which are rhesus monkeys, the most widely used nonhuman primate for HIV research and a wide range of translational studies.

Strengthen the Research Workforce.—The success of the Federal Government's efforts in enhancing public health is contingent upon the quality of research resources that enable scientific research ranging from the most basic and fundamental to the most highly applied. Biomedical researchers have relied on one such resource—the NPRCs—for nearly 50 years for research models and expertise with nonhuman primates. The NPRCs are highly specialized facilities that foster the development of nonhuman primate animal models and provide expertise in all aspects of nonhuman primate biology. NPRC facilities and resources are currently used by more than 2,000 NIH funded investigators around the country.

The NPRCs are also supportive of students interested in the biomedical research at an early age. For example, the Yerkes NPRC supports a program that connects with local high schools and colleges in Atlanta, Georgia, and provides high school science students and teachers with summer-long internships to participate in re-

search projects taking place at their center. Other NPRCs have similar programs that help develop a pipeline of aspiring science students and teachers.

Offer Technologies to Advance Translational Research and Expand Informatics Approaches to Support Research.—The NPRCs have been leading the development of a new Biomedical Informatics Research Network (BIRN) for linking brain imaging, behavior, and molecular informatics in nonhuman primate preclinical models of neurodegenerative diseases. Using the cyberinfrastructure of BIRN for data-sharing, this project will link research and information to other primate centers, as well as other geographically-distributed research groups.

The Need for Facilities Support

The NPRC program is a vital resource for enhancing public health and spurring innovative discovery. In an effort to address many of the concerns within the scientific community regarding the need for funding for infrastructure improvements, the NPRCs support the continuation of a robust construction and instrumentation grant program at NIH.

Animal facilities, especially primate facilities, are expensive to maintain and are subject to abundant “wear and tear.” In prior years, funding was set aside that fulfilled the infrastructure needs of the NPRCs and other animal research facilities. The NPRCs are dependent on strong support for the P51 base grant program which is essential for the operational costs, and the C06 and G20 programs which support construction and renovation of animal facilities. Without proper infrastructure, the ability for animal research facilities, including the NPRCs, to continue to meet the high demand of the biomedical research community will be unsustainable.

Thank you for the opportunity to submit this written testimony and for your attention to the critical need for primate research and the continuation of infrastructure support. We thank you for your support of NIH and urge you to provide \$32 billion for the agency in the fiscal year 2013 appropriations bill.

PREPARED STATEMENT OF THE NATIONAL RESPITE COALITION

Mr. Chairman, I am Jill Kagan, Chair of the National Respite Coalition (NRC), a network of respite providers, family caregivers, national, State and local agencies and organizations who support respite. Thirty State respite coalitions are also affiliated with the NRC. This statement is presented on behalf of these organizations. The NRC also facilitates the Lifespan Respite Task Force, a coalition of more than 200 national, State and local groups who support the Lifespan Respite Program and its continued funding. We are requesting that the Subcommittee include \$5 million for the Lifespan Respite Care Program administered by the U.S. Administration on Aging in the fiscal year 2013 Labor, HHS, and Education appropriations bill. Given the serious fiscal constraints facing the Nation, this request is only one-tenth of the request the NRC made last year. This will enable:

- State replication of best practices in Lifespan Respite to allow all family caregivers, regardless of the care recipient’s age or disability, to have access to affordable respite, and to be able to continue to play the significant role in long-term care that they are fulfilling today;
- Improvement in the quality of respite services currently available;
- Expansion of respite capacity to serve more families by building new and enhancing current respite options, including recruitment and training of respite workers and volunteers; and
- Greater consumer direction by providing family caregivers with training and information on how to find, use and pay for respite services.

WHO NEEDS RESPITE?

In 2009, about 61.6 million family caregivers provided care at some time during the year. The estimated economic value of their unpaid contributions was approximately \$450 billion, up from an estimated \$375 billion in 2007. This amount is more than total 2009 Medicaid spending, including both Federal and State contributions for healthcare and long-term services and supports (\$361 billion). Including caregiving for children with special needs in the total would add at least 4 to 8 million additional caregivers and another \$50 to \$100 billion to the economic value of family caregiving (Feinberg, L.; Reinhard, S., et al, Valuing the Invaluable: 2011 Update, The Growing Contributions and Costs of Family Caregiving, AARP Public Policy Institute, 2011).

Family caregiving is not just an aging issue, but a lifespan one. While the aging population is growing rapidly, the majority of family caregivers are caring for someone under age 75 (56 percent); 28 percent of family caregivers care for someone be-

tween the ages of 50–75, and 28 percent care for someone under age 50 (NAC and AARP, 2009). Many family caregivers are in the sandwich generation—46 percent of women who are caregivers of an aging family member and 40 percent of men also have children under the age of 18 at home (Aumann, Kerstin and Ellen Galinsky, et al. 2008). And 6.7 million children, are in the primary custody of an aging grandparent or other relative.

Families of the wounded warriors, military personnel who returned from Iraq and Afghanistan with traumatic brain injuries and other serious chronic and debilitating conditions, don't have full access to respite. Even with enactment of the new VA Family Caregiver Support Program, the need for respite will remain high for all veterans and their family caregivers. Among family caregivers of veterans whose illness, injury or condition is in some way related to military service surveyed in 2010, only 15 percent had received respite services from the VA or other community organization within the past 12 months. Caregivers whose veterans have PTSD are only about half as likely as other caregivers to have received respite (11 percent vs. 20 percent) (NAC, *Caregivers Of Veterans—Serving On The Homefront*, November 2010). Sixty-eight percent of veterans' caregivers reported their situation as highly stressful compared to 31 percent of caregivers nationally, and three times as many say there is a high degree of physical strain (40 percent vs. 14 percent) (NAC, 2010). Veterans' caregivers specifically asked for up-to-date lists of respite providers in their communities and help to find services, the very thing Lifespan Respite is charged to provide (NAC, 2010).

National, State and local surveys have shown respite to be the most frequently requested service of the Nation's family caregivers (The Arc, 2011; National Family Caregivers Association, 2011). Other than financial assistance for caregiving through direct vouchers payments or tax credits, respite is the number one national policy related to service delivery that family caregivers prefer (NAC and AARP, 2009). Yet respite is unused, in short supply, inaccessible, or unaffordable to a majority of the Nation's family caregivers. The NAC 2009 survey found that despite the fact that among the most frequently reported unmet needs of family caregivers were "finding time for myself" (32 percent), "managing emotional and physical stress" (34 percent), and "balancing work and family responsibilities" (27 percent), nearly 90 percent of family caregivers across the lifespan are not receiving respite services at all.

An estimated 80 percent of all long-term care in the United States is provided at home. This percentage will only rise in the coming decades with greater life expectancies of individuals with disabling and chronic conditions living with their aging parents or other caregivers, the aging of the baby boom generation, and the decline in the percentage of the frail elderly who are entering nursing homes.

RESPIRE BARRIERS AND THE EFFECT ON FAMILY CAREGIVERS

Barriers to accessing respite include reluctance to ask for help, fragmented and narrowly targeted services, cost, and the lack of information about respite or how to find or choose a provider. Even when respite is an allowable funded service, a critically short supply of well-trained respite providers may prohibit a family from making use of a service they so desperately need. Lifespan Respite is designed to help States eliminate these barriers through improved coordination and capacity building.

While most families take great joy in helping their family members to live at home, it has been well documented that family caregivers experience physical and emotional problems directly related to their caregiving responsibilities. In a 2009 survey of family caregivers, a majority (51 percent) who are caring for someone over age 18 have medium or high levels of burden of care, measured by the number of activities of daily living with which they provide assistance, and 31 percent were identified as "highly stressed" (NAC and AARP, 2009). While family caregivers of children with special healthcare needs are younger than caregivers of adults, they give lower ratings to their health. Caregivers of children are twice as likely as the general adult population to say they are in fair/poor health (26 percent vs 13 percent) (Provisional summary Health Statistics for U.S. Adults, National Health Interview Survey, 2008, dated August 2009).

The decline of family caregiver health is one of the major risk factors for institutionalization of a care recipient, and there is evidence that care recipients whose caregivers lack effective coping styles or have problems with depression are at risk for falling, developing preventable secondary complications such as pressure sores and experiencing declines in functional abilities (Elliott & Pezent, 2008). Care recipients may also be at risk for encountering abuse from caregivers when the recipients have pronounced need for assistance and when caregivers have pronounced lev-

els of depression, ill health, and distress (Beach et al., 2005; Williamson et al., 2001).

Supports that would ease family caregiver stress, most importantly respite, are too often out of reach or completely unavailable. Restrictive eligibility criteria also preclude many families from receiving services or continuing to receive services for which they once were eligible. Children with disabilities will age out of the system when they turn 21 and they will lose many of the services, such as respite. A recent survey of nearly 5,000 caregivers of individuals with intellectual and developmental disabilities (I/DD) conducted by The Arc found: the vast majority of caregivers report that they are suffering from physical fatigue (88 percent), emotional stress (81 percent) and emotional upset or guilt (81 percent) some or most of the time; 1 out of 5 families (20 percent) report that someone in the family had to quit their job to stay home and support the needs of their family member; and more than 75 percent of family caregivers caring for adult children with developmental disabilities could not find respite services (The Arc, 2011). Respite may not exist at all in some States for individuals with Alzheimer's, those under age 60 with conditions such as ALS, MS, spinal cord or traumatic brain injuries, or children with serious emotional conditions.

RESPITE BENEFITS FAMILIES AND IS COST SAVING

Respite has been shown to be an effective way to reduce stress and improve the health and well-being of family caregivers that in turn helps avoid or delay out-of-home placements, such as nursing homes or foster care, minimizes the precursors that can lead to abuse and neglect, and strengthens marriages and family stability. A U.S. Department of Health and Human Services report prepared by the Urban Institute found that higher caregiver stress among those caring for the aging increases the likelihood of nursing home entry. Reducing key stresses on caregivers, such as physical strain and financial hardship, through services such as respite would reduce nursing home entry (Spillman and Long, USDHHS, 2007). The budgetary benefits that accrue because of respite are just as compelling. Delaying a nursing home placement for just one individual with Alzheimer's or other chronic condition for several months can save thousands of dollars. Researchers at the University of Pennsylvania studied the records of more than 28,000 children with autism ages 5 to 21 who were enrolled in Medicaid in 2004. They concluded that for every \$1,000 States spent on respite services in the previous 60 days, there was an 8 percent drop in the odds of hospitalization (Mandell, David S., et al, 2012). In an Iowa survey of parents of children with disabilities, a significant relationship was demonstrated between the severity of a child's disability and their parents missing more work hours than other employees. It was also found that the lack of available respite appeared to interfere with parents accepting job opportunities. (Abelson, A.G., 1999)

In the private sector, the Metropolitan Life Insurance Company and the National Alliance for Caregivers found that U.S. businesses lose from \$17.1 billion to \$33.6 billion per year in lost productivity of family caregivers. (MetLife and National Alliance for Caregiving, 2006). Another study from the National Alliance on Caregiving and Evercare demonstrated that the economic downturn has had a particularly harsh effect on family caregivers. Of the 6 in 10 caregivers who are employed, 50 percent of them are less comfortable during the economic downturn with taking time off from work to care for a family member or friend. A similar percentage (51 percent) says the economic downturn has increased the amount of stress they feel about being able to care for their relative or friend. Respite for working family caregivers could help improve job performance and employers could potentially save billions.

LIFESPAN RESPITE CARE PROGRAM WILL HELP

The Lifespan Respite Care Program is based on the success of statewide Lifespan Respite programs in Oregon, Nebraska, Wisconsin and Oklahoma. The Federal Lifespan Respite program is administered by the U.S. Administration on Aging, Department of Health and Human Services (HHS). AoA provides competitive grants to State agencies in concert with Aging and Disability Resource Centers working in collaboration with State respite coalitions or other State respite organizations. The program was authorized at \$53.3 million in fiscal year 2009 rising to \$95 million in fiscal year 2011. Congress appropriated \$2.5 million in fiscal year 2009-2012. Since 2009, 30 States have received 3-year \$200,000 Lifespan Respite Grants from AoA since 2009. Last year, seven States and the District of Columbia received one-time \$150,000 expansion grants to focus on direct services, especially for those who are currently unserved.

The purpose of the law is to expand and enhance respite services, improve coordination, and improve respite access and quality. States are required to establish State and local coordinated Lifespan Respite care systems to serve families regardless of age or special need, provide new planned and emergency respite services, train and recruit respite workers and volunteers and assist caregivers in gaining access to services. Those eligible would include family members, foster parents or other adults providing unpaid care to adults who require care to meet basic needs or prevent injury and to children who require care beyond that required by children generally to meet basic needs.

Lifespan Respite, defined as a coordinated system of community-based respite services, helps States use limited resources across age and disability groups more effectively. Provider pools can be recruited, trained and shared, administrative burdens reduced by coordinating resources, and savings used to fund new respite services for families who do not qualify for any Federal or State program. The Government Accountability Office summarized the innovative activities undertaken by the first 24 States to implement Lifespan Respite Systems in its report to the Congress, Respite Care: Grants and Cooperative Agreements Awarded to Implement the Lifespan Respite Care Act. GAO-11-28R, Oct. 22, 2010.

HOW IS LIFESPAN RESPITE PROGRAM MAKING A DIFFERENCE?

With limited funds, Lifespan Respite grantees are engaged in innovative activities such as:

- In Tennessee and Rhode Island, the Lifespan Respite program is building respite capacity by expanding volunteer networks of providers by recruiting University students or Senior Corps volunteers or expanding the national TimeBanks model for establishing voluntary family cooperative respite strategies.
- In Texas, the Lifespan Respite program has established a statewide Respite Coordination Center, and an online database.
- In North Carolina, South Carolina, and Alabama, the State respite coalition and the Lifespan Respite programs are partnering in new ways with the untapped faith community to provide respite, especially in rural areas.
- The North Carolina Lifespan Respite Program has challenged each of its 100 counties to come up with a strategy, no matter how great or how small, to improve respite service delivery locally.
- In New Hampshire, new providers have been recruited and trained through partnerships with the New Hampshire National Alliance on Mental Illness, New Hampshire Family Voices, and the College of Direct Support with funding from the Department of Labor to expand the pool of respite providers to work with teens and older individuals with mental health conditions or other groups where respite is in short supply.
- In Illinois and Arizona, State grantees and their partners are working with child and adult protective services to ensure respite is available on an emergency basis for the most vulnerable families.

Across the board, States are building respite registries and “no wrong door systems” in collaboration with State respite coalitions and Aging and Disability Resource Centers to help family caregivers access respite and funding sources. Oklahoma, Alabama, Nevada, Tennessee and others are using Lifespan Respite grants to expand or implement participant-directed respite through coordinated voucher systems so that family caregivers have greater control over the type and quality of the respite they select. All State grantees secure commitments from partnering State agencies to share information and coordinate resources to build a seamless Lifespan Respite system for accessing respite.

Even with these State efforts, current funding is wholly inadequate. Close to 90 percent of the Nation’s family caregivers still are not receiving respite. More than half of them are caring for someone under age 75 with early Alzheimer’s, MS, ALS, traumatic brain or spinal cord injury, mental health conditions, developmental disabilities or cancer. The goal of Lifespan Respite System is to coordinate respite services and funding, maximize existing resources and leverage new dollars in both the public and private sectors to build respite capacity and serve the unserved; \$5 million in fiscal year 2013 could allow new States to start Lifespan Respite Programs and ensure that the 2010–2012 grantees be able to complete the work that they have started. As it is, given the inadequate funding for fiscal year 2012, only up to 5 of the original 12 2009 grantees will be funded again before they have had a chance to make a lasting impact.

No other Federal program mandates respite as its sole focus. No other Federal program would help ensure respite quality or choice, and no current Federal pro-

gram allows funds for respite start-up, training or coordination or to address basic accessibility and affordability issues for families. We urge you to include at least \$5 million in the fiscal year 2013 Labor, HHS, Education appropriations bill so that Lifespan Respite Programs can be replicated and sustained in the States and more families, with access to respite, will be able to continue to play the significant role that they are fulfilling today.

PREPARED STATEMENT OF THE NATIONAL TECHNICAL INSTITUTE FOR THE DEAF AND
ROCHESTER INSTITUTE OF TECHNOLOGY

Mr. Chairman and members of the subcommittee: I am pleased to present the fiscal year 2013 budget request for NTID, one of nine colleges of RIT, in Rochester, New York. Created by the Congress by Public Law 89-36 in 1965, we provide university technical and professional education for students who are deaf and hard-of-hearing, leading to successful careers in high-demand fields for a sub-population of individuals historically facing high rates of unemployment and under-employment. We also provide baccalaureate and graduate level education for hearing students in professions serving deaf and hard-of-hearing individuals. NTID students live, study and socialize with more than 15,000 hearing students on the RIT campus.

Budget Request

On behalf of NTID, for fiscal year 2013 I would like to request \$70,577,000, of which \$68,577,000 would be for Operations and \$2,000,000 for Construction. This funding is necessary to allow us to continue to support record levels of enrollment, respond to increased demand for access services, and address strategic initiatives. Construction funds will be used for major renovations to a building designed more than 30 years ago that houses two major NTID programs.

I make this request within the context of definitive actions taken by NTID to recognize the difficult economic times in which we operate. In fiscal year 2012, NTID operated with essentially the same level of Federal support as in fiscal year 2011. We accomplished this through the sound management of resources that were available as well as reducing 3 percent of our headcount. We have continued to increase tuition and fees, as these are our primary sources of non-Federal support. Over the past 6 years, tuition and fees have increased by 40 percent. These non-Federal revenues now represent 27 percent of our operating budget—up from 9 percent in 1970.

Enrollment

In fiscal year 2012 (Fall 2011), we attracted the largest enrollment in our history—1,547 students. Truly a national program, NTID has enrolled students from all 50 States. Over the last 6 years, our enrollment has increased 24 percent (297 students). By granting this request for fiscal year 2013, NTID will be able to serve this record high enrollment level. Our enrollment history over the last 6 years is shown below:

NTID ENROLLMENTS: SIX-YEAR HISTORY

Fiscal Year	Deaf/Hard-of-Hearing Students				Hearing Students			Grand Total
	Undergrad	Grad RIT	MSSE	Subtotal	Interpreting Program	MSSE	Subtotal	
2007	1,017	47	31	1,095	130	25	155	1,250
2008	1,103	51	31	1,185	130	28	158	1,343
2009	1,212	48	24	1,284	135	31	166	1,450
2010	1,237	38	32	1,307	138	29	167	1,474
2011	1,263	40	29	1,332	147	42	189	1,521
2012	1,281	42	31	1,354	160	33	193	1,547

NTID Academic Programs

NTID offers high quality, career-focused associate degree programs preparing students for specific well-paying technical careers. NTID also is expanding the number of its transfer associate degree programs, currently numbering seven, to better serve the higher achieving segment of our student population seeking bachelor's and master's degrees in an increasingly demanding marketplace. These transfer programs provide seamless transition to baccalaureate studies in the other colleges of RIT. In support of those deaf and hard-of-hearing students enrolled in the other RIT colleges, NTID provides a range of access services (including interpreting, real-time speech-to-text captioning, and note-taking) as well as tutoring services. One of

NTID's greatest strength is our outstanding track record of assisting high-potential students to gain admission to, and graduate from, the other colleges of RIT at rates comparable to their hearing peers.

A cooperative education (co-op) component is an integral part of academic programming at NTID and prepares students for success in the job market. A co-op gives students the opportunity to experience a real-life job situation and focus their career choice. Students develop technical skills and enhance vital personal skills such as teamwork and communication, which will make them better candidates for full-time employment after graduation. More than 250 students each year participate in 10-week co-op experiences that augment their academic studies, refine their social skills, and prepare them for the competitive working world.

Student Accomplishments

For our graduates, over the past 5 years, an average of 92 percent have been placed in jobs commensurate with the level of their education. Of our fiscal year 2010 graduates (the most recent class for which numbers are available), 57 percent were employed in business and industry, 27 percent in education/nonprofits, and 16 percent in government.

Graduation from NTID has a demonstrably positive effect on students' earnings over a lifetime, and results in a noteworthy reduction in dependence on Supplemental Security Income (SSI), Social Security Disability Insurance (SSDI) and public assistance programs. In fiscal year 2007, NTID, the Social Security Administration, and Cornell University examined approximately 13,000 deaf and hard-of-hearing individuals who applied and attended NTID over our entire history. The studies show that NTID graduates over their lifetimes are employed at a much higher rate, earn substantially more (therefore paying significantly more in taxes), and participate at a much lower rate in SSI, SSDI, and public assistance programs than those who withdraw or who apply but do not attend NTID. Considering the reduced dependency on these Federal income support programs, the Federal investment in NTID not only makes a positive difference in individual earnings, but also returns significant societal dividends.

Access Services

NTID provides an access services system to meet the needs of a large number of deaf and hard-of-hearing students enrolled in baccalaureate and graduate degree programs in RIT's other colleges as well as students enrolled in NTID programs who take courses in the other colleges of RIT. Access services also are provided for events and activities throughout the RIT community. Access services include sign language interpreting, real-time captioning, classroom notetaking services, captioned classroom video materials, and Assistive Listening Services.

As enrollments have steadily increased, so has the demand for access services. In fiscal year 2011, 131,065 hours of interpreting were provided—an increase of 18 percent compared to fiscal year 2007. In fiscal year 2011, 21,493 hours of real-time captioning were provided to students—a 39 percent increase over fiscal year 2007. The increase in demand is partly a result of the increase in the number of students enrolled in baccalaureate programs at RIT and the number of students with cochlear implants. In fiscal year 2012, there were 515 deaf and hard-of-hearing students enrolled in baccalaureate programs at RIT—a 17 percent increase compared to fiscal year 2007. In fiscal year 2012, there were 331 students with cochlear implants—a 56 percent increase over fiscal year 2007. We will be able to address this growing demand with our fiscal year 2013 funding request.

Strategic Decisions 2020

In 2010, NTID completed Strategic Decisions 2020, a strategic plan based on our founding mission statement. This statement sets forth our institutional responsibility to work with students to develop their academic, career and life-long learning skills as future contributors in a rapidly changing world. It also recognizes our role as a special resource for preparing individuals who are deaf and hard-of-hearing, for conducting applied research in areas critical to the advancement of individuals who are deaf and hard-of-hearing, and for disseminating our collective and cumulative expertise.

Strategic Decisions 2020 establishes key initiatives responding to future challenges and shaping future opportunities. These initiatives, which began implementation in fiscal year 2011, include:

- Pursuing enrollment targets and admissions and programming strategies that will result in increasing numbers of our graduates achieving baccalaureate degrees and higher, while maintaining focus and commitment to quality associate-level degree programs leading directly to the workplace;

- Improving services to under-prepared students through working with regional partners to implement intensive summer academic preparation programs in selected high-growth, ethnically diverse areas of the country;
- Expanding NTID's role as a National Resource Center of Excellence regarding the education of deaf and hard-of-hearing students in senior high school (grades 10, 11 and 12) and at the postsecondary level; and
- Enhancing efforts to become a recognized national leader in the exploration, adaptation, testing, and implementation of new technologies to enhance access to, and support of, learning by deaf and hard-of-hearing individuals.

Construction Needs

On behalf of NTID, I am requesting \$2,000,000 for Construction to begin critical and long-overdue renovations to a 30-year-old building that houses 2 major programs and one-third of the NTID workforce. The original building design provided office space for approximately 98 access service staff members. Today, there are 200 staff housed in the building. The academic program in Information and Computing Studies has been unable to keep their teaching laboratories, originally designed in 1981, up to date in terms of functionality and accessibility (including ADA compliance). Failure to renovate this building will materially impact students' educational opportunities as well as the ability to provide them with quality access services. NTID is focused only on renovations that are absolutely necessary to maintain educational quality. For the past 2 fiscal years, most or all of NTID's Construction request has been diverted to Operations.

Summary

It is extremely important that our fiscal year 2013 funding request be granted in order that we might continue our mission to prepare deaf and hard-of-hearing people to enter the workplace and society. Our alumni have demonstrated that they can achieve independence, contribute to society, and find sustainable employment as a result of NTID.

We are hopeful that the members of the subcommittee will agree that NTID, with its long history of successful stewardship of Federal funds and outstanding educational record of service with people who are deaf and hard-of-hearing, remains deserving of your support and confidence. Likewise, we will continue to demonstrate to the Congress and the American people that NTID is a proven economic investment in the future of young deaf and hard-of-hearing citizens. Quite simply, NTID is a Federal program that works.

PREPARED STATEMENT OF THE POPULATION ASSOCIATION OF AMERICA/ASSOCIATION OF POPULATION CENTERS

Introduction

Thank you, Chairman Harkin, Ranking Member Shelby, and other distinguished members of the Subcommittee, for this opportunity to express support for the National Institutes of Health (NIH), the National Center for Health Statistics (NCHS), and Bureau of Labor Statistics (BLS).

Background on the PAA/APC and Demographic Research

The Population Association of America (PAA) (www.populationassociation.org) is a scientific organization comprised of more than 3,000 population research professionals, including demographers, sociologists, statisticians, and economists. The Association of Population Centers (APC) (www.popcenters.org) is a similar organization comprised of more than 40 universities and research groups that foster collaborative demographic research and data sharing, translate basic population research for policymakers, and provide educational and training opportunities in population studies. Population research centers are located at public and private research institutions nationwide.

Demography is the study of populations and how or why they change. Demographers, as well as other population researchers, collect and analyze data on trends in births, deaths, and disabilities as well as racial, ethnic, and socioeconomic changes in populations. Major policy issues population researchers are studying include the demographic causes and consequences of population aging, trends in fertility, marriage, and divorce and their effects on the health and well-being of children, and immigration and migration and how changes in these patterns affect the ethnic and cultural diversity of our population and the Nation's health and environment.

The NIH mission is to support biomedical, social, and behavioral research that will improve the health of our population. The health of our population is fundamen-

tally intertwined with the demography of our population. Recognizing the connection between health and demography, the NIH supports extramural population research programs primarily through the National Institute on Aging (NIA) and the National Institute of Child Health and Human Development (NICHD).

National Institute on Aging

According to the U.S. Census Bureau, the number of people age 65 and older will more than double between 2010 and 2050 to 88.5 million or 20 percent of the population; and those 85 and older will increase three-fold, to 19 million. The substantial growth in the older population is driving policymakers to consider dramatic changes in Federal entitlement programs, such as Medicare and Social Security, and other budgetary changes that could affect programs serving the elderly. To inform this debate, policymakers need objective, reliable data about the antecedents and impact of changing social, demographic, economic, health and well being characteristics of the older population. The NIA Division of Behavioral and Social Research (BSR) is the primary source of Federal support for basic research on these topics.

In addition to supporting an impressive research portfolio, that includes the prestigious Centers of Demography of Aging, the Roybal Centers for Translational Research on Aging, and the Research Centers for Minority Aging, the NIA BSR program also supports several large, accessible data surveys. These surveys include a new study, the National Health and Aging Trends Study (NHATS) will soon start providing detailed and nationally representative information on older people (and their informal caregivers) with disabilities. Another survey, the Health and Retirement Study (HRS), has become one of the seminal sources of information to assess the health and socioeconomic status of older people in the United States. Since 1992, the HRS has tracked 27,000 people, providing data on a number of issues, including the role families play in the provision of resources to needy elderly and the economic and health consequences of a spouse's death. HRS is particularly valuable because its longitudinal design allows researchers to study immediately the impact of important policy changes such as Medicare Part D and the opportunity to gain insight into emerging health-related policy issues, such as HRS data indicating an increase in pre-retirees self-reported rates of disability. It is so respected that the study is being replicated in 30 other countries, providing important data on how the United States compares with other countries whose populations are aging more rapidly. In March 2012, HRS took an important step forward by announcing that genetic data from approximately 13,000 individuals were posted to dbGAP, the NIH's online genetics database. The data are comprised of approximately 2.5 million genetic markers from each person and are now available for analysis by qualified researchers. These data will enhance the ability of researchers to track the onset and progression of diseases and conditions affecting the elderly.

Despite its ability to support important research projects and programs, the NIA faces unique funding challenges. While the current dollars appropriated to NIA seem to have risen significantly since fiscal year 2003, when adjusted for inflation, they have decreased almost 18 percent in the last 9 years. Further, according to the NIH Almanac, out of each dollar appropriated to NIH, only 3.6 cents goes toward supporting the work of the NIA-compared to 16.5 cents to the National Cancer Institute, 14.6 cents to the National Institute of Allergy and Infectious Diseases, 10 cents to the National Heart, Lung, and Blood Institute, and 6.3 cents to the National Institute of Diabetes and Digestive and Kidney Diseases. Finally, despite enacting cost cutting measures, such as differing paylines for projects costing above and below \$500,000 and a decrease in non-competing commitments, NIA's success rates remained below the NIH average in 2011.

As research costs increase, NIA faces the prospect of funding fewer grants to sustain larger ones in its commitment base. With additional support in fiscal year 2013, the NIA BSR program could fully fund its large-scale projects, including the existing centers programs and ongoing surveys, without resorting to cost cutting measures, such as cutting sample size, while continuing to support smaller investigator initiated projects. PAA and APC support providing a funding level recommended by the Friends of the National Institute on Aging and the Leadership Conference on Aging coalitions to provide NIA with a \$300 million increase in fiscal year 2013, bringing NIA to \$1.4 billion.

Eunice Kennedy Shriver National Institute on Child Health and Human Development

Since its establishment in 1968, the Eunice Kennedy Shriver NICHD Center for Population Research has supported research on population processes and change. Today, this research is housed in the Center's Demographic and Behavioral Sciences Branch (DBSB). DBSB supports research in three broad areas: demography, HIV/

AIDs, other sexually transmitted diseases, and other reproductive health; and population health, with focus on early life influences and policy.

DBSB is the major supporter of the national studies that track the health and well-being of children and their families from childhood through adulthood. These studies include Fragile Families and Child Well Being, the first scientific study to track the health and development of children born to unmarried parents; the National Longitudinal Study of Youth, a multigenerational of health and development; and the National Longitudinal Study of Adolescent Health (Add Health), tracing the effects of childhood and adolescent exposures on later health. DBSB supports the prompt and widespread release of demographic data collected with NIH and other Federal Government funding through the Demographic Data Sharing and Archiving project.

One of the most important programs the NICHD DBSB supports is the Research Infrastructure for Demographic and Behavioral Population Science (DBPop). This program promotes innovation, supports interdisciplinary research, translates scientific findings into practice, and develops the next generation of population scientists, while at the same time providing incentives to reduce the costs and increase the efficiency of research by streamlining and consolidating research infrastructure within and across research institutions. DBPop supports research at 24 private and public research institutions nationwide, the focal points for the demographic research field for innovative research and training and the development and dissemination of widely used large-scale databases.

NIH-funded demographic research provides critical scientific knowledge on issues of greatest consequence for American families: marriage and childbearing, childcare, work-family conflicts, and family and household behavior. Demographic research is having a large impact in public health, particularly on issues such as infant and child health and development, and adolescent and young adult health, and health disparities. Research supported by DBSB has revealed the critical role of marriage and stable families in ensuring that children grow up healthy, achieving developmental and educational milestones. DBSB supported projects provides policymakers and communities with evidence-based knowledge on the critical intervention points and effective interventions to promote health. An example is a new finding from DBSB supported research on low birth weight, a condition associated with higher risk of a number of serious medical complications and learning disabilities for children. Based on an analysis of more than 5 million medical records, researchers found that pregnant women assaulted by an intimate partner are at increased risk of giving birth to infants at lower birth weights. This finding was adopted by the American College of Obstetricians and Gynecologists to develop physician training materials for screening patients for intimate partner violence.

With additional support in fiscal year 2013, NICHD could sustain full funding to its large-scale surveys, which serve as a resource for researchers nationwide. Furthermore, the Institute could apply additional resources toward improving its funding payline, which is one of the lowest of the NIH Institutes and Centers. Additional support could be used to support and stabilize essential training and career development programs necessary to prepare the next generation of researchers and to support and expand proven programs, such as DBPop. For these reasons, PAA and APC endorse the funding level recommended by the Friends of the NICHD to fund the Institute at \$1.37 billion in fiscal year 2013.

National Children's Study

The PAA and APC are concerned about language included in the President's fiscal year 2013 proposed budget regarding the National Children's Study (NCS). Specifically, our organizations are troubled that in its budget, NIH suggested abandoning its previous commitment to a national probability sample because the study's recruitment goals have fallen short and because cost containment remains a priority. Our organizations have written to the NIH, urging them to work with experts in probability sampling and to conduct research to evaluate the feasibility and scientific value of any new sampling strategy—particularly as it potentially affects the inclusion of vulnerable, hard-to-reach populations, such as the children of legal and illegal immigrants. We also encourage the agency to contract with an independent scientific agency, such as the National Academy of Sciences, to assess any new proposed study designs. Given the magnitude of the study's scope, cost, and potential value to the scientific research community in particular, PAA and APC believe the agency should proceed cautiously before dramatic changes are made to this consequential, national study.

National Center for Health Statistics

Located within the Centers for Disease Control (CDC), the National Center for Health Statistics (NCHS) is the Nation's principal health statistics agency, providing data on the health of the U.S. population and backing essential data collection activities. Most notably, NCHS funds and manages the National Vital Statistics System, which contracts with the States to collect birth and death certificate information. NCHS also funds a number of complex large surveys to help policymakers, public health officials, and researchers understand the population's health, influences on health, and health outcomes. These surveys include the National Health and Nutrition Examination Survey (NHANES), National Health Interview Survey (HIS), and National Survey of Family Growth. Together, NCHS programs provide credible data necessary to answer basic questions about the state of our Nation's health.

Despite recent steady funding increases, NCHS continues to feel the effects of long-term funding shortfalls, compelling the agency to undermine, eliminate, or further postpone the collection of vital health data. For example, in 2009, sample sizes in HIS and NHANES were cut, while other surveys, most notably the National Hospital Discharge Survey, were not fielded. In 2009, NCHS proposed purchasing only "core items" of vital birth and death statistics from the States (starting in 2010), effectively eliminating three-fourths of data routinely used to monitor maternal and infant health and contributing causes of death. Fortunately, the Congress and the new administration worked together to give NCHS adequate resources and avert implementation of these draconian measures. Also, funding from the Prevention and Public Health Fund has been an invaluable source of support for the agency in fiscal year 2011 and fiscal year 2012, providing much needed funding to, for example, add components to NHANES and the National Hospital Ambulatory Medical Care Survey to assess physical activity in children and gather information on patients with heart disease and stroke, respectively. Despite the recent infusion of vital funding, the agency's long-term fiscal stability remains unstable.

PAA and APC, as members of The Friends of NCHS, support the administration's request for fiscal year 2013, \$162 million, a \$23 million (17 percent) increase over the agency's fiscal year 2012 appropriation. This funding increase will fully support NCHS's ongoing seminal surveys, enable the purchase of vital statistics data for 12 months within the calendar year, and allow the agency to proceed with the goal of fully implementing electronic death records in all States for more timely and accurate vital statistics collection.

Bureau of Labor Statistics

During these turbulent economic times, data produced by the Bureau of Labor Statistics (BLS) are particularly relevant and valued. PAA and APC members have relied historically on objective, accurate data from the BLS. In recent years, our organizations have become increasingly concerned about the state of the agency's funding.

We support the administration's request for BLS, which would provide the agency with a total of \$647 million in fiscal year 2013. We are, however, opposed to the administration's proposed \$6 million cut to the National Longitudinal Surveys (NLS) program within BLS in fiscal year 2013. A cut of this magnitude would force triennial fielding, which will create serious respondent recall problems and degrade data quality.

NLS data are essential to understanding how labor market experiences evolve over the life-cycle, and how labor market outcomes differ for Hispanics and non-Hispanics. The NLS data have been collected for 47 years and are essential to understanding how labor market experiences and outcomes evolve and differ. The proposed BLS budget cuts will be devastating to the social science research community and to policymakers who rely on the survey's findings. We are pleased that the BLS restored funding to the NLS that it had initially proposed to cut in fiscal year 2012. We hope that the Congress will reject this proposed cut in fiscal year 2013.

Summary of fiscal year 2013 Recommendations

In sum, the PAA and APC asks the Subcommittee to consider our requests for fiscal year 2013:

- provide the NIH with \$32 billion;
- provide the NIA with \$1.4 billion;
- provide the NICHD with \$1.37 billion;
- support the administration's request for the NCHS, \$162 million; and
- reject the administration's proposed \$6 million cut to the National Longitudinal Studies program at the Bureau of Labor Statistics.

Thank you for considering our requests and for supporting Federal programs that benefit the population sciences.

PREPARED STATEMENT OF THE PHYSICIAN ASSISTANT EDUCATION ASSOCIATION

On behalf of its membership, 164 accredited physician assistant (PA) education programs in the United States, the Physician Assistant Education Association (PAEA) is pleased to submit these comments on the fiscal year 2013 appropriations for PA education and other health professionals programs that are authorized through Title VII and VIII of the Public Health Service Act and administered through the Health Resources and Services Administration (HRSA).

PAEA is a member of the Health Professions and Nursing Education Coalition (HPNEC) and we support the HPNEC recommendation for funding of at least \$520 million in fiscal year 2013 for the health professions education programs authorized under Title VII and VIII. HPNEC is an informal alliance of more than 60 national organizations representing schools, programs, health professionals and students dedicated to ensuring that the healthcare workforce is trained to meet the needs of the country's growing, aging and increasingly diverse population.

The Need for Increased Federal Funding for Physician Assistants

PAs are licensed healthcare professionals who practice medicine as members of a team in concert with a supervising physician. PAs are medical professionals trained at the graduate level who have the advanced training to autonomously diagnose, treat, and prescribe medication for patients in a cost-effective manner. PAs typically complete their education and training within 27 months, and can enter the workforce much more quickly than other post-graduate health professions. PAs can only help meet the challenges facing America's healthcare system if appropriate resources are available to meet the demand for PA education. Title VII funding is the sole source of Federal dollars available for PA education.

The way that PAs are trained in the United States—the caliber of the institutions and the expertise of the educators—is the gold-standard throughout the world. However, clinical site availability is one of the profession's critical unmet needs, as schools are struggling to train the growing classes of PAs. In order to support the growth of the profession and enable PAs to enter the workforce, additional Federal funding is needed to build infrastructure and improve the quality of clinical sites used to train PAs. Incentives for appropriate locations to offer their space can make a significant difference in helping PAs complete their education in a timely manner and begin treating patients. Similarly, a lack of preceptors is impeding the PA educational system's ability to train adequate numbers of PAs. Choosing a teaching career must be a practical and financially desirable option for practicing and returning PAs in order for the profession to grow and meet the demand for care. Financial incentives can help create such an environment, ensuring the United States can increase the supply of primary care clinicians and provide comprehensive clinical experiences for students.

Physician Assistant Practice

The PA practice model is, by design, a team-based approach to patient care and fits well into the patient-centered, medical home and accountable care organization models expected to transform our reformed healthcare system. The profession is projected to continue to grow as a result of the projected shortage of physicians, the demand for services from an aging population, and the continuously strong PA applicant pool.

The base of applicants for PA programs has grown by more than 10 percent each year since 2000, and the Bureau of Labor Statistics projects a 39 percent increase in the number of PA jobs between 2008 and 2018. With its relatively short initial training time and the flexibility of generalist-training, the PA profession is well-positioned to help fill projected shortages of available healthcare professionals.

The need for generalist medical training, workforce diversity and health providers willing to practice in underserved areas are key priorities identified by HRSA. Studies have found that health professionals from underserved areas are three to five times more likely to return to underserved areas to provide care. To provide the highest quality care, it is increasingly important that the health workforce better represent America's changing demographics, as well as addresses issues of disparities in healthcare. PA programs have been successful in attracting students from underrepresented minority groups and disadvantaged backgrounds. Title VII grants are also weighted toward programs with a high success rate of placing PAs in underserved communities and are helping the profession make even greater strides toward these goals.

Title VII Funding

Title VII funding is the only potential source of Federal funding for PA programs. These Federal dollars play a crucial role in developing and supporting PA education programs, and are helping to facilitate the growth of a profession that meets many of the 21st century health system demands for improvements in quality, access and cost of care.

Title VII funding fills a specific need for both curriculum and faculty development. These grants enhance primary care clinical training and education, assist PA programs with recruiting applicants from minority and disadvantaged backgrounds, and fund innovative programs that focus on educating a culturally competent workforce. Title VII funding also increases the likelihood that PA students will practice in medically underserved communities with health professional shortages.

PA programs have already used Title VII funds to creatively expand care to underserved areas and populations, as well as develop a diverse PA workforce.

- A Texas program has used its PA training grant to support a distant site in an underserved area. This grant provides assistance to the program to recruit, educate and train PA students in the largely Hispanic South Texas and mid-Texas/Mexico border areas and supports new faculty development.
- A Utah program has used its PA training grant to promote interprofessional teams—an area of strong emphasis in the Patient Protection and Affordable Care Act. The grant allowed the program to optimize its relationships with three service-learning partners, develop new partnerships with service-learning sites, and create a model geriatric curriculum that includes didactic and clinical education.
- An Alabama program used its PA training grant to update and expand current health behavior educational curriculum and HIV/STD training. It was also able to include PA students from other programs who were interested in rural, primary care medicine for a 4-week comprehensive educational program in HIV diagnosis and management.
- A South Carolina program has developed a model program that offers a 2-year academic fellowship for recent PA graduates with at least 1 year of clinical experience. To further enhance an evidence-based approach to education and practice, two specific practice projects were embedded in the fellowship experience. Fellows direct and evaluate PA students' involvement in the "Towards No Tobacco" curriculum, aimed at fifth graders, and the PDA Patient Data experience, aimed at assessing healthcare services.

Title VII support for PA programs has been strengthened with the enactment of the Patient Protection and Affordable Health Care Act (Public Law 111-148), which provides a 15 percent allocation in the appropriations process for PA programs at the primary care medicine line. This funding will enhance capabilities to train a growing PA workforce and is likely to increase the pool of faculty positions as PA programs will now be eligible for faculty loan repayment. As is true of many post-graduate programs, loan burdens are barriers to physician assistant entry into academia.

In fiscal year 2013, a new priority for PA training grants will focus on training 1,400 additional physician assistants over a 5 year period, by providing funding to "develop the infrastructure necessary to expand and improve teaching quality at clinical sites for Physician Assistant students." (Department of Health and Human Services, Fiscal Year 2013, HRSA Justification for Estimates for Appropriations Committee, Executive Summary). The future of the profession and its ability to meet patients' demands for care rests in large part on the ability to train the next generation of PAs. Title VII provides the support needed to ensure both the quantity and quality of teaching staff in the United States will continue to reflect the highest educational standards in the world.

The History of Physician Assistant Education

The first physician assistant class of 1965 was comprised of Navy corpsmen who served during the Vietnam war and applied their direct medical experience in the military to practicing primary care. Since those first three PAs graduated from Duke University, the profession has grown dramatically. Today, there are 164 accredited PA programs which graduate more than 6,000 new PAs each year, and more than 60 new programs are in the pipeline.

The growth rate in the applicant pool is remarkable. Tracked via the Centralized Application Service (CASPA), in March 2006 there were a total of 7,608 applicants to PA education programs; as of March 2011, there were 16,112—a 112 percent increase over the past 5 years.

One reason for the appeal of the PA profession is that the average PA education program is 27 months in length, significantly shorter than other post-graduate pro-

grams. Typically, 1 year is devoted to classroom study and approximately 15 months are devoted to clinical rotations. The curriculum generally includes 400 hours of basic sciences and nearly 600 hours of clinical medicine. Within the healthcare workforce, only physicians receive more clinical education than PAs.

Federal support has been critical to the development of the profession at several key points, including the creation of the PAEA Faculty Development Institute, which provides training for new and experienced faculty to improve teaching quality and encourage sharing of curricular resources. To allow the profession to meet the obvious and growing demands of students and their future patients, continued funding is critical.

Honoring the Roots of the PA Profession

As the first class of PAs demonstrated, veterans with medical backgrounds are excellent potential candidates for PA programs due to their leadership and professional skills. Special incentives for both PA schools and students with a military background can help expedite the process of matriculation into the educational system. PAEA and other interested stakeholders are currently working with HRSA to identify best practices in “bridge programs” and career counseling services provided to service members and veterans interested in a health career. Additionally, there is a new priority included in the fiscal year 2013 PA training grant to identify best practices for:

- Expedited curricula;
- Enhanced veteran recruiting;
- Enhanced retention; and
- Enhanced mentoring services for veterans.

This program ensures that our Nation’s service members with medical skill and specialties are able to transition into a career in the civilian workforce when they leave the military. They, too, can contribute to a solution to the primary healthcare workforce shortage if given the right opportunities.

Summary of fiscal year 2013 Funding Recommendations

The Physician Assistant Education Association requests that the Appropriations Committee support funding for Title VII and VIII health professions programs at a minimum of \$520 million for fiscal year 2013. This level of funding is needed to adequately support the Nation’s demand for primary care practitioners, particularly those who will practice in medically underserved areas and serve vulnerable populations. The Physician Assistant Education Association also respectfully asks for support for the \$12 million allocation in the President’s fiscal year 2013 budget request for PA education programs.

We thank the members of the subcommittee for their continued support of the health professions and look forward to working with you to solve the Nation’s health workforce shortage and meet the need for high quality, affordable healthcare accessible to all. We appreciate the opportunity to present the Physician Assistant Education Association’s fiscal year 2013 funding recommendation.

PREPARED STATEMENT OF PREVENT BLINDNESS AMERICA

Funding Request Overview

Prevent Blindness America appreciates the opportunity to submit written testimony for the record regarding fiscal year 2013 funding for vision and eye health related programs. As the Nation’s leading nonprofit, voluntary health organization dedicated to preventing blindness and preserving sight, Prevent Blindness America maintains a long-standing commitment to working with policymakers at all levels of government, organizations and individuals in the eye care and vision loss community, and other interested stakeholders to develop, advance, and implement policies and programs that prevent blindness and preserve sight. Prevent Blindness America respectfully requests that the Subcommittee provide the following allocations in fiscal year 2013 to help promote eye health and prevent eye disease and vision loss:

- Provide at least \$1 million to maintain vision and eye health efforts at the Centers for Disease Control and Prevention (CDC).
- Support the Maternal and Child Health Bureau’s (MCHB) National Center for Children’s Vision and Eye Health (Center).
- Provide at least \$645 million in fiscal year 2013 to sustain programs under the Maternal and Child Health (MCH) Block Grant.
- Provide \$730 million to the National Eye Institute (NEI) in order to bolster efforts to identify the underlying causes of eye disease and vision loss, improve early detection and diagnosis, and advance prevention and treatment efforts.

Introduction and Overview

Vision-related conditions affect people across the lifespan from childhood through elder years. Good vision is an integral component to health and well-being, affects virtually all activities of daily living, and impacts individuals physically, emotionally, socially, and financially. Loss of vision can have a devastating impact on individuals and their families. An estimated 80 million Americans have a potentially blinding eye disease, 3 million have low vision, more than 1 million are legally blind, and 200,000 are more severely visually blind. Vision impairment in children is a common condition that affects 5 to 10 percent of preschool age children. Vision disorders, including amblyopia (“lazy eye”), strabismus (“cross eye”), and refractive error are the leading cause of impaired health in childhood.

Alarming, while half of all blindness can be prevented through education, early detection, and treatment, the NEI reports that “the number of Americans with age-related eye disease and the vision impairment that results is expected to double within the next three decades.”¹ Among Americans age 40 and older, the four most common eye diseases causing vision impairment and blindness are age-related macular degeneration (AMD), cataract, diabetic retinopathy, and glaucoma.² Refractive errors are the most frequent vision problem in the United States—an estimated 150 million Americans use corrective eyewear to compensate for their refractive error.² Uncorrected or under-corrected refractive error can result in significant vision impairment.²

To curtail the increasing incidence of vision loss in America, Prevent Blindness America advocates sustained and meaningful Federal funding for programs that help promote eye health and prevent eye disease, vision loss, and blindness; needed services and increased access to vision screening; and vision and eye disease research. We thank the Subcommittee for its consideration of our specific fiscal year 2013 funding requests, which are detailed below.

Vision and Eye Health at the CDC: Helping to Save Sight and Save Money

The CDC serves a critical national role in promoting vision and eye health. Since 2003, the CDC and Prevent Blindness America have collaborated with other partners to create a more effective public health approach to vision loss prevention and eye health promotion. The CDC works to:

- Promote eye health and prevent vision loss.
- Improve the health and lives of people living with vision loss by preventing complications, disabilities, and burden.
- Reduce vision and eye health related disparities.
- Integrate vision health with other public health strategies.

Prevent Blindness America requests at least \$1 million in fiscal year 2013 to maintain vision and eye health efforts of the CDC. Adequate fiscal year 2013 resources will allow the CDC to continue to address the growing public health threat of preventable chronic eye disease and vision loss among at-risk and underserved populations through increased coordination and integration of vision and eye health at State and local health departments, and through community health centers and rural services.

Integrating Vision Health into Broader Disease Prevention and Health Promotion Efforts

A cornerstone activity of the vision and eye health work at the CDC is its support and encouragement of efforts to better integrate State-level initiatives to address vision and eye disease by approaching vision health through other public health prevention, treatment, and research efforts. Vision loss is associated with a myriad of other serious, chronic, life threatening, and disabling conditions, including diabetes, depression, unintentional injuries, and behavioral risk factors such as tobacco use. Leveraging scarce resources and recognizing the numerous connections between eye health and other diseases, the CDC works to integrate and connect vision health initiatives to other State, local, and community health programs.

For example, State-based programs to prevent and reduce diabetes should include efforts to educate patients and healthcare providers on the relationship between diabetes and certain eye problems, such as diabetic retinopathy, glaucoma, and cataracts. Similarly, State initiatives to reduce the incidence of falls among older Americans should include vision screening, as studies have found that one of the leading causes of falls and injuries among older adults is unaddressed vision problems.

¹“Vision Problems in the U.S.: Prevalence of Adult Vision Impairment and Age-Related Eye Disease in America,” Prevent Blindness America and the National Eye Institute, 2008.

²Ibid.

To advance State-based vision health integration, funding to the CDC has supported two joint efforts, one in New York and the other in Texas, focused on integrating vision-related services at the State and local level. Working together, the State health departments of these States and the State-based affiliates of Prevent Blindness America promoted vision loss prevention strategies among community groups and vision partners, and established State vision preservation plans. The goal of these integration efforts was to ensure that vision loss and eye health promotion are incorporated into all relevant local, State, and Federal public health interventions, prevention and treatment programs, and other initiatives that impact causes of—and factors that contribute to—vision problems and blindness. By integrating efforts and coordinating approaches in this manner, Federal and State resources were used more efficiently, eye health problems and vision loss were reduced, and the overall health and well-being of individuals and communities were improved.

Investing in the Vision of Our Nation's Most Valuable Resource—Children

While the risk of eye disease increases after the age of 40, eye and vision problems in children are of equal concern. If left untreated, they can lead to permanent and irreversible visual loss and/or cause problems socially, academically, and developmentally. Although more than 12.1 million school-age children have some form of a vision problem, only one-third of all children receive eye care services before the age of six.³

In 2009, the MCHB established the National Center for Children's Vision and Eye Health (the Center), a national vision health collaborative effort aimed at developing the public health infrastructure necessary to promote eye health and ensure access to a continuum of eye care for young children.

The Center has established a National Expert Panel comprised of experts in ophthalmology, optometry, pediatrics, public health, childcare, academia, family advocacy, and others who have a stake in the field of children's vision. Members of the National Expert Panel provide recommendations toward national guidelines for quality improvement strategies, vision screening and developing a continuum of children's vision and eye health. In addition, they serve as advisors to the Center as it pursues its goals and objectives.

With this support the Center, will continue to:

- Provide national leadership in dissemination of best practices, infrastructure development, professional education, and national vision screening guidelines that ensure a continuum of vision and eye healthcare for children;
- Advance State-based performance improvement systems, screening guidelines, and a mechanism for uniform data collection and reporting; and
- Provide technical assistance to States in the implementation of strategies for vision screening, establishing quality improvement measures, and improving mechanisms for surveillance.

Prevent Blindness America also requests at least \$645 million in fiscal year 2013 to sustain programs under the MCH Block Grant. The MCH Block Grant enables States to expand critical healthcare services to millions of pregnant women, infants and children, including those with special healthcare needs. In addition to direct services, the MCH Block Grant supports vital programs, preventive and systems building services needed to promote optimal health.

Advance and Expand Vision Research Opportunities

Prevent Blindness America calls upon the Subcommittee to provide \$730 million for the NEI to bolster its efforts to identify the underlying causes of eye disease and vision loss, improve early detection and diagnosis of eye disease and vision loss, and advance prevention and treatment efforts. Research is critical to ensure that new treatments and interventions are developed to help reduce and eliminate vision problems and potentially blinding eye diseases facing consumers across the country.

Through additional support, the NEI will be able to continue to grow its efforts to:

- Expand capacity for research, as demonstrated by the significant number of high-quality grant applications submitted in response to the American Recovery and Reinvestment Act opportunities.
- Address unmet need, especially for programs of special promise that could reap substantial downstream benefits.
- Fund research to reduce healthcare costs, increase productivity, and ensure the continued global competitiveness of the United States.

³“Our Vision for Children's Vision: A National Call to Action for the Advancement of Children's Vision and Eye Health, Prevent Blindness America,” Prevent Blindness America, 2008.

By providing additional funding for the NEI at the NIH, essential efforts to identify the underlying causes of eye disease and vision loss, improve early detection and diagnosis of eye disease and vision loss, and advance prevention, treatment efforts and health information dissemination will be bolstered.

Conclusion

On behalf of Prevent Blindness America, our Board of Directors, and the millions of people at risk for vision loss and eye disease, we thank you for the opportunity to submit written testimony regarding fiscal year 2013 funding for the CDC's vision and eye health efforts, the MCHB's National Center for Children's Vision and Eye Health, and the NEI. Please know that Prevent Blindness America stands ready to work with the Subcommittee and other Members of Congress to advance policies that will prevent blindness and preserve sight. Please feel free to contact us at any time; we are happy to be a resource to Subcommittee members and your staff. We very much appreciate the Subcommittee's attention to—and consideration of—our requests.

PREPARED STATEMENT OF THE PULMONARY HYPERTENSION ASSOCIATION

Pulmonary Hypertension Association Fiscal Year 2013 LHHS Appropriations Recommendations

\$7 billion for HRSA, an increase of \$500 million over fiscal year 2012, including proportional increases for the Healthcare Systems Bureau and Organ Donation and Transplantation activities to promote PH education amongst healthcare providers and improve health outcomes for PH transplant patients.

\$7.8 billion for CDC, an increase of \$1.7 billion over fiscal year 2012, including a proportional increase for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) to facilitate critical PH education and awareness activities.

\$32 billion for NIH, an increase of \$1.3 billion over fiscal year 2012, including proportional increases for the National Heart, Lung, and Blood Institute (NHLBI); National Center for Advancing Translational Sciences (NCATS); Office of the Director (OD); and other NIH Institutes and Centers to facilitate adequate growth in the pulmonary hypertension (PH) research portfolio.

Chairman Harkin, Ranking Member Shelby, and distinguished members of the Subcommittee, thank you for the opportunity to submit testimony on behalf of PHA. It is my honor to represent the hundreds of thousands of Americans who are affected by this devastating disease.

I'd like to open with a personal story. Several years ago, I had the opportunity to visit the Pulmonary Hypertension Association of China and the Taiwan Foundation for Rare Disorders. On my return flight, I began to speak with the passenger in the seat next to mine, a resident of Taipei. He told me that he had once lived in Bethesda. I asked him what brought him back to Taiwan. He said, "I'm a research scientist, an oncologist. I used to work at NIH. The research money dried up in the United States. It's flowing in Asia." To me, those four short sentences sum up the dangers of allowing a carefully built infrastructure to decline. Loss of leadership in science today will mean loss of quality healthcare and business markets tomorrow.

PHA has served the PH community for more than 20 years. In 1990, three PH patients found each other with the help of the National Organization for Rare Disorders and shortly thereafter founded PHA. At that time, the condition was largely unknown amongst the general public and within the medical community; there were fewer than 200 diagnosed cases of the disease. Since then, PHA has grown into a nationwide network of more than 20,000 members and supporters, including more than 230 support groups across the country.

PHA is dedicated to improving treatment options and finding cures for PH, and supporting affected individuals through coordinated research, education, and advocacy activities. Since 1996, nine medications for the treatment of PH have been approved by the Food and Drug Administration (FDA), eight of those since 2001. These innovative treatment options represent important steps forward in the medical understanding of PH and the care of PH patients, but more needs to be done to end the suffering caused by this disease.

PH is a debilitating and often fatal condition where the blood pressure in the lungs rises to dangerously high levels. In PH patients, the walls of the arteries that take blood from the right side of the heart to the lungs thicken and constrict. As a result, the right side of the heart has to pump harder to move blood into the

lungs, causing it to enlarge and ultimately fail. Symptoms of PH include shortness of breath, fatigue, chest pain, dizziness and fainting.

I would like to extend my sincere gratitude to the Subcommittee for your historic support of PH programs at HRSA, CDC, and NIH. Thanks to your leadership, the PH research portfolio at NIH has advanced and improved our understanding of the disease, and awareness of PH by the general public has led to earlier diagnosis and improved health outcomes for patients. Please continue to support PH activities moving forward.

Health Resources and Services Administration

PHA joins the other voluntary patient and medical organizations comprising the public health community in requesting that you support HRSA by providing the agency with an appropriation of \$7 billion in fiscal year 2013. Such a funding increase would allow the agency to implement a PH education and awareness campaign focused on healthcare providers, and take on activities that would improve health outcomes for PH patients who rely on heart or lung transplantation.

PHA has had a very successful partnership with HRSA's "Gift of Life" Donation Program in recent years. Collectively, we have worked to increase organ donation rates and raise awareness about the need for PH patients to "early list" on transplantation waiting lists. For fiscal year 2013, PHA recommends an appropriation of \$26 million for this important program. Furthermore, we ask for your support in encouraging HRSA, specifically the United Network for Organ Sharing, to engage in active and meaningful dialogue with medical experts at the REVEAL Registry. Such a dialogue has the potential to improve the methodology used to determine lung transplantation eligibility for PH patients and to improve survivability and health outcomes following a transplantation procedure.

Centers for Disease Control and Prevention

PHA joins the other voluntary patient and medical organizations comprising the public health community in requesting that you support CDC by providing the agency with an appropriation of \$7.8 billion in fiscal year 2013. Such a funding increase would allow CDC to undertake critical PH education and awareness activities, which would promote early detection and appropriate intervention for PH patients.

We are grateful to the Subcommittee for providing past support of PHA's Pulmonary Hypertension Awareness Campaign. We know for a fact that Americans are dying due to a lack of awareness of PH and a lack of understanding about the many new treatment options. This unfortunate reality is particularly true among minority and underserved populations and citizens in rural areas remote from medical centers with PH expertise. More needs to be done to educate both the general public and healthcare providers if we are to save lives.

To that end, PHA has utilized the funding provided through the CDC to (1) launch a successful media outreach campaign focusing on both print and online outlets, (2) expand our support programs for previously underserved patient populations, and (3) establish PHA Online University, an interactive curriculum-based website for medical professionals that targets pulmonary hypertension experts, primary care physicians, specialists in pulmonology/cardiology/rheumatology, and allied health professionals. The site is continually updated with information on early diagnosis and appropriate treatment of pulmonary hypertension. It serves as a center point for discussion among PH-treating medical professionals and offers Continuing Medical Education and CEU credits through a series of online classes.

In fiscal year 2013, we ask the Subcommittee to encourage CDC to partner with us once again to collaborate on and support PH education and awareness activities. This would make a tremendous difference in the fight against this devastating disease.

National Institutes of Health

PHA joins the other voluntary patient and medical organizations comprising the public health community in requesting that you support NIH by providing the agency with an appropriation of \$32 billion in fiscal year 2013. This modest 4 percent funding increase would ensure that biomedical research inflation does not result in a loss of purchasing power at NIH, critical new initiatives like the Cures Acceleration Network (CAN) are adequately supported, and the PH research portfolio can continue to progress.

Less than two decades ago, a diagnosis of PH was essentially a death sentence, with only one approved treatment for the disease. Thanks to advancements made through the public and private sector, patients today are living longer and better lives with a choice of nine FDA approved medications. Sustained investment in basic, translational, and clinical research can ensure that we capitalize on recent

advancement and emerging opportunities to speed the discovery of improved treatment option and cures.

Expanding clinical research remains a top priority for patients, caregivers, and PH investigators. We are particularly interested in establishing a pulmonary hypertension research network. Such a network would link leading researchers around the United States, providing them with access to a wider pool of shared patient data. In addition, the network would provide researchers with the opportunities to collaborate on studies and to strengthen the connections between basic and clinical science in the field of pulmonary hypertension research. Such a network is in the tradition of the NHLBI, which, to its credit and to the benefit of the American public, has supported numerous similar networks including the Acute Respiratory Distress Syndrome Network and the Idiopathic Pulmonary Fibrosis Clinical Research Network. We ask that you provide NHLBI with sufficient resources and encouragement to move forward with the establishment of a PH network in fiscal year 2013.

We applaud the recent establishment of the National Center for Advancing Translational Sciences (NCATS) at NIH. Housing translational research activities at a single Center at NIH will allow these programs to achieve new levels of success. Initiatives like CAN are critical to overhauling the translational research process and overcoming the research “valley of death” that currently plagues treatment development. In addition, new efforts like taking the lead on drug repurposing hold the potential to speed new treatment to patients, particularly patients who struggle with rare or neglected diseases. We ask that you support NCATS and provide adequate resources for the Center in fiscal year 2013.

Social Security Administration

We would like to thank the Subcommittee for its commitment to addressing the longstanding backlog of disability claims at the Social Security Administration (SSA). We greatly appreciate this investment as a growing number of our patients are applying for disability coverage. Recently, SSA convened an Institute of Medicine (IOM) panel to recommend revisions to the disability criteria for cardiovascular diseases. The IOM worked closely with our medical experts to update the disability criteria for our patient population and we were pleased to receive their recommendations last year. As we continue to work with SSA on this important effort, we encourage the Congress to continue to support this process moving forward.

On a related note, we continue to applaud SSA for their leadership of the Compassionate Allowances Initiative (CAL), which seeks to speed the process of accessing disability benefits for patients diagnosed with serious conditions that undoubtedly leave them disabled. Last year, CAL concluded its initial roll out by reviewing conditions and designating a list of 113 as “compassionate allowances.” While we understand CAL will continue to designate conditions as compassionate allowances moving forward, it is unclear what this process will be now that the initial program roll out has concluded. We encourage you to work with CAL and stakeholder organizations to lay out the process for expansion of this important initiative moving forward.

Thank you for your time and your consideration of our requests. Please contact me if you have any questions or if you require any additional information.

PREPARED STATEMENT OF RESEARCH!AMERICA

Thank you, Chairman Harkin and Ranking Member Shelby, for the opportunity to submit testimony regarding fiscal year 2013 appropriations under the jurisdiction of the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. Our testimony will highlight the strength of public support for increased funding of several agencies within the Department of Health and Human Services (DHHS): the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ)—agencies that play an essential role in advancing health, fueling business development and job growth, and combating spiraling healthcare costs.

Research!America appreciates the subcommittee’s past support for research conducted and supported by NIH, CDC and AHRQ. We appreciate that NIH received a budget increase in fiscal year 2012. Unfortunately, CDC and AHRQ received budget cuts, muting the capacity of these agencies to contribute to our Nation’s research enterprise and fulfill other facets of their crucial missions.

It is counterproductive to discontinue our Nation’s long-standing commitment to strong and sustained investments in research for health. Studies have shown that health research is a tool with the unique, dual capability of growing the economy and reducing Federal healthcare costs. And for research to be effective, it must be

sustained. Progress is an iterative process that requires consistent support. We urge the subcommittee to provide funding increases for NIH, CDC and AHRQ, preventing further erosion in their capabilities and enabling them to continue to contribute meaningfully to the health and economic well-being of Americans.

In January 2013, the sequester is scheduled to be triggered, which would have a disastrous impact on these agencies, the health of Americans and our economy. NIH alone would stand to lose billions in funding, most of which is used to support extramural grants at institutions in every State. Such dramatic cuts would greatly hamper medical innovation, depriving patients of new potential cures and treatments. New investigators are already facing unprecedented challenges in receiving funding—a situation that would become even more dire in the face of a sequester. Virtually stagnant funding for health research has already diminished our Nation's global competitiveness, and the sequester may result in the United States forfeiting its role as the world leader in research for health.

Each agency plays a unique role in promoting the best interests of our Nation:

- Research funded by the National Institutes of Health at universities, academic medical centers, independent research institutions and small businesses across the country lays the foundation for new products development by the private sector. Since much of the research NIH supports is at the non-commercial stages of the research pipeline, NIH funding does not compete with, but rather sets the stage for, critical private sector investment and development. Recent studies have demonstrated that the NIH is an immense driver of job creation and economic development in every State. One study found that the NIH supported 432,000 jobs in 2011 alone.¹ Overall, Federal and private investments are complementary funding streams that lead to business development, job growth and beneficial medical advances. Taxpayer-funded research through the NIH has allowed us to convert HIV/AIDS from a death sentence to a treatable chronic disease; has reduced the costly toll of premature heart disease death and disability and made childhood cancers treatable diagnoses; the secrets of diabetes, Alzheimer's, Parkinson's and host of cancers and many other diseases can and will be unlocked by science—the question is not if but when we will achieve our goals in these arenas. Whether viewed through the lens of advancing the health, well-being and longevity of Americans or of gaining control over health spending that is driving up the Federal budget, overcoming these health threats must remain a top priority.
- The Centers of Disease Control and Prevention engage in research that stems deadly and costly pandemics, bolsters our Nation's defenses against bioterrorism, and helps prevent the onset of debilitating and expensive diseases. The CDC is the Nation's first responder to lethal viruses and infections, including life-threatening and costly drug-resistant infections that pose a particular threat to children and young adults, as well as investigating tragic phenomena like cancer clusters. Due to cuts in recent years, the CDC is functioning with one hand tied behind its back, even as health challenges like the obesity epidemic, autism and infectious disease outbreaks capture headlines and ruin lives.
- Research supported by the Agency for Healthcare Research and Quality identifies inefficiencies in healthcare delivery that inflate the cost of public and private insurance. AHRQ-supported research also improves the quality of care to help reduce the length and intensity of disability and disease, and helps patients and physicians make informed treatment decisions, improving outcomes and reducing costly “false starts” in the provision of healthcare services. Given the enormity of the challenge of inefficiency in healthcare delivery, AHRQ is severely under-powered.

As national polling commissioned by Research!America in October 2011 demonstrates, the American public strongly supports robust investment in research to improve health. The poll, which surveyed a nationwide mix of self-described conservatives (36.8 percent), liberals (27.9 percent) and moderates (35.3 percent), found that:

- 86 percent of Americans say that investing in health research is important to job creation and economic recovery;
- 77 percent think the United States is losing its global competitive edge in science, technology and innovation;
- 50 percent of Americans would be willing to pay higher taxes if they were certain that all of the money would be spent on additional medical research;

¹United for Medical Research. *NIH's Role in Sustaining the U.S. Economy A 2011 Update*. <http://www.unitedformedicalresearch.com/wp-content/uploads/2012/03/NIHs-Role-in-Sustaining-the-US-Economy-2011.pdf>.

- 78 percent of Americans say the United States is not spending enough of our healthcare dollars on research;
- 58 percent of Americans believe we are not making enough progress in medical research in the United States;
- 79 percent of Americans agree with the following statement: “Even if it brings no immediate benefits, basic scientific research that advances the frontiers of knowledge is necessary and should be supported by the Federal Government”;
- 92 percent of Americans say it is important that our Nation supports research that focuses on how well the healthcare system is functioning;
- 82 percent of Americans say that the Government should play a role in prevention research; and
- 54 percent of Americans say research to improve health is part of the solution to rising healthcare costs.

These findings bear out some important points:

- Americans not only value medical research that leads directly to advances in healthcare, they appreciate the importance of basic research that lays the groundwork for these discoveries, as well as health research, which focuses on such goals as improving healthcare delivery and identifying effective prevention strategies.
- Americans recognize that our Nation’s hold on global leadership in the R&D arena is precarious. Our leadership position will evaporate if policymakers shortchange Government investment in the basic research and development that fuels private sector innovation. As it stands, China, Brazil and India are rapidly increasing investments in R&D, while the United States invests less than 3 percent of its GDP.
- Americans know that our Nation’s best weapon against spiraling healthcare costs is research. Ignoring growing healthcare costs is a ticket to disaster. Alzheimer’s disease alone is projected to cost the Federal Government trillions of dollars over the next 20 years. Ultimately, we must prevent and cure disease in order to tackle the costs associated with it.

Beyond research focused on domestic health issues, Americans strongly support global health research. Some 78 percent of Americans say that it is important that the United States work to improve health globally through research and innovation. Compassion and common sense converge in the global health R&D arena. Tuberculosis alone represents a major humanitarian crisis, taking 1.8 million lives a year and leaving countless orphans and widows.

In addition to the ethical imperative driving global health R&D, such research benefits our troops abroad and is an investment in the health of Americans. International travel means that it is not a matter of if, but when, deadly global threats, such as multiple-drug resistant tuberculosis, reach the United States. Every year, 60 million Americans travel to other countries and 50 million people from abroad travel to the United States.² In an interconnected world, U.S. global health research saves lives at home and abroad. And like domestically focused research, global health research conducted in the United States drives new businesses and new jobs. Further, major global health threats individually and collectively represent one of the most significant destabilizing forces in the developing world. Diseases like HIV/AIDS, tuberculosis and malaria take the lives of tens of millions working-aged adults in developing countries, leaving poverty and social and political instability in their wake. Ultimately, global health is a global security, global development and global humanitarian assistance issue. Reducing the burden of disease in developing countries is a stabilization strategy that can save millions of precious lives and hundreds of billions of dollars going forward.

There are few Federal investments that confer as many benefits as research to improve health—new cures, new businesses, new jobs, new answers to spiraling healthcare costs, new tools to promote humanitarian and national security goals, and new fuel to drive U.S. leadership in a global economy increasingly shaped by the ability of competitor countries to continuously innovate.

Research!America appreciates the difficult task facing the subcommittee as it seeks to simultaneously confront the budget deficit, strengthen the United States and promote the well-being of Americans. We firmly believe that investing in NIH, CDC, and AHRQ is a means of advancing all three of these fundamental goals.

Thank you, Mr. Chairman, Ranking Member Shelby, and members of the subcommittee.

²ITA (International Trade Administration), Office of Travel and Tourism Industries, “Total International Travelers Volume to and from the U.S. 1995-2005,” available online at http://tinet.ita.doc.gov/outreachpages/inbound.total_intl_travel_volume_1995-2005.html.

PREPARED STATEMENT OF THE RESEARCH WORKING GROUP OF THE FEDERAL AIDS
POLICY PARTNERSHIP

Chairman Harkin, Ranking Member Shelby and members of the subcommittee, thank you for the opportunity to provide testimony on the National Institutes of Health (NIH) budget overall and for AIDS research in fiscal year 2013. Tomorrow's scientific and medical breakthroughs depend on your vision, leadership and commitment towards robust NIH funding over the next year. To this end, the Research Working Group (RWG) urges this Committee to support—at minimum—the President's NIH budget request and also recommends a funding target of \$35 billion in fiscal year 2013 to maintain the U.S.'s position as the world leader in medical research and innovation.

Investments in health research via NIH have paid enormous dividends in the health and well-being of people in the United States and around the world. NIH funded HIV and AIDS research has supported innovative basic science for better drug therapies, evidence-based behavioral and biomedical prevention interventions and promising vaccine candidates which have saved and improved the lives of millions and holds great promise for significantly reducing HIV infection rates and providing more effective treatments for those living with HIV/AIDS in the coming decade.

Despite these advances, the number of new HIV/AIDS cases continues to rise in various populations in the United States and around the world. There are more than 1 million HIV-infected people in the United States, the highest number in the epidemic's 31-year history; additionally more than 56,000 Americans become newly infected every year. The evolving HIV epidemic in the United States disproportionately affects the poor, sexual and racial minorities and the most disenfranchised and stigmatized members of our communities. Globally, around 34 million people are living with HIV; 3.4 million of them are children.¹ However, with proper funding coupled with the promotion of evidence based policies, 2012 will be a time of great scientific progress in prevention science, vaccines and finding a cure for HIV as well as addressing the co-morbid illnesses that affect patients with HIV such as viral hepatitis and tuberculosis. Further, as Washington, DC is set to host the International AIDS Conference this summer, the gains in science made by NIH funded research programs will reflect our preeminence as the world's most powerful research enterprise fighting this deadly global epidemic.

Major advances over the last 2 years in HIV prevention technologies—in particular with microbicides, HIV vaccines, circumcision, antiretroviral treatment as prevention and pre exposure prophylaxis using antiretrovirals (PrEP)—demonstrate that adequately resourced NIH programs can transform our lives. Federal support for AIDS research has also led to new treatments for other diseases, including cancer, heart disease, Alzheimer's, hepatitis, osteoporosis and a wide range of autoimmune disorders. Over the years, NIH has sponsored the evaluation of a host of HIV vaccine candidates, some of which are advancing to efficacy trials. The recent successful iPrEx and HPTN 052 trials have shown the potential of antiretroviral drugs to prevent HIV infection. Moreover increased funding will support the future testing of new microbicides and therapeutics in the pipeline via the implementation of a newly restructured, cross-cutting HIV clinical trials network which translates NIH-funded scientific innovation into critical quality of life gains for those most affected with HIV. The ultimate goal of a cure for HIV infection increasingly seems within reach based on scientific advances facilitated by NIH funding. Several major new NIH-supported projects are underway and they have helped spur international efforts to secure additional non-NIH financing and create a global strategy for HIV cure-related research.

Increased funding for NIH in fiscal year 2013 makes good bipartisan economic sense, especially in shaky times. Robust funding for NIH overall will enable research universities to pursue scientific opportunity, advance public health, and create jobs and economic growth. In every State across the country, the NIH supports research at hospitals, universities, private enterprises and medical schools. This includes the creation of jobs that will be essential to future discovery. Sustained investment is also essential to train the next generation of scientists and prepare them to make tomorrow's HIV discoveries. NIH funding puts 350,000 scientists to work at research institutions across the country. According to NIH, each of its research grants creates or sustains six to eight jobs and NIH supported research grants and technology transfers have resulted in the creation of thousands of new independent private sector companies. NIH Director Francis Collins has stated that for every dollar invested in NIH research generates more than \$2 for that local com-

¹ <http://www.avert.org/worldstatinfo.htm>.

munity within the same year.² Strong, sustained NIH funding is a critical national priority that will foster better health and economic revitalization.

Let's not jeopardize our future. Since 2003, funding for the NIH has failed to keep up with our existing research needs—damaging the success rate of approved grants and leaving very little money to fund promising new research. The real value of the increases prior to 2003 has been precipitously reduced because of the relatively higher inflation rate for the cost of research and development activities undertaken by NIH. According to the Biomedical Research and Development Price Index—which calculates how much the NIH budget must change each year to maintain purchasing power—between fiscal year 2003 and fiscal year 2011, the cost of NIH activities according to the BRDI will have increased by 32.8 percent. By comparison, the overall budget of the NIH increased by \$3.6 billion or 13.4 percent over fiscal year 2003. So in real terms, the NIH has already sustained budget decreases of close to 20 percent over the past 9 years due to inflation alone. As such, any further cuts to NIH will have the clear and devastating effects of undermining our Nation's leadership in health research and our scientists' ability to take advantage of the expanding opportunities to advance healthcare at home and around the world. The race to find better treatments and a cure for cancer, heart disease, AIDS and other diseases, and for controlling global epidemics like AIDS, tuberculosis and malaria, all depend on a robust long term investment strategy for health research at NIH.

In conclusion, the RWG calls on the Congress to sustain what has been a bipartisan Federal commitment toward combating HIV as well as other chronic and life threatening illnesses by increasing funding for NIH to \$35 billion in fiscal year 2013. A meaningful commitment toward stemming the epidemic and securing the well being of people with HIV cannot be met without prioritizing the research investment at NIH that will lead to tomorrow's lifesaving vaccines, treatments and cures. Thank you for the opportunity to provide these comments.

PREPARED STATEMENT OF THE RYAN WHITE MEDICAL PROVIDERS COALITION

Introduction

I am Dr. Jim Raper, an HIV medical provider and Director of the 1917 Clinic, a comprehensive HIV clinic funded in part by Part C of the Ryan White Program at the University of Alabama at Birmingham. I am submitting written testimony on behalf of the Ryan White Medical Providers Coalition.

Thank you for the opportunity to discuss the important HIV/AIDS care conducted at Ryan White Part C funded programs nationwide. Specifically, the Ryan White Medical Providers Coalition, the HIV Medicine Association, the CAEAR Coalition, and the American Academy of HIV Medicine estimate that approximately \$461 million is needed to provide the standard of care for all Part C program patients. (This estimate is based on the current cost of care and the number of patients that Part C clinics serve.) Because these are exceptionally challenging economic times, we request \$285.8 million for Ryan White Part C programs in fiscal year 2013, the authorized amount that the Congress legislated for Part C programs in its 2009 reauthorization of the Ryan White Program.

The Ryan White Medical Providers Coalition was formed in 2006 to be a voice for medical providers across the Nation who deliver quality care to their patients through Part C of the Ryan White program. We represent every kind of program, from small and rural to large urban sites in every region in the country, and we advocate for a full range of primary care services for patients living with HIV.

Adequate funding for Part C of the Ryan White Program is essential to providing both effective and efficient care for individuals living with HIV/AIDS, and we thank the Subcommittee for its support of the Ryan White Part C Program in fiscal year 2012. And while we also are grateful for the \$15 million in additional funding that the administration invested in Part C programs in honor of World AIDS Day 2011 and its request to invest additional funding in fiscal year 2013, the economic pressures that Part C clinics face in order to serve all patients requesting HIV care and treatment remain significant.

HIV Treatment is HIV Prevention: Part C Programs Save Both Lives and Money

Investing in Part C services improves lives and saves money. Part C of the Ryan White Program funds comprehensive HIV care and treatment, services that are directly responsible for the dramatic decreases in AIDS-related mortality and mor-

² NIH Fiscal Year 2012 Congressional Budget Justification. <http://officeofbudget.od.nih.gov/pdfs/FY12/Volume%201%20-%20Overview.pdf>.

bidity over the last decade. Part C providers serve more than 255,000 patients with HIV/AIDS per year, or over half of the individuals in regular care and treatment.

The Ryan White Program has supported the development of expert HIV care and treatment programs that provide medical homes for patients with this serious, chronic condition. In 2011, a ground-breaking clinical trial (HPTN 052)—named the scientific breakthrough of the year by *Science* magazine—found that HIV treatment not only saves patient lives, but also reduces HIV transmission by more than 96 percent—proving that HIV treatment is also HIV prevention.

Now is the time to support the comprehensive medical care provided by Ryan White Part C clinics to save lives and better address the HIV epidemic in the United States. Early and reliable access to HIV care and treatment both helps patients with HIV live relatively healthy and productive lives and is more cost effective. One study from my Part C clinic at the University of Alabama at Birmingham found that patients treated at the later stages of HIV disease required 2.6 times more healthcare dollars than those receiving earlier treatment meeting Federal HIV treatment guidelines.

Additionally, in the face of the potentially significant expansion of healthcare coverage for low income Americans through the Affordable Care Act, maintaining the infrastructure and expertise of Ryan White Part C programs is particularly important because these centers of excellence will help keep patients engaged in essential HIV care and treatment while the system around them is transforming.

Patient Loads Are Increasing at an Unsustainable Rate

Patient loads have been increasing at Part C clinics nationwide. This continued steady increase in patients has occurred on account of higher diagnosis rates and declining insurance coverage resulting in part from the economic downturn. The CDC reports that the number of HIV/AIDS cases increased by 15 percent from 2004 to 2007 in 34 States.¹

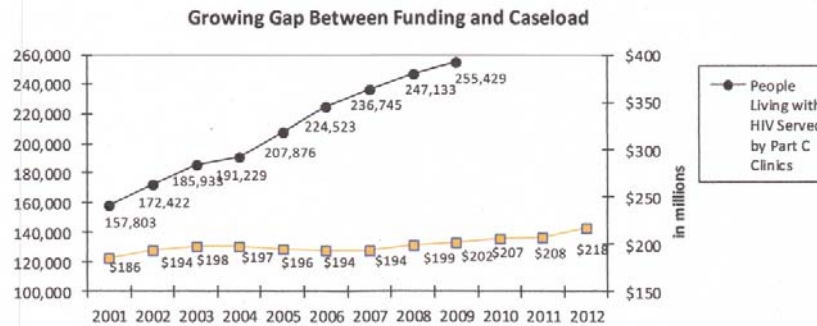
Last year in New York, when St. Vincent's Hospital in New York City closed, a Part C clinic at St. Luke's-Roosevelt Hospital had to absorb almost the entire St. Vincent's HIV/AIDS clinic, approximately 1,000 patients, over the course of just a few days. Additional clinics have closed, such as one in Sonoma County, California, and others having longer wait times for new patient appointments (8 weeks long in some places). Other programs, such as one Part C clinic in Arizona, are deciding whether to close their doors to new patients entirely because of an inability to treat additional patients within existing financial and HIV workforce resources.

Our patients struggle in times of plenty, and during this economic downturn they have relied on Part C programs more than ever. While these programs have been under-funded for years, economic pressures are creating a crisis. Clinics are discontinuing primary care and other critical medical services, such as laboratory monitoring; suffering eviction from their clinic locations; operating only 4 days per week; and laying off staff just to get by. Years of nearly flat funding combined with large increases in the patient population and the recent economic crisis are negatively impacting the ability of Part C providers to serve their patients.

The following graph demonstrates the growing disparity between funding for Part C and the increasing patient population. I refer to this gap between funding and patients as the "Triangle of Misery" because it represents the thousands of patients in HIV/AIDS care and treatment and the Part C programs nationwide that are struggling to serve them with extremely limited resources.

¹Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report, 2007. Vol. 19. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009:5. www.cdc.gov/hiv/topics/surveillance/resources/reports/.

The Triangle of Misery: Part C Caseload Increases Outpace Funding Increases 7 to 1



Conclusion

These are challenging economic times, and we recognize the severe fiscal constraints the Congress faces in allocating limited Federal dollars. The significant financial and patient pressures that we face in our clinics at home propel us to make the request for \$285.8 million in fiscal year 2013 funding for Ryan White Part C programs. This funding would help to support medical providers nationwide in delivering life-saving, effective HIV/AIDS care and treatment to their patients.

Thank you for your time and consideration of our request. If you have any questions, please do not hesitate to contact the Ryan White Medical Providers Coalition Convener, Jenny Collier, at jennycollierjd@yahoo.com.

PREPARED STATEMENT OF THE SPINA BIFIDA ASSOCIATION

Background and Overview

On behalf of the estimated 166,000 individuals and their families who are affected by all forms of Spina Bifida—the Nation’s most common, permanently disabling birth defect—Spina Bifida Association (SBA) appreciates the opportunity to submit public written testimony for the record regarding fiscal year 2013 funding for the National Spina Bifida Program and other related Spina Bifida initiatives. SBA is a national patient advocacy organization, working on behalf of people with Spina Bifida and their families through education, advocacy, research and service. SBA stands ready to work with Members of Congress and other stakeholders to ensure our Nation mounts and sustains a comprehensive effort to reduce and prevent suffering from Spina Bifida.

Spina Bifida, a neural tube defect (NTD), occurs when the spinal cord fails to close properly within the first few weeks of pregnancy and most often before the mother knows that she is pregnant. Over the course of the pregnancy—as the fetus grows—the spinal cord is exposed to the amniotic fluid, which increasingly becomes toxic. It is believed that the exposure of the spinal cord to the toxic amniotic fluid erodes the spine and results in Spina Bifida. There are varying forms of Spina Bifida occurring from mild—with little or no noticeable disability—to severe—with limited movement and function. In addition, within each different form of Spina Bifida the effects can vary widely. Unfortunately, the most severe form of Spina Bifida occurs in 96 percent of children born with this birth defect.

The result of this NTD is that most people with it suffer from a host of physical, psychological, and educational challenges—including paralysis, developmental delay, numerous surgeries, and living with a shunt in their skulls, which seeks to ameliorate their condition by helping to relieve cranial pressure associated with spinal fluid that does not flow properly. As we have testified previously, the good news is that after decades of poor prognoses and short life expectancy, children with Spina Bifida are now living into adulthood and increasingly into their advanced years. These gains in longevity, principally, are due to breakthroughs in research, combined with improvements generally in healthcare and treatment. However, with this extended life expectancy, our Nation and people with Spina Bifida now face new challenges, such as transitioning from pediatric to adult healthcare providers, education, job training, independent living, healthcare for secondary conditions, and aging concerns, among others. Individuals and families affected by Spina Bifida face

many challenges—physical, emotional, and financial. Fortunately, with the creation of the National Spina Bifida Program in 2003, individuals and families affected by Spina Bifida now have a national resource that provides them with the support, information, and assistance they need and deserve.

As is discussed below, the daily consumption of 400 micrograms of folic acid by women of childbearing age, prior to becoming pregnant and throughout the first trimester of pregnancy, can help reduce the incidence of Spina Bifida, by up to 70 percent. The Centers for Disease Control and Prevention (CDC) calculates that there are approximately 3,000 NTD births each year, of which an estimated 1,500 are Spina Bifida, and, as such, with the aging of the Spina Bifida population and a steady number of affected births annually, the Nation must take additional steps to ensure that all individuals living with this complex birth defect can live full, healthy, and productive lives.

Cost of Spina Bifida

It is important to note that the lifetime costs associated with a typical case of Spina Bifida—including medical care, special education, therapy services, and loss of earnings—are as much as \$1 million. The total societal cost of Spina Bifida is estimated to exceed \$750 million per year, with just the Social Security Administration payments to individuals with Spina Bifida exceeding \$82 million per year. Moreover, tens of millions of dollars are spent on medical care paid for by the Medicaid and Medicare programs. Efforts to reduce and prevent suffering from Spina Bifida will help to not only save money, but will also save—and improve—lives.

Improving Quality-of-Life through the National Spina Bifida Program

Since 2001, SBA has worked with Members of Congress and staff at the CDC to help improve our Nation's efforts to prevent Spina Bifida and diminish suffering—and enhance quality-of-life—for those currently living with this condition. With appropriate, affordable, and high-quality medical, physical, and emotional care, most people born with Spina Bifida will likely have a normal or near normal life expectancy. The CDC's National Spina Bifida Program works on two critical levels—to reduce and prevent Spina Bifida incidence and morbidity and to improve quality-of-life for those living with Spina Bifida.

The National Spina Bifida Program established the National Spina Bifida Resource Center housed at the SBA, which provides information and support to help ensure that individuals, families, and other caregivers, such as health professionals, have the most up-to-date information about effective interventions for the myriad primary and secondary conditions associated with Spina Bifida. Among many other activities, the program helps individuals with Spina Bifida and their families learn how to treat and prevent secondary health problems, such as bladder and bowel control difficulties, learning disabilities, depression, latex allergies, obesity, skin breakdown, and social and sexual issues. Children with Spina Bifida often have learning disabilities and may have difficulty with paying attention, expressing or understanding language, and grasping reading and math. All of these problems can be treated or prevented, but only if those affected by Spina Bifida—and their caregivers—are properly educated and given the skills and information they need to maintain the highest level of health and well-being possible. The National Spina Bifida Program's secondary prevention activities represent a tangible quality-of-life difference to the estimated 166,000 individuals living with all forms of Spina Bifida, with the goal being living well with Spina Bifida.

An important resource to better determine best clinical practices and the most cost effective treatments for Spina Bifida is the National Spina Bifida Registry, now in its third year. A total of 19 sites throughout the Nation are collecting patient data, which supports the creation of quality measures and will assist in improving clinical research that will truly save lives, while also realizing a significant cost savings.

SBA understands that the Congress and the Nation face unprecedented budgetary challenges. However, the progress being made by the National Spina Bifida Program must be sustained to ensure that people with Spina Bifida—over the course of their lifespan—have the support and access to quality care they need and deserve. To that end, SBA respectfully urges the Subcommittee to Congress allocate \$6.25 million in fiscal year 2013 to the program, so it can continue and expand its current scope of work; further develop the National Spina Bifida Patient Registry; and sustain the National Spina Bifida Resource Center. Sustaining funding for the National Spina Bifida Program will help ensure that our Nation continues to mount a comprehensive effort to prevent and reduce suffering from—and the costs of—Spina Bifida.

Preventing Spina Bifida

While the exact cause of Spina Bifida is unknown, over the last decade, medical research has confirmed a link between a woman's folate level before pregnancy and the occurrence of Spina Bifida. Sixty-five million women of child-bearing age are at-risk of having a child born with Spina Bifida. As mentioned above, the daily consumption of 400 micrograms of folic acid prior to becoming pregnant and throughout the first trimester of pregnancy can help reduce the incidence of Spina Bifida, by up to 70 percent. There are few public health challenges that our Nation can tackle and conquer by nearly three-fourths in such a straightforward fashion. However, we must still be concerned with addressing the 30 percent of Spina Bifida cases that cannot be prevented by folic acid consumption, as well as ensuring that all women of childbearing age—particularly those most at-risk for a Spina Bifida pregnancy—consume adequate amounts of folic acid prior to becoming pregnant.

Since 1968, the CDC has led the Nation in monitoring birth defects and developmental disabilities, linking these health outcomes with maternal and/or environmental factors that increase risk, and identifying effective means of reducing such risks. The good news is that progress has been made in convincing women of the importance of folic acid consumption and the need to maintain a diet rich in folic acid. This public health success should be celebrated, but still too many women of childbearing age consume inadequate daily amounts of folic acid prior to becoming pregnant, and too many pregnancies are still affected by this devastating birth defect. The Nation's public education campaign around folic acid consumption must be enhanced and broadened to reach segments of the population that have yet to heed this call—such an investment will help ensure that as many cases of Spina Bifida can be prevented as possible.

The goal is to increase awareness of the benefits of folic acid, particularly for those at elevated risk of having a baby with neural tube defects (those who have Spina Bifida themselves, or those who have already conceived a baby with Spina Bifida). With continued funding in fiscal year 2013, CDC's folic acid awareness activities could be expanded to reach the broader population in need of these public health education, health promotion, and disease prevention messages. SBA advocates that the Congress provide adequate funding to CDC to allow for a targeted public health education and awareness focus on at-risk populations (e.g., Hispanic-Latino communities) and health professionals who can help disseminate information about the importance of folic acid consumption among women of childbearing age.

In addition to a \$6.25 million fiscal year 2013 allocation for the National Spina Bifida Program, SBA urges the Subcommittee to provide \$2.8 million for the CDC's national folic acid education and promotion efforts to support the prevention of Spina Bifida and other NTD; \$22.3 million to strengthen the CDC's National Birth Defects Prevention Network; and \$137.2 million to fund the National Center on Birth Defects and Developmental Disabilities.

Sustain and Seize Spina Bifida Research Opportunities

Our Nation has benefited immensely from our past Federal investment in biomedical research at the NIH. SBA joins with other in the public health and research community in advocating that NIH receive increased funding in fiscal year 2013. This funding will support applied and basic biomedical, psychosocial, educational, and rehabilitative research to improve the understanding of the etiology, prevention, cure and treatment of Spina Bifida and its related conditions. In addition, SBA respectfully requests that the Subcommittee include the following language in the report accompanying the fiscal year 2013 LHHS appropriations measure:

“The Committee encourages NIDDK, NICHD, and NINDS to study the causes and care of the neurogenic bladder in order to improve the quality of life of children and adults with Spina Bifida; to support research to address issues related to the treatment and management of Spina Bifida and associated secondary conditions, such as hydrocephalus; and to invest in understanding the myriad co-morbid conditions experienced by children with Spina Bifida, including those associated with both paralysis and developmental delay.”

Conclusion

Please know that SBA stands ready to work with the Subcommittee and other Members of Congress to advance policies and programs that will reduce and prevent suffering from Spina Bifida. Again, we thank you for the opportunity to present our views regarding fiscal year 2013 funding for programs that will improve the quality-of-life for the estimated 166,000 Americans and their families living with all forms of Spina Bifida.

PREPARED STATEMENT OF THE SCLERODERMA FOUNDATION

The members of the Scleroderma Foundation (SF) are pleased to submit this statement for the record recommending \$32 billion in fiscal year 2013 for the National Institutes of Health (NIH), and an increase for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) concurrent with the overall increase to NIH. The Scleroderma Foundation also recommends encouraging the Centers for Disease Control and Prevention to partner with the scleroderma community in promoting increased awareness of scleroderma among the general public and healthcare providers.

STATEMENT OF CYNTHIA CERVANTES, HUNTINGTON PARK, CALIFORNIA

Mr. Chairman, I am Cynthia Cervantes, and I am 17 years old. I live in Southern California and in October 2006 I was diagnosed with scleroderma. Scleroderma means "hard skin" which is literally what scleroderma does and, in my case, also causes my internal organs to stiffen and contract. This is called diffuse scleroderma. It is a relatively rare disorder effecting only about 300,000 Americans. Just this year I was in the hospital for 4 weeks with intense pain, nausea, and dizziness. The doctors believe I had an unknown virus but could not control my symptoms. It was a very frightening time for my family and I.

About 7 years ago I began to experience sudden episodes of weakness, my body would ache and my vision was worsening, some days it was so bad I could barely get myself out of bed. I was taken to see a doctor after my feet became so swollen that calcium began to ooze out. It took the doctors months to figure out exactly what was wrong with me, because of how rare scleroderma is.

There is no known cause for scleroderma, which affects three times as many women as men. Generally, women are diagnosed between the ages of 25 and 55, but some kids, like me, are affected earlier in life. There is no cure for scleroderma, but it is often treated with skin softening agents, anti-inflammatory medication, and exposure to heat. Sometimes a feeding tube must be used with a scleroderma patient because their internal organs contract to a point where they have extreme difficulty digesting food.

The Scleroderma Foundation has been very helpful to me and my family. They have provided us with materials to educate my teachers and others about my disease. Also, the support groups the foundation helps organize are very helpful because they help show me that I can live a normal, healthy life, and how to approach those who are curious about why I wear gloves, even in hot weather. It really means a lot to me to be able to interact with other people in the same situation as me because it helps me feel less alone.

Mr. Chairman, because the causes of scleroderma are currently unknown and the disease is so rare, and we have a great deal to learn about it in order to be able to effectively treat it. I would like to ask you to please increase funding for the National Institute of Health so treatments can be found for other people like me who suffer from scleroderma. It would also be helpful to start a program at the Centers for Disease Control and Prevention to educate the public and physicians about scleroderma.

OVERVIEW OF THE SCLERODERMA FOUNDATION

The Scleroderma Foundation is a nonprofit organization based in Danvers, Massachusetts with a three-fold mission: support, education, and research. The Foundation provides support for people living with scleroderma and their families through programs such as peer counseling, doctor referrals, and educational information, along with a toll-free telephone helpline for patients.

The Foundation also provides education about the disease to patients, families, the medical community, and the general public through a variety of awareness programs at both the local and national levels. More than \$1 million in peer-reviewed research grants are awarded annually to institutes and universities to stimulate progress in the search for a cause and cure for scleroderma.

WHO GETS SCLERODERMA?

There are many clues that define the susceptibility to develop scleroderma. A genetic basis for the disease has been suggested by the fact that it is more common among patients whose family members have other autoimmune diseases (such as lupus). In rare cases, scleroderma runs in families, although for the vast majority of patients there is no other family member affected. Some Native Americans and African Americans suffer a more severe form of the disease. Caucasians. Women between the ages of 25–55 are more likely to develop scleroderma.

CAUSES OF SCLERODERMA

The cause of scleroderma is unknown. However, we do understand a great deal about the biological processes involved. In localized scleroderma, the underlying problem is the overproduction of collagen (scar tissue) in the involved areas of skin. In systemic sclerosis, there are three processes at work: blood vessel abnormalities, fibrosis (which is overproduction of collagen) and immune system dysfunction, or autoimmunity.

RESEARCH

Scleroderma research at the NIH was funded at a level of \$25 million in fiscal year 2012. This is of great concern to scleroderma patients and families who view biomedical research as their best hope for an enhanced quality of life. It is also of great concern to our researchers who have promising ideas they would like to explore if resources were available.

TYPES OF SCLERODERMA

There are two main forms of scleroderma: systemic (systemic sclerosis, SSc) that usually affects the internal organs or internal systems of the body as well as the skin, and localized that affects a local area of skin either in patches (morphea) or in a line down an arm or leg (linear scleroderma), or as a line down the forehead (scleroderma en coup de sabre). It is very unusual for localized scleroderma to develop into the systemic form.

Systemic Sclerosis

There are two major types of systemic sclerosis or SSc: limited cutaneous SSc and diffuse cutaneous SSc. In limited SSc, skin thickening only involves the hands and forearms, lower legs and feet. In diffuse cutaneous disease, the hands, forearms, the upper arms, thighs, or trunk are affected.

People with the diffuse form of SSc are at risk of developing pulmonary fibrosis (scar tissue in the lungs that interferes with breathing, also called interstitial lung disease), kidney disease, and bowel disease. The risk of extensive gut involvement, with slowing of the movement or motility of the stomach and bowel, is higher in those with diffuse rather than limited SSc. Symptoms include feeling bloated after eating, diarrhea or alternating diarrhea and constipation.

Pulmonary Hypertension (PH) is high blood pressure in the blood vessels of the lungs. It is totally independent of the usual blood pressure that is taken in the arm. This tends to develop in patients with limited SSc after several years of disease. The most common symptom is shortness of breath on exertion. However, several tests need to be done to determine if PH is the real culprit. There are now many medications to treat PH.

*Localized Scleroderma**Morphea*

Morphea consists of patches of thickened skin that can vary from half 1 inch to 6 inches or more in diameter. The patches can be lighter or darker than the surrounding skin and thus tend to stand out. Morphea, as well as the other forms of localized scleroderma, does not affect internal organs.

Linear scleroderma

Linear scleroderma consists of a line of thickened skin down an arm or leg on one side. The fatty layer under the skin can be lost, so the affected limb is thinner than the other one. In growing children, the affected arm or leg can be shorter than the other.

PREPARED STATEMENT OF THE SOCIETY OF GYNECOLOGIC ONCOLOGY

The Society of Gynecologic Oncology (SGO) thanks the Subcommittee for the opportunity to submit comments for the record regarding SGO's fiscal year 2013 funding recommendations for the National Institutes of Health and the National Cancer Institute. We believe these recommendations are critical to ensure that advances can be made to help reduce and prevent suffering from gynecologic cancer.

The SGO is a national medical specialty organization of physicians who are trained in the comprehensive management of women with malignancies of the reproductive tract. Our purpose is to improve the care of women with gynecologic cancer by encouraging research, disseminating knowledge which will raise the standards of practice in the prevention and treatment of gynecologic malignancies and co-

operating with other organizations interested in women's healthcare, oncology and related fields. The Society's membership, totaling more than 1,600, is comprised of gynecologic oncologists, as well as other related women's cancer healthcare specialists including medical oncologists, radiation oncologists, nurses, social workers and pathologists. SGO members provide multidisciplinary cancer treatment including surgery, chemotherapy, radiation therapy, and supportive care. More information on the SGO can be found at www.sgo.org.

Each day in the United States, one woman will be diagnosed with a gynecologic cancer every 7 minutes. That's more than 200 women today and close to 80,000 this year. One-third of these women will die unnecessarily. If detected early, the vast majority of these cancers are curable. The SGO believes that the Congress can take action to save the lives of thousands of our mothers, sisters, and daughters who die each year from gynecologic cancer, starting with this Subcommittee making a commitment to increase the funding in fiscal year 2013 for Federal research programs focused on education, prevention, screening and treatment of gynecologic cancers.

Now is not the time to cut research funding for these devastating diseases. We must do better for the women of our great Nation. Therefore, the SGO joins with the broader public health and research community urging the Congress to provide \$32.7 billion for the National Institutes of Health (NIH) in fiscal year 2013. This is the minimal level of funding that will allow the NIH to maintain current initiatives and investments.

SGO is aware of the fiscal challenges facing the Subcommittee in fiscal year 2013; however, more than 10 million cancer survivors can attest to the fact that when investments are made in cancer research-related programs thousands of lives are saved. Therefore, the SGO recommends that this Subcommittee provide the NCI with \$5.36 billion for fiscal year 2013.

Pathways to Progress in Gynecologic Cancer Research

In 2010, the leadership of the SGO organized a Research Summit on the Pathways to Progress in Women's Cancers. The Summit brought together gynecologic oncologists, medical oncologists, radiation oncologists, basic science researchers, epidemiologists, and educators to assess the landscape of gynecologic cancer research and recommend strategic goals for the next 10 years.

The strongest priority emerging from the Research Summit was the need to identify a mechanism to maintain infrastructure for clinical trials in gynecologic oncology. Two out of three NCI clinical alerts ("Addition of Cisplatin to Radiation Therapy in Cervical Cancer", and "Prolonged Survival in Ovarian Cancer with Intraperitoneal Chemotherapy") have been issued as a direct result of the clinical trials structure in gynecologic oncology. However, it was recognized that the current clinical trials mechanism must adapt to include novel agents and new imaging endpoints. The women of America deserve to have more breakthroughs advanced by well-designed clinical trials research dedicated to gynecologic cancers.

Prior investment into the infrastructure of tissue banking has positioned gynecologic oncology research to both contribute to and benefit from national cancer resources, such as The Cancer Genome Atlas (TCGA). The Gynecologic Oncology Group (GOG) tissue bank was able to provide high quality ovarian cancer specimens as one of the first tissues in the TCGA, followed by endometrial cancers. By leveraging the TCGA and other resources, sophisticated research questions can begin to be addressed. These resources may be deployed to answer questions that cross biologic cancer sites, such as the mechanism of cancer cell invasion or the molecular markers of cancer initiating cells.

Scientific innovation has provided the promise of personalized cancer therapies. Certainly, novel agents targeting specific tumor pathways are one part of personalized medicine. However, that concept does not encompass the spectrum of both treatment and survivorship, which is the ultimate goal. For instance, surgical intervention in endometrial cancer can be curative. But, the side effect of lymphedema may significantly affect the quality of a woman's life as well as her economic and social productivity. Women with gynecologic malignancies, as well as all cancer patients and survivors, deserve personal, specialized care to identify the essential interventions required at diagnosis and/or recurrence to maximize quantity and quality of life. In addition, personalized medicine must utilize multidisciplinary interventions to modify the overall trajectory of disease and evaluate their economic impact.

In the past decade, cervical cancer became the first gynecologic cancer to be successfully prevented by a vaccine, which will continue to be refined and studied in different populations in for modifiers of efficacy. Prevention of cancer is also possible in endometrial cancer, where epidemiologic data supports the role of obesity in the development of endometrial cancer. Certainly education of the public about the con-

nection between obesity and endometrial cancer as well as study of the cancer preventative effects of obesity reduction strategies, such as bariatric surgery are warranted at this time.

Finally, sustaining a cadre of researchers in gynecologic malignancies will require resources targeted for women’s cancer. While we anticipate that established national funding mechanisms will fund our most exciting research, public-private partnerships will become increasingly important. Previously, a successful partnership between the Gynecologic Cancer Foundation (GCF, now known as the Foundation for Women’s Cancer) and the NCI provided training in basic science research for budding gynecologic oncologists. Creation of a similar cross-disciplinary gynecologic malignancies training grant would enhance the depth and breadth of researchers in women’s cancers. For researchers already committed to research in women’s cancers, private cancer advocacy groups and professional societies might be able to partner with the NCI to create a Women’s Cancer Bridge Program to sustain such investigators during a funding shortfall.

Fifteen years ago, the roadmap defined by the “New Directions in Ovarian Cancer Research” conference spurred progress in ovarian cancer research that has directly affected patient care and saved lives. It is our hope and confidence that this new “Pathways to Progress” research agenda will prompt similar acceleration in research in all gynecologic malignancies. The women of America deserve nothing less. To read the entire “Pathways to Progress in Women’s Cancer,” A Research Agenda Proposed by the Society of Gynecologic Oncology, please visit the SGO’s website at www.sgo.org.

TABLE E-1.—GYNECOLOGIC MALIGNANCIES RESEARCH PRIORITIES

	Short (0–3 years)	Intermediate (4–6 years)	Long (7–10 years)
Low Risk	4A1) Maintain infrastructure for clinical trials in gynecologic oncology. 2E4) Prevalence/QOL trial of lymphedema in EC. 5A1) Identify the essential interventions all cancer survivors require at diagnosis and/or recurrence to maximize quantity and QOL.	1E1, 1B3, 1B6) Develop new trial endpoints and biomarkers through imaging and circulating analytes.	4F2) Establish collaborative teams of investigators to utilize banked specimens for gynecologic malignancies research.
Intermediate Risk	3D5) Cervical cancer health disparities. 3D4) Cervical cancer genetic and epigenetic susceptibility genes (TCGA).	2E2) Quality outcomes of first surgery by gynecologic oncologist.	2A3) Outcomes research on bariatric surgery/EC risk.
High Risk	2A6) CDC educational campaign EC and obesity. 3E1) Progression of CIN3–SCC (biology of invasion).	1A1, 1A3, 1A5, 1B2) Define the ovarian cancer initiating stem-like cell. 4G2) Promote legislation and regulation at State and Federal level for insurance cost coverage of clinical trials costs. 6H2) Develop and implement a training grant specific to Gynecologic Oncology.	5G1) Utilize multidisciplinary interventions to modify the overall trajectory of disease and evaluate their economic impact. 6I1) Develop a bridge program to sustain investigators who have lost extramural funding.

CDC Centers for Disease Control; CIN3 Cervical Intraepithelial Neoplasia 3; EC Endometrial Cancer; QOL Quality of Life; SCC Squamous Cell Carcinoma; TCGA The Cancer Genome Atlas.

The SGO appreciates the opportunity to submit these comments and again urges this Subcommittee to increase Federal funding to \$32.7 billion for the National Institutes of Health (NIH) in fiscal year 2013 and to provide from that at least \$5.36 billion for the NCI for fiscal year 2013.

This will allow for discoveries and research breakthroughs, while also investing in research infrastructure and training for the next generations of scientists. It will provide the resources needed for the implementation of the research agenda for the next decade in gynecologic cancers. The SGO thanks you for your leadership and the leadership of the Subcommittee on this issue.

PREPARED STATEMENT OF THE SOCIETY FOR NEUROSCIENCE

Introduction

Mr. Chairman and Members of the Subcommittee, my name is Moses Chao, PhD. I am a professor of Cell Biology, Physiology and Neuroscience, and Psychiatry at the New York University School of Medicine, and President of the Society for Neuroscience. My major research efforts have been focused on growth factors (also called neurotrophins). These proteins are crucial for everything from neuron differentiation, growth, and survival during development to learning and memory in children and adults. Deficits in neurotrophins are involved in neurodegenerative disorders such as Alzheimer's, Parkinson's and Huntington's diseases, and Amyotrophic Lateral Sclerosis (ALS) as well as limiting recovery after stroke or brain injury.

Founded in 1969, SfN has grown from a membership of 500 to more than 42,000, representing researchers working in more than 80 countries. This rapid growth reflects the tremendous progress made in understanding brain cell biology, physiology, and chemistry, and the tremendous potential and importance of this field. Today, the field sits on the cusp of revolutionary advances, and NIH-funded research has played an essential role by enabling advances in brain development, imaging, genomics, circuit function, computational neuroscience, neural engineering and many other disciplines.

To continue this important work SfN stands with partners in the medical and scientific community to request at least \$32 billion for NIH in fiscal year 2013. In this testimony, I will highlight how these advances have benefited taxpayers, and some of the challenges that need to be addressed to prevent lapsing further behind other nations throughout the world both scientifically and economically.

What is the Society for Neuroscience?

SfN is a nonprofit membership organization of basic scientists and physicians who study the brain and nervous system. The SfN mission is to advance the understanding of the brain and the nervous system by bringing together scientists of diverse backgrounds, by facilitating the integration of research directed at all levels of biological organization, and by encouraging translational research and the application of new scientific knowledge to develop improved disease treatments and cures; provide professional development activities, information, and educational resources for neuroscientists at all stages of their careers, including undergraduates, graduates, and postdoctoral fellows, and increase participation of scientists from a diversity of cultural and ethnic backgrounds; promote public information and general education about the nature of scientific discovery and the results and implications of the latest neuroscience research, and support active and continuing discussions on ethical issues relating to the conduct and outcomes of neuroscience research; and inform legislators and other policymakers about new scientific knowledge and recent developments in neuroscience research and their implications for public policy, societal benefit, and continued scientific progress.

What is Neuroscience?

Neuroscience is the study of the nervous system. It advances the understanding of human function on every level: movement, thought, emotion, behavior, and much more. Neuroscientists use tools across disciplines—from biology and computer science to physics and chemistry—to examine molecules, nerve cells, networks, brain system, and behavior. Through research, neuroscientists work to understand normal functions of the brain and determine how the nervous system develops, matures, and maintains itself through life. This research is the foundation for preventing, treating or curing more than 1,000 neurological and psychiatric disorders that result in more hospitalizations in the United States than any other disease group, including heart disease and cancer. In 2007, the World Health Organization estimated that neurological disorders affect up to 1 billion people worldwide. In fact, neurological diseases make up 11 percent of the world's disease burden, not including mental health and addiction disorders.

Neuroscience includes basic, clinical and translational research. Basic science unlocks the mysteries of the human body by exploring the structure and function of molecules, genes, cells, systems, and complex behaviors, and basic science funding at NIH continues to be a springboard for discoveries that spur medical progress for future generations.

The following are just three of many emerging stories of important progress in neuroscience research, and these are based in large part on strong historic investment in NIH and other research agencies:

Neurotrophic Factors.—Maintaining brain health throughout life is an important public health goal. Extensive research has demonstrated that cognitive function can

be enhanced with increased levels of Brain-Derived Neurotrophic Factor (BDNF) and other growth factors. These proteins are released in the brain with exercise, neuronal activity and behavioral stimulation, resulting in increased resistance to brain injury, the birth of new neurons and improved learning and mental performance. BDNF increases and strengthens the number of connections in the brain and promotes plasticity, by generating positive signals in neurons. Depression and anxiety are also influenced by neurotrophic factors. Future research will define new ways to use the knowledge from neurotrophic factors to protect the nervous system from damage and maintain brain function and plasticity during aging.

Epigenetics Research.—Is it “nature” or “nurture” that influences behavior and health outcomes? Researchers now know these factors are not independent: experience and environment (“nurture”) modify genes (“nature”)—a phenomenon known as epigenetics. Some of these modifications can be passed to the next generation, suggesting it may be possible for our life experiences to affect our children and grandchildren. Recent research finds epigenetics affects normal brain processes—such as development or memory—and abnormal brain processes like depression and disease. Emerging studies in people suggest epigenetics may affect human behavior and be a factor in neurological and psychiatric disease. One example is Rett syndrome, a genetic disorder that almost exclusively affects young girls and currently has no cure, as well as schizophrenia, autism, and Alzheimer’s disease. Also, unlike most genetic mutations, epigenetic marks can be reversed. In fact, the U.S. Food and Drug Administration have approved several drugs that work to improve health outcomes by modifying these marks. Many of these drugs were originally identified by cancer researchers, and brain scientists are now working to develop safer, more effective drugs to improve cognitive function and behavior in people—highlighting the importance of collaboration across scientific institutes and disciplines and the powerful potential to apply basic and applied research well beyond its original intent.

Fear and Post-Traumatic Stress Disorder.—In a given year, about 3.5 percent of Americans suffer from post-traumatic stress disorder (PTSD), a punishing disorder marked by intense fear, anxiety, and flashbacks that follow a traumatic experience. For U.S. military personnel returning from Iraq and Afghanistan, the prevalence of PTSD may be as high as one in five. Until now, there have been few treatment options for PTSD. However, new basic science and clinical research on the biological basis of fear suggests promising new therapeutic avenues. Rat studies determined that those with lesions in a brain region called the amygdala failed to associate a neutral stimulus, like a tone, with a fearful event, like a mild shock. Furthermore, people who had surgery to remove the portion of the temporal lobe that contains the amygdala, a treatment for some forms of epilepsy, had difficulty learning to associate a flash of light with an unpleasant noise. These findings suggest that fear is a special type of learning and memory.

Rewriting fearful memories or forgetting them altogether might therefore help conquer fears. But as researchers learn how fear memories are encoded in the brain, and as animal research helps to identify new treatments, there may be new therapeutic options. One new treatment is the antibiotic D-cycloserine. This drug activates receptors in the amygdala that are important in extinction. Additionally, drugs called beta blockers are used to treat people with high blood pressure—they stabilize the body’s response to a stressor, preventing the fight-or-flight response. A recent human study showed that, when given during recollection of a frightening memory, the beta blocker propranolol reduced fear but did not affect knowledge of an event. Researchers are currently evaluating propranolol’s ability to prevent PTSD in trauma patients. These promising results of repurposing existing drugs would not have been possible without basic scientific research, funded largely by the NIH, National Science Foundation, and Department of Defense.

Economic Impact

These and thousands of other studies are advancing our understanding of the brain and nervous system, and are translating into potential treatments for patients in the future. Federal investments in scientific research fuel the Nation’s pharmaceutical, biotechnology and medical device industries. The private sector utilizes basic scientific discoveries funded through NIH to improve health and foster a sustainable trajectory for American’s Research and Development (R&D) enterprise. Basic science generates the knowledge needed to uncover the mysteries behind human diseases, which eventually leads to private sector development of new treatments and therapeutics. This important first step is not ordinarily funded by industry given the long-term path of basic science and the pressures for shorter-term return on investments by industry.

Also, these investments contribute to economic growth in hundreds of communities nationwide, as more than 83 percent of NIH funding is distributed to more

than 3,000 institutions in communities in every State. Moreover, it will help preserve and expand America's role as leader in biomedical research, which fosters a wide range of private enterprises in the pharmaceutical, biotechnology, medical device, and many others. For example, in fiscal year 2010, NIH investments led to the creation of 487,900 jobs, and produced more than \$68 billion in new economic activity—helping 16 States to experience job growth of 10,000 jobs or more at a time when unemployment was otherwise rising.

Conclusion

With its rapid growth in countries worldwide, the SfN membership is a metaphor for the extraordinary opportunity and future of neuroscience. Like SfN, the study of neuroscience is growing rapidly, with young people flocking to the field. Tools to study the living brain and to connect brain structure and function to physiology, disease, and behavior give unmatched opportunities for scientists to understand how the brain works. The growth of neuroscience also reflects increased societal recognition of the field's importance. Understanding the brain is vitally important and urgent if humankind is to address successfully major challenges facing our society and our world, such as drug addiction, obesity and depression. As populations grow and age, understanding how to enhance human development and performance, and preserve function during aging, are critical to social and economic prosperity.

I also submit that it is vital for this subcommittee to continue to recognize and sustain U.S. leadership in the global scientific arena. Neuroscience, like all fields of science, is an increasingly global enterprise, creating opportunities for both collaboration and competition. Fundamentally, neuroscientists worldwide are motivated to answer the question "I wonder why?"—often, they seek to pursue those answers collaboratively, working across borders to tackle large problems with sophisticated technologies and coordinated sub-specialties. To that end, many countries other than the United States demonstrate established and growing scientific excellence in the field, and this is a healthy and very positive trend.

At the same time, for the United States there is growing competition for leadership in science worldwide, as many nations recognize it will be the foundation for economic prosperity in the coming decades. Over the last century, the United States has served as the global pace-setter on investment in science, and leveraged research as a primary engine for economic growth and prosperity, but this leadership is at risk. The United States has an opportunity to retain its strong and unassailable leadership in global neuroscience by continuing to invest strongly in biomedical research. An investment in basic research is an essential component for reducing healthcare spending and improving healthcare delivery. We now stand at the precipice of an economic disaster because the costs of treating many diseases, such as Alzheimer's, will be astronomical in the next 50 years. Additional scientific research is necessary to develop new treatments and cures, which will produce longer, healthier and more productive lives for Americans and create greater economic growth for our Nation.

In conclusion, NIH investments have made it possible for the field of neuroscience research to make tremendous progress to understand basic biological principles and to advance the knowledge and treatments for hundreds of neurological and psychiatric illnesses. However, continued progress can only be accomplished by consistent and reliable support. This year's investment is a building block for success 10, 15, even 20 years or more from now.

The administration's budget request for NIH is \$30.7 billion, the same amount that was funded last year. This is a welcome start but it is insufficient to maintain the scientific progress and leadership required of the United States in the 21st century. This subcommittee knows that a flat budget is a cut, given the rate of inflation. The Society for Neuroscience does not believe that reducing our commitment to research is medically or economically justified. An fiscal year 2013 NIH appropriation of at least \$32 billion and sustained reliable growth in the future is essential to take the research to the next level in order to improve the health of Americans and to maintain American leadership in science worldwide. Thank you for this opportunity to testify.

PREPARED STATEMENT OF THE SOCIETY FOR PUBLIC HEALTH EDUCATION

The Society for Public Health Education (SOPHE) is a 501(c)(3) professional organization founded in 1950 to provide global leadership to the profession of health education and health promotion. SOPHE contributes to the health of all people and the elimination of health disparities through advances in health education theory and research; excellence in professional preparation and practice; and advocacy for

public policies conducive to health. SOPHE is the only independent professional organization devoted exclusively to health education and health promotion. Members include behavioral scientists, faculty, practitioners, and students engaged in disease prevention and health promotion in both the public and private sectors. Collectively, SOPHE's 4,000 national and chapter members work in universities, medical/healthcare settings, businesses, voluntary health agencies, international organizations, and all branches of Federal/State/local government. There are currently 19 SOPHE chapters covering more than 30 States and regions across the country.

SOPHE's vision of a healthy world through health education compels us to advocate for increased resources targeted at the most pressing public health issues and disparate populations. For the fiscal year 2013 funding cycle, SOPHE encourages the Labor, Health and Human Services, Education and Related Agencies (Labor-HHS) Subcommittee to increase funding for public health programs that focus on preventing chronic disease and other illnesses in adults as well as youth, and eliminating health disparities. In particular, SOPHE requests the following fiscal year 2013 funding levels for Labor-HHS programs:

- \$7.8 billion for the Centers for Disease Control and Prevention (CDC);
- \$1 billion for the Prevention and Public Health Fund;
- \$226 million for the Community Transformation Grants (CTG) Program;
- \$100 million for the CDC Preventive Health and Health Services Block Grant;
- and
- \$378 million for the CDC Coordinated Chronic Disease Prevention and Health Promotion Program.

The discipline of health education and health promotion, which is some 100 years old, uses sound science to plan, implement, and evaluate interventions that enable individuals, groups, and communities to achieve personal, environmental and population health. There is a robust, scientific evidence-base documenting not only that various health education interventions work but that they are also cost effective. These principles serve as the basis for our support for the programs outlined below and can help ensure our Nation's resources are targeted for the best return on investment.

PREVENTING CHRONIC DISEASE

The data are clear: chronic diseases are the Nation's leading causes of morbidity and mortality and account for 75 percent of every dollar spent on healthcare in the United States. Collectively, they account for 70 percent of all deaths nationwide. Thus, it is highly likely that 3 of 4 persons living in the districts of the Labor-HHS Subcommittee members will develop a chronic condition requiring long-term and costly medical intervention in their lifetimes. Health expenditures increased from \$1.4 trillion in 2000 to \$2.6 trillion in 2010, and from 14 percent of the Gross Domestic Product to 18 percent. Yet evidence shows that investing just \$1 in preventing disease will yield a \$5 return on investment.

SOPHE is requesting a fiscal year 2013 funding level \$7.8 billion for CDC in order to prevent chronic diseases and other illnesses, promote health, prevent injury and disability, and ensure preparedness against health threats. CDC is at the forefront of U.S. efforts to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop sound public health strategies, and foster safe and healthful environments. More than 80 percent of all CDC funds are returned to States to address State and local health issues. The President's fiscal year 2013 budget proposal would reduce CDC's budget authority by \$664 million, for a total reduction of \$1.4 billion since fiscal year 2010. Studies show that spending as little as \$10 per person on proven preventive interventions could save the country more than \$16 billion in just 5 years. The public overwhelmingly supports increased funding for disease prevention and health promotion programs. Investing now in community-led, innovative programs will help to increase our Nation's productivity and performance in the global market; help ensure military readiness; decrease rates of infant mortality, deaths due to cancer, cardiovascular disease, diabetes, and HIV/AIDS, and; increase immunization rates.

SOPHE is requesting a fiscal year 2013 funding level of \$1 billion for the Prevention and Public Health Fund to sustain essential core public health infrastructure, the workforce, and our capacity to improve health in our communities. The Prevention Fund helps States tackle the leading causes of death and root causes of costly, preventable chronic disease; detect and respond rapidly to health security threats; and prevent accidents and injuries. With this investment, the Fund helps States and the Nation as a whole focus on fighting disease and illness before they happen. A July 2011 study published in the journal *Health Affairs* found that increased spending by local public health departments can save lives currently lost to prevent-

able illnesses; a 2011 Urban Institute study concluded that it is in the Nation's best interest from both a health and economic standpoint to maintain funding for evidence-based, public health programs that save lives and bring down costs; and finally, a 2011 study in Health Affairs showed a combination of three strategies (i.e. delivering better preventive and chronic care, expanding health insurance coverage, and focusing on protection) is more effective at saving lives and money than implementing any one of these strategies alone.

Although the enactment of the Middle Class Tax Relief and Job Creation Act of 2012 will reduce the Prevention and Public Health Fund by more than \$5 billion over the next 10 years, SOPHE strongly discourages further reductions in the Fund so that we can continue to strengthen core public health infrastructure, the workforce, and our capacity to improve health in our communities.

SOPHE is requesting a fiscal year 2013 funding level of \$226 million for the CTG program to empower communities to transform places where people live, work, learn, and play to promote prevention and improve health by lowering rates of chronic disease. The CTG program supports States and communities tackle the root causes of poor health so Americans can lead healthier, more productive lives. All grantees work to address the following priority areas: (1) tobacco-free living; (2) active living and healthy eating; and (3) quality clinical and other preventive services. Two-thirds of current CTG grantees address one or more other population groups experiencing disparities, including but not limited to the homeless and those living in underserved geographic areas.

The CTG program is especially needed to address the health of our Nation's youth. In the last 20 years, the percentage of overweight youth has more than doubled, and for the first time in two centuries, children may have a shorter life expectancy than their parents. Fifteen percent of children and adolescents are overweight and more than half of these children have at least one cardiovascular disease risk factor, such as elevated cholesterol or high blood pressure. At the same time that obesity is becoming an epidemic, the CDC School Health Programs and Policy Study found that the majority of schools are teaching nutrition with health education teachers who do not meet even minimal certification standards.

As part of the CTG initiative, SOPHE strongly supports CDC's Racial and Ethnic Approaches to Community Health Across the U.S. (REACH U.S.) program, which addresses health risk behaviors in both children and adults. Chronic diseases account for the largest health gap among populations and increase health disparities among racial and ethnic minority groups. As the U.S. population becomes increasingly diverse, the Nation's health expenditures will be heavily influenced by the morbidity of racial and ethnic minority communities. With CTG funding, the National REACH Coalition will address strategies in the areas of tobacco-free living, active living and healthy eating, clinical and other preventive services, social and emotional wellness, and healthy and safe physical environments—with a primary focus on African-American/Black, Hispanic/Latino, Asian, Native Hawaiian/Pacific Islander, and American Indian/Alaskan Native populations.

SOPHE is requesting a fiscal year 2013 funding level of \$100 million for the CDC's Preventive Health and Health Services Block Grant to allow each State/territory to target resources to its unique public health challenges, while requiring timely reporting and accountability. The Block Grant was eliminated in the President's fiscal year 2013 budget proposal. As a critical public health resource, the Block Grant gives States the autonomy and flexibility to tailor prevention and health promotion programs to their particular public health needs. Grantees use funds to support to areas where no Federal resources exist, or where categorical States funds are grossly insufficient for leading causes of illness, disability and death in their States/territories. With the uncertainty of State and local budgets, the proposed elimination of the Block Grant will limit the ability of public health departments to carry out essential services for chronic disease prevention, HIV/AIDs, food and water safety, bioterrorism and emergency preparedness, and other areas.

SOPHE applauds the request of \$378 million for the Coordinated Chronic Disease Prevention and Health Promotion Program, an increase of \$128 million above the fiscal year 2012 level. The approach will enable CDC to create a coordinated, national response to school health and chronic disease, maximizing program effectiveness, reducing interrelated risk factors, and accelerating health improvements. Almost 80 percent of young people do not eat the recommended 5 servings of fruits and vegetables each day. Daily participation in high school physical education classes dropped from 42 percent in 1991 to 32 percent in 2001. Among 38 States that participated in CDC's latest School Health Policies and Programs Study, the percentage of schools that required a health education course decreased between 1996 and 2000, as did the percentage of schools that taught about dietary behaviors and nutrition. Patterns of poor nutrition, lack of physical activity, and other behaviors

such as alcohol and tobacco use established during youth often continue into adulthood and contribute markedly to costly, chronic conditions.

CDC's Coordinated School Health Programs have been shown to be cost effective in improving children's health, their behavior, and their academic success. This funding builds bridges between State education and public health departments to coordinate health education, nutritious meals, physical education, mental health counseling, health services, healthy school environments, health promotion of faculty, and parent and community involvement. Gallup polls show strong parental, teacher, and public support for school health education.

Thank you for this opportunity to present our views to the Subcommittee. SOPHE gratefully acknowledges the strong support that the Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies has given to public health and prevention initiatives. We look forward to working with you to prevent chronic illness, improve the quality of lives, and save billions of dollars in healthcare spending.

PREPARED STATEMENT OF THE SLEEP RESEARCH SOCIETY

The members of the Sleep Research Society (SRS) are pleased to submit this statement for the record recommending \$32 billion in fiscal year 2013 for the National Institutes of Health (NIH). The Scleroderma Foundation also recommends maintaining the Sleep Program at the Centers for Disease Control and Prevention (CDC). Established in 1961, the Sleep Research Society (SRS) is a member organization of scientists that exists to foster scientific investigation on all aspects of sleep and its disorders, to promote training and education in sleep research, and to provide forums for the exchange of knowledge pertaining to sleep.

Sleep and circadian disturbances and disorders affect millions of Americans across all demographic groups. An estimated 25–30 percent of the general adult population, and a comparable percentage of children and adolescents, is affected by decrements in sleep health that are proven contributors to disability, morbidity, and mortality. As a result, sleep and circadian disturbances and disorders have been recognized by the Congress and the Department of Health and Human Services as high priority targets for basic and clinical scientific investigation.

In November 2011 a new NIH Sleep Research Plan was released. It identifies new opportunities for continued advances in understanding the function of sleep to inform lifestyle choices and improve the opportunity of individuals to achieve their optimal health outcome. The plan was developed through an open process with the Sleep Disorders Research Advisory Board and with input from the public, academia and healthcare professionals. The plan provides the following insights regarding sleep loss's effects on society:

Chronic sleep deficiency and circadian disruption is an emerging characteristic of modern urban lifestyles and is associated with increase disease risk through multiple complex pathways in all age groups. Developing a mechanistic understanding of the threat posed by sleep deficiency and circadian disturbance to health, healthy equity, and health disparities is an urgent challenge for biomedical research in many domains. Population-based data on the prevalence of circadian disruption and its relationship to disease risk is relatively limited. However, recent findings from large multi-site cohort studies and nationally representative surveillance data from the Centers for Disease Control indicate that sleep deficiency among Americans is pervasive, and much higher than inferred from clinical data. For example:

- Nearly 70 percent of high school adolescents sleep less than the recommended 8–9 hours of sleep on school nights despite a physiological need. Short sleep in this age group is associated with suicide risk, obesity, depression and mood problems, low grades, and delinquent behavior.
- Nationwide, 70 percent of adults report that they obtain insufficient sleep or rest at least once each month, and 11 percent report insufficient sleep or rest every day of the month.
- Frequent sleep problems are reported by 65 percent of Americans including difficulty falling asleep, waking during the night, and waking feeling unrefreshed at least a few times each week, with nearly half (44 percent) of those saying they experience that sleep problem almost every night.
- Short and long sleep duration is associated with up to a two-fold increased risk of obesity, diabetes, hypertension, incident cardiovascular disease, stroke, depression, substance abuse, and all-cause mortality in multiple studies.
- Drowsy driving may be a factor in 20 percent of all serious motor vehicle crash injuries. A large naturalistic study of 100 drivers and nearly 2 million miles of driving identified sleepiness as a factor in 22 percent of crashes, and 16 percent

of near-crashes. A third of Americans report falling asleep while driving 1 to 2 times per month and 26 percent drive drowsy during the workday.

Although knowledge of basic sleep and circadian mechanisms and the pathophysiology of sleep and circadian disorders and disturbances has advanced considerably since the 1996 NIH Sleep Disorders Research Plan was developed, important questions remain. For instance, studies are needed to stratify risks to health and identify vulnerable populations. Mechanistic studies are needed to define the genomic, physiological, neurobiological, and developmental impact of sleep and circadian disturbances. Recent findings indicate that sleep and circadian rhythms are coupled to chromatin remodeling and regulate as much as 20 percent of gene expression in peripheral tissues including the heart, liver, pancreatic islets, adipose, and immune system. Genome-wide association studies have implicated pancreatic melatonin receptor polymorphism in both blood glucose regulation and diabetes risk. Research is also needed to enhance the translation of sleep and circadian scientific advances to clinical practice, researchers in cross-cutting domains, and communities.

Advances in basic sleep and circadian knowledge are poised to provide an improved foundation for understanding how sleep and circadian rhythms contribute to health, and why a wide range of health, performance and safety problems emerge when sleep and circadian rhythms are disrupted. Strengthening and preserving our Nation's biomedical research enterprise through investment in NIH fosters economic growth and is vital to the innovations that enhance the health and well-being of the American people.

PREPARED STATEMENT OF THE SAFE STATES ALLIANCE

On behalf of the Safe States Alliance, a national membership association representing public health injury and violence prevention professionals engaged in building a safer, healthier America, we thank you for the opportunity to provide our testimony in support of the Centers for Disease Control and Prevention (CDC) and the National Center for Injury Prevention and Control (NCIPC). Safe States is committed to raising the visibility of the critical need for continued funding in State and local public health department injury and violence prevention programs.

The Safe States Alliance supports restoration of the Preventive Health and Health Services Block Grant to its fiscal year 2011 funding level of \$100 million and restoration of the CDC Injury Center to its fiscal year 2011 funding level of \$147.8 million. Preventable injuries exact a heavy burden on Americans through premature deaths and disabilities, pain and suffering, medical and rehabilitation costs, disruption of quality of life for families, and disruption of productivity for employers. Strengthening investments in public health injury and violence prevention programs is a critical step to keep Americans safe and productive for the 21st century.

The CDC Injury Center is the only Federal agency that exclusively focuses on injury and violence prevention in home, recreational, and other non-occupational settings. It leads a coordinated public health approach to addressing critical health and safety issues. Despite the enormous toll of injury and violence and the existence of cost-effective interventions, there is no dedicated and ongoing Federal, State, or local funding to adequately respond to these problems. The CDC Injury Center only receives 2 percent of the CDC/Agency for Toxic Substances and Disease Registry (ATSDR) budget to address the significant burden of injuries and violence nationwide. In fiscal year 2012, the total Injury Center budget was only \$137.7 million, down from \$147 million in fiscal year 2011.

Injuries are the leading cause of death among persons 1–44 years of age, and are a major cause of death, disability, and hospitalization for all age groups. Every 3 minutes, a person dies from a preventable injury. Every 45 minutes, one of those preventable deaths is a child. In fact, more than 500 people die each day and 180,000 die each year from injuries in the United States. More than 29 million individuals survive non-fatal injuries, only to cope with painful recoveries and rehabilitation. Among the survivors are the nearly 9.2 million children under age 19 that are seen in emergency departments for injuries.

Every year, injuries and violence will cost the United States \$406 billion: more than \$80 billion in medical costs (6 percent of total health spending) and \$326 billion in lost productivity. Long term disabilities from brain and spinal cord injuries, burns, and fall-related hip fractures frequently result in high-cost, extended care. Injuries, especially fractures, for persons age 65 and older make up a substantial proportion of Medicare expenditures. As the U.S. population continues to age, this problem will be an even more significant burden on the Medicare system.

However, injuries and violence can be prevented, and their consequences can be reduced. For example: seat belts have saved an estimated 255,000 lives between

1975 and 2008; school-based programs to prevent violence have reduced violent behavior among high school students by 29 percent; and Tai chi and other exercise programs for older adults have been shown to reduce falls by as much as half among participants.

Injuries, including falls among older adults, have significant costs for our mandatory spending programs. Currently, 35 million Americans are 65 years of age or older; by 2020 this number is expected to reach 77 million.

—The annual costs for fall-related injuries are expected to reach \$54.9 billion by 2020¹.

—Falls account for 10 percent of visits to an emergency department and 6 percent of hospitalizations among Medicare beneficiaries².

—In 2002, about 22 percent of community-dwelling seniors reported falling in the previous year. Medicare costs per fall averaged between \$9,113 and \$13,507³.

—Among community-dwelling seniors treated for fall injuries, 65 percent of direct medical costs were for inpatient hospitalizations; 10 percent each for medical office visits and home health care, 8 percent for hospital outpatient visits, 7 percent for emergency room visits, and 1 percent each for prescription drugs and dental visits. About 78 percent of these costs were reimbursed by Medicare⁴.

CDC's research has also identified other cost impacts of injuries on CMS populations including costs related to prescription drug overdoses. In Washington State, for example, from 2004 to 2007, 1,668 people died of prescription opioid-related overdoses. Of those, 45.4 percent were Medicaid enrolled, and this population had a 5.7 fold increased risk of prescription opioid-related overdose death⁵. Adoption of lock-in programs can produce significant cost benefits as in Florida, where its Medicaid lock-in program saved the State Medicaid program \$12 million in less than 3 years⁶. Washington State has informally reported savings of \$1.5 million per month with their program. Missouri, Hawaii, and Oklahoma have also reported some success. Medicaid programs spend well over \$1 billion annually on opioid painkillers, and a 2009 GAO report found that these reimbursements are rife with fraud. A survey of five States identified 65,000 beneficiaries visiting six or more doctors to acquire prescriptions for the same controlled substances. These beneficiaries cost the programs \$63 million in reimbursements for those drugs, and this number does not account for other related costs⁷.

Safe States Alliance believes that all State and territorial health departments (SHDs) in the United States must have a comprehensive injury and violence surveillance and prevention programs, similar to other public health programs for chronic disease and infectious disease prevention. These programs must be adequately staffed and funded commensurate with the magnitude of the burden of injury and violence in each State with programs and expertise to address the leading causes of unintentional and violent injuries, and have disaster and terrorism epidemiology and injury mitigation programs. SHDs bring significant leadership to reduce injuries and injury-related healthcare costs by informing the development of public policies through data and evaluation; designing, implementing, and evaluating injury and violence prevention programs in cooperation with other agencies and organizations; collaborating with partners in healthcare and throughout the community; collecting and analyzing a variety of injury and violence data to identify high-risk groups; disseminating effective practices, and providing technical support and training to injury prevention partners and local-level public health professionals. The following are examples of how SHDs have prevented injuries and protected the lives of Americans throughout the United States:

—An estimated 3,143 lives potentially have been saved since 1998 as a result of CDC-funded smoke alarm installation and fire safety education programs in

¹Englander F, Hodson TJ, Terregrossa RA. Economic dimensions of slip and fall injuries. *Journal of Forensic Science* 1996;41(5):733–46. *Journal of Gerontology* 1994;34(1):16–23.

²Carroll NV, Slattum PW, Cox FM. The cost of falls among the community-dwelling elderly. *Journal of Managed Care Pharmacy*. 2005;11(4):307–16.

³Shumway-Cook A, Ciol MA, Hoffman J, Dudgeon BJ, Yorston K, Chan L. Falls in the Medicare population: incidence, associated factors, and impact on health care. *Physical Therapy* 2009;89(4):1–9.

⁴Carroll NV, Slattum PW, Cox FM. The cost of falls among the community-dwelling elderly. *Journal of Managed Care Pharmacy*. 2005;11(4):307–16.

⁵CDC. Overdose deaths involving prescription opioids among Medicaid enrollees—Washington, 2004–2007. *MMWR*. 2010;59:705–9.

⁶Florida Medicaid. Medicaid Prescribed Drug Spending Control Program Initiatives: Quarterly Report January 1–March 31, 2005. Available at URL: http://www.fdhc.state.fl.us/medicaid/prescribed_drug/pdf%5Cquarterly_report_03_31_05.pdf.

⁷GAO. Fraud and abuse related to controlled substances identified in selected States. Sept. 2009. Available at URL: <http://www.gao.gov/new.items/d09957.pdf>.

high-risk communities. In funded States, more than 487,800 smoke alarms have been installed in approximately 250,000 homes. High-risk homes that were targeted by the program included children age 5 and younger and adults age 65 and older.

- The Bureau of Injury Prevention at the New York State Department of Health conducted a study which was published in the 2010 September issue of *Pediatrics* that found that the injury rate for motor vehicle crashes decreased by 18 percent for children 4 to 6 years of age after the State law requiring booster seats was implemented in 2005.
- Oregon's Prescription Drug Monitoring Program (PDMP) was launched by the State Injury and Violence Prevention Section in 2011 as a tool to help patients better manage their prescriptions 24 hours a day, 7 days a week. Within months, 76 percent of pharmacists were submitting to the PDMP system, more than 699,000 prescriptions had been submitted to the system, and 8,999 queries had been made by healthcare providers. The aggregate data that will be available will provide a vast new source of information for understanding the overdose epidemic in Oregon.
- Following passage of Complete Streets legislation in Hawaii, the Injury Prevention and Control Program (IPCP) was selected to participate on a statewide taskforce which was responsible for providing guidance to the State and individual counties on road design that can safely accommodate all road users.
- In 2010, with support from the CDC's Core State Injury program, the Colorado State Health Department Injury Program provided the science and data on child passenger safety to State advocates. Changes to strengthen Colorado's Child Passenger Safety Law were passed in August 2010. Colorado is now conducting a community education campaign about the change of law to support its law enforcement partners.
- In 2007, Massachusetts Department of Public Health's Traumatic Brain Injury (TBI) Task Force report identified sports concussions as a leading and growing cause of TBI in the State. In January 2009, the Massachusetts injury prevention planning group (MassPINN)—which is coordinated by the Department of Public Health using CDC Core State Injury Program funds—forged a partnership with the Sports Legacy Institute and other partners to form the Massachusetts Youth Sports Concussion Prevention Team to raise awareness of the dangers of sports-related concussions and other head injuries among youth. Over a 14-month period, more than 1,500 CDC "Heads Up" kits were distributed and more than 2,000 parents, coaches, and athletes were educated about the dangers of youth sports concussions.
- The South Carolina Department of Health and Environmental Control (DHEC) used surveillance data collected and analyzed by staff supported through CDC's Core State Injury program, to thoroughly understand the burden of older adult falls in their State and to inform partners on how this issue impacts quality of life for seniors. This data was used by a State workgroup and resulted in the funding and implementation of an evidence-based fear of fall prevention program in select communities. DHEC provides personnel time for instruction and funds to purchase training materials.

When evidence-based injury prevention strategies are implemented, the estimated return on investment is substantial. For instance, home visitation programs have been demonstrated to be particularly effective in reducing child abuse and injury, and provide a cost savings of nearly \$3 to \$6 for every \$1 spent. Other proven cost-effective injury prevention strategies include booster seats, child bicycle helmets, motorcycle helmets, sobriety checkpoints, smoke alarms and fall prevention for the elderly with total costs ranging from \$31 to \$9,600 each for cost-savings and total benefits to society⁸ between \$570 and \$73,000 for each.

Currently, NCIPC provides up to \$250,000 to 28 SHDs through the Core Violence and Injury Prevention Program (VIPP) to maintain and enhance effective delivery systems for dissemination, implementation and evaluation of best practice programs and policies. This includes support for the SHDs and their local partners, as well as strategy-specific support for the implementation of direct best practice interventions. In addition, Core VIPP supports SHDs in their efforts to work toward integration and strategically align their resources for meaningful change. According to Safe States Alliance's 2009 State of the States report, States received NCIPC Core funding were more likely to have a centralized program, a full-time director, and greater

⁸The total benefit to society is defined as the amount injury prevention interventions saved by preventing injuries, including medical costs, other resource costs (police, fire services, property damages, etc.), work loss, and quality of life costs. These benefits are calculated in 2004 dollars.

access to key injury data sets. They were more likely to provide support to local injury efforts, provide surveillance data and technical assistance. States with Core VIPP funding are also well-positioned to leverage additional resources, implement and evaluate interventions, and raise awareness of injury trends.

CDC Injury Center's Core Violence and Injury Prevention Program is the only program of its kind in the Nation. No other Federal agency funds overall injury and violence prevention capacity development. An additional investment of just \$10 million would allow the CDC Injury Center to fund all State and territorial public health departments through the Core VIPP. This funding would allow for expansion and stabilization of resources for State injury and violence prevention programs; strengthening the ability of States to improve the collection and analysis of injury data, build coalitions, and establish partnerships to promote evidence-based interventions; and dissemination of proven injury and violence prevention strategies, with a focus on persons at highest risk.

In addition to the Core VIPP program, SHDs rely on the CDC Preventive Health and Health Services Block Grant which provides approximately \$20 million for injury and violence prevention, including approximately \$6 million set-aside specifically for sexual assault prevention. According to initial findings from the 2011 State of the States survey, 30 SHD injury and violence prevention programs reported receiving an average of \$313,000 for injury and violence prevention efforts, much of which is used for local implementation of evidence-based practices. Safe States Alliance would like to thank the Committee for its consideration of this testimony.

PREPARED STATEMENT OF THE SOCIETY FOR WOMEN'S HEALTH RESEARCH

The Society for Women's Health Research (SWHR) is pleased to have the opportunity to submit the following testimony in support of ongoing Federal funding for biomedical research and specifically into biological sex differences and total women's health research—within the Department of Health and Human Services (HHS) at the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare and Research Quality (AHRQ).

SWHR believes that sustained funding for biomedical and women's health research programs conducted and supported across the Federal agencies is absolutely essential if the United States is going to meet the health needs of women and men. A well-designed and appropriately funded Federal research agenda does more than avoid dangerous and expensive "trial and error" medicine for patients—it advances the Nation's research capability, continues growth in a sector with proven return on investment, and takes a proactive approach to maintaining America's position as worldwide leader in medical research, education, and development.

In his State of the Union address, President Obama stated that investment in biomedical research "will strengthen our security, protect our planet, and create countless new jobs for our people". Proper investment in health research will save valuable dollars that are currently wasted on inappropriate treatments and procedures. Additionally, SWHR believes that targeted research into biological sex differences will help determine targeted treatments that will propel the United States into the realm of personalized medicine and usher in a 21st century approach to patient care.

NATIONAL INSTITUTES OF HEALTH

SWHR realizes that the Federal Government's focus is on austerity; however, past congressional investment for the NIH positioned the United States as the world's leader in biomedical research and has provided a direct and significant impact on women's health research and the careers of women scientists over the last decade. In recent years, that investment has declined and jeopardized America's place as the gold standard in biomedical research. Cutting NIH funding threatens scientific advancement, substantially delays cures becoming available in the United States, and puts the innovative research practices and reputation that America is known for in jeopardy.

From 2003-2012, NIH has faced a 20.8 percent decrease in buying power as a direct result of budget cuts. When faced with budget cuts, NIH is left with no other option but to reduce the number of grants it is able to fund. The number of new grants funded by NIH had dropped steadily with declining budgets, growing at a percent less than that of inflation since fiscal year 2003. A shrinking pool of available grants has a significant impact on scientists who depend upon NIH support to cover both salaries and laboratory expenses to conduct high quality biomedical research, putting both medical advancement and job creation at risk. More than 83 percent of NIH funding is spent in communities across the Nation, creating jobs at

more than 3,000 universities, medical schools, teaching hospitals, and other research institutions in every State.

Reducing the number of grants available to researchers further decreases publishing of new findings and decreases the number of scientists gaining experience in research, impacting a scientist's likelihood of continuing research. New and less established researchers are forced to consider other careers, or take positions outside the United States, resulting in the loss of the skilled bench scientists and researchers desperately needed to sustain America's cutting edge in biomedical research.

While the U.S. deficit requires careful consideration of all funding and investments, cutting relatively small discretionary funding within the NIH budget will not make a substantial impact on the deficit, but will drastically hamper the ability of the United States to remain the global leader in biomedical research. SWHR and WHRC recommend that the Congress set, at a minimum, a budget of \$32 billion for NIH for fiscal year 2013.

Study of Sex Differences

Scientists have just begun to uncover the significant biological and physiological differences between women and men and its impact health and medicine. Sex-based biology, the study of biological and physiological differences between women and men, has revolutionized the way that the scientific community views the sexes. Sex differences play an important role in disease susceptibility, prevalence, time of onset and severity and are evident in cancer, obesity, heart disease, immune dysfunction, mental health disorders, and many other illnesses. Medications can have different effects in woman and men, based on sex specific differences in absorption, distribution, metabolism and elimination. It is imperative that research addressing these important differences be supported and encouraged.

SWHR recommends that NIH, with the funds provided, be mandated to report sex/gender differences in all research findings, including those studying a single sex but with explanation and justification. Further, NIH should seek to expand its inclusion of women in basic, clinical and medical research to Phase I, II, and III studies. By currently mandating sufficient female subjects only in Phase III, researchers often miss out on the chance to look for variability by sex in the early phases of research, where scientists look at treatment safety and determine safe and effective dose levels for new medications. By including female subjects in earlier phases of clinical research studies, the NIH will serve as a role model for industry research, as well as other nations. Only by gaining more information on how therapies work in women will medicine be able to advance toward more targeted and effective treatments for all patients, women and men alike.

Office of Research on Women's Health

The NIH's Office of Research on Women's Health (ORWH) serves as the focal point for coordinating women's health and sex differences research at NIH, advising the NIH Director on matters relating to research on women's health and sex differences research, strengthening and enhancing research related to diseases, disorders, and conditions that affect women; working to ensure that women are appropriately represented in research studies supported by NIH; and developing opportunities for and support of recruitment, retention, re-entry and advancement of women in biomedical careers.

The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR) are two ORWH programs that benefit the health of both women and men through sex and gender research, interdisciplinary scientific collaboration, and provide tremendously important support for young investigators in a mentored environment.

The BIRCWH program, created in 2000, is an innovative, trans-NIH career development program that provides protected research time for junior faculty by pairing them with senior investigators in an interdisciplinary mentored environment. Each BIRCWH receives approximately \$500,000 a year, most from the ORWH budget. To date, more than 400 scholars have been trained in 41 centers, and 80 percent of those scholars have been female. The BIRCWH centers have produced more than 1,300 publications, 750 abstracts, 200 NIH grants and 85 awards from industry and institutional sources.

SCORs, established in 2003, are designed to increase innovative, interdisciplinary research focusing on sex differences and major medical problems that affect women through centers that facilitate basic, clinical, and translational research. Each SCOR program results in unique research and has resulted in more than 150 published journal articles, 214 abstracts and presentations and 44 other publications.

Additionally, ORWH has created several additional programs to advance the science of sex differences research and research into women's health. The Advancing Novel Science in Women's Health Research (ANSWHR) program, created in 2007, promotes innovative new concepts and interdisciplinary research in women's health research and sex/gender differences. The Research Enhancement Awards Program (REAP) supports meritorious research on women's health that otherwise would have missed the NIH institute and center (IC) pay line.

In addition to its funding of research on women's health and sex differences research, ORWH has established several methods for dissemination information about women's health and sex differences research. ORWH created the Women's Health Resources web portal in collaboration <http://www.womenshealthresources.nlm.nih.gov> with that National Library of Medicine, to serve as a resource for researchers and consumers on the latest topics in women's health and uses social media to connect the public to health awareness campaigns.

To allow ORWH's programs and research grants to continue make their impact on research and the public, the Congress must direct that NIH continue its support of ORWH and provide it with a \$1 million budget increase, bringing its fiscal year 2013 total to \$43.3 million.

Health and Human Services' Office of Women's Health

The HHS Office of Women's Health (OWH) is the Government's champion and focal point for women's health issues. It works to redress inequities in research, healthcare services, and education that have historically placed the health of women at risk. Without OWH's actions, the task of translating research into practice would be only more difficult and delayed.

Under HHS, the agencies currently with offices, advisors or coordinators for women's health or women's health research include the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Quality and Research (AHRQ), Indian Health Service (INS), Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), and Centers for Medicare and Medicaid Services (CMS). It is imperative that all these offices are funded at levels which are adequate for them to perform their assigned missions, and are sustainable so as to support needed changes in the long term. This is especially true for HRSA, which promotes an integrated approach to women's health across the lifespan and helps low income women access necessary health services. SAMHSA has taken a lead role promoting improvement in women's mental health services and best-practices. The agency also devotes significant resources to assist the VA and DOD with mental health services and support for members of the armed services, their families and veterans. It is only through consistent funding that these offices, as well as the OWH are able to achieve their goals.

We ask that the Committee report reflect the Congress' support for these Federal women's health offices, and recommend that they are appropriately funded on a permanent basis to ensure that these programs can continue and be strengthened in the coming fiscal year. These offices do important work, both individually and in collaboration with other offices and Federal agencies—to ensure that women receive the appropriate care and treatments in a variety of different areas. The budgets for these offices have been flat-lined in recent years, which results in effectively a net decrease due to inflation. Considering the impact of women's health programs from OWH on the public, we urge the Congress to provide an increase of \$1 million for the HHS OWH, a total \$34.7 million requested for fiscal year 2013.

CENTERS FOR DISEASE CONTROL AND PREVENTION

The CDC's Office of Women's Health (OWH) works to promote and protect the health, safety, and quality of life of women at every stage of life. SWHR supports the domestic and international work of the office. While SWHR is delighted that the CDC's OWH is now codified in statute, we are concerned that proposed cuts to the CDC budget by the administration will significantly jeopardize programs that benefit women, leaving them with even fewer options for sound clinical information. Research and clinical medicine are still catching up from decades of a male-centric focus, and when diseases strike women, there remains a paucity of basic knowledge on how diseases affect female biology, a lack of drugs that have been adequately tested in women. Now even fewer options for information through the many educational outreach programs of the CDC.

The OWH within CDC plays a fundamental role in the agency; leading the CDC in the collaboration with other offices in CDC, HHS, and the State Department in the early development of the Global Health Initiative. In 2012, CDC OWH functioned with a budget of just \$473,291 and routinely collaborates with other agencies

to advance the knowledge and research into women's health issues. In a time of limited budgetary dollars, the Congress should invest in those offices that promote working in collaboration with other agencies, which shares much needed expertise while avoiding unnecessary duplication. SWHR recommends that the Congress provide the CDC OWH with a 1.06 percent increase for fiscal year 2013, bringing their total to \$478,000.

AGENCY FOR HEALTHCARE AND RESEARCH QUALITY

The Agency for Healthcare Research and Quality's work serves as a catalyst for change by promoting the results of research findings and incorporating those findings into improvements in the delivery and financing of healthcare. Through AHRQ's research projects, lives have been saved. For example, it was AHRQ who first discovered that women treated in emergency rooms are less likely to receive life-saving medication for a heart attack. AHRQ funded the development of two software tools, now standard features on hospital electrocardiograph machines, which have improved diagnostic accuracy and dramatically increased the timely use of "clot-dissolving" medications in women having heart attacks. As efforts to improve the quality of care, not just the quantity of care, progress, findings such as these coming out of AHRQ reveal where relatively modest investments can offer significant improvement to women's health outcomes, as well as a better return on investment for scarce healthcare dollars.

While AHRQ has made great strides in women's health research, the agency has always lacked the funding to truly revolutionize healthcare in America. Funds from the American Recovery and Reinvestment Act moved AHRQ in the right direction; however, those funds were never added to AHRQ's base funding level. SWHR recommend the Congress fund AHRQ at the President's request for fiscal year 2013, with \$334 million acting as AHRQ's base discretionary funds. This investment ensures that adequate resources are available for high priority research, including women's healthcare, sex- and gender-based analyses, and health disparities—valuable information that can help to better personalize treatments, lower overall medical spending, and improve outcomes for female and male patients nationwide.

In conclusion, Mr. Chairman, we thank you and this Committee for its strong record of support for medical and health services research and its commitment to the health of the Nation through its support of peer-reviewed research. We look forward to continuing to work with you to build a healthier future for all Americans.

PREPARED STATEMENT OF THE TRUST FOR AMERICA'S HEALTH

My name is Jeff Levi, and I am Executive Director of Trust for America's Health (TFAH), a nonprofit, nonpartisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. I am grateful for the opportunity to submit testimony to the Subcommittee regarding funding for key public health programs. As you craft the fiscal year 2013 Labor, Health and Human Services, Education and Related Agencies (LHHS) appropriations bill, I urge you to include adequate funding for prevention and preparedness programs to promote America's health. Moreover, as you work with the Department of Health and Human Services (HHS) to allocate funding from the Prevention and Public Health Fund (Fund), I urge you to ensure that the Fund is invested in transformative programs that will modernize our public health system, lower health costs, and enable Americans to lead longer, healthier lives.

Centers for Disease Control and Prevention (CDC).—TFAH is extremely concerned by the diminished funding proposed for the Centers for Disease Control and Prevention. The President's fiscal year 2013 budget calls for a \$664 million reduction in budget authority for CDC, which is an 11.7 percent cut from fiscal year 2012, and a \$1.4 billion cut since fiscal year 2010. These cuts will force the Agency to choose between vaccinating children against deadly, preventable illnesses, detecting foodborne outbreaks, and preventing death and injury from the next disaster. We urge you to restore base funding to no less than last year's level, or at least protect CDC from further cuts and focus our investment on cost-effective public health and prevention programs.

The Prevention and Public Health Fund.—The Prevention and Public Health Fund is the only dedicated funding for prevention and public health in U.S. history. Despite the cut contained in the Middle Class Tax Relief and Job Creation Act, the Fund will still provide an additional \$12.5 billion over the next 10 years (fiscal year 2013 to fiscal year 2022) to enable communities in every State to invest in effective, proven prevention efforts. To date, the Fund has invested \$2.25 billion since fiscal year 2010 to support State and local public health efforts to transform and revitalize

communities, build epidemiology and laboratory capacity to track and respond to disease outbreaks, train the Nation's public health and health workforce, prevent the spread of HIV/AIDS, expand access to vaccines, reduce tobacco use, and help control the obesity epidemic.

The Fund was intended to supplement, not supplant, existing investments with the first-ever, reliable national funding stream for public health, while creating jobs, bending the healthcare cost curve, and prioritizing disease prevention. In the long-run, expenditures from the Fund should be guided by the National Prevention Strategy (NPS). The Fund gives the Congress the authority to direct the investment, while at the same time guaranteeing an ongoing commitment to prevention unprecedented in today's "sick care" system. Eliminating the Fund, or using a substantial portion of it to supplant existing discretionary dollars, would be an enormous step backwards in our progress on cost containment, public health modernization, and wellness promotion. We urge the Committee to protect the Fund and ensure it is used to reduce healthcare costs and help create a long-term path to a healthier and economically sound America.

Community Transformation Grants.—Chronic diseases are responsible for 75 percent of healthcare costs in the United States, and the causes are often environmental, social, or economic and not addressed by the clinical care system. The Community Transformation Grants (CTG) program, administered by the CDC, implements and evaluates evidence-based community preventive health activities to reduce chronic disease and address health disparities. The program focuses on innovative, cross-cutting approaches to reducing health risks. The program aligns with the NPS by funding multi-sector coalitions to make healthy living easier and more affordable where people work, live, learn, play, and exercise. We recommend the Committee allocate \$250 million for the CTG program in fiscal year 2013, which will permit CDC to continue funding the current grantees and fund additional communities to broaden the scope and success of the program to reach millions more Americans. Grants will be used for both community prevention capacity building and investing in targeted interventions to reduce the prevalence of the leading causes of death, associated risk factors, and health disparities.

National Center for Chronic Disease Prevention and Health Promotion.—Starting in 2011, CDC awarded coordinated chronic disease State grants to all 50 States to begin to build a core capacity to address common risk factors and implement comprehensive strategies for promoting health. CDC recently concluded its first round of meetings with regional grantees and many States are already reporting considerable progress in their efforts to reorganize and achieve progress toward this new approach. TFAH recommends a funding level of \$42 million for the Coordinated Chronic Disease State Grants for fiscal year 2013, which will permit CDC to continue to support all States in their efforts to coordinate and integrate chronic disease funding and activities. The President's proposal to consolidate budget lines for the Center is another approach that could further aid coordination of national and State chronic disease activities.

Racial and Ethnic Approaches to Community Health (REACH) programs work in communities across the country to eliminate racial and ethnic disparities in health and reduce the burden of chronic disease among at-risk populations. REACH partners employ innovative, culturally competent, community-based, and participatory approaches to develop and implement evidence-based practices, empower communities, and reduce health disparities. TFAH recommends maintaining the REACH program at the fiscal year 2012 funding level of \$53.94 million. Eliminating REACH would have a devastating impact on the underserved communities benefiting from REACH, and would prevent dissemination of best practices from REACH communities that can reduce health disparities throughout the Nation.

National Center for Environmental Health (NCEH).—Since fiscal year 2009, NCEH funding has been cut approximately 25 percent. NCEH cannot afford to sustain additional funding cuts without critically damaging our Nation's core environmental health infrastructure. The cuts implemented to the Healthy Homes and Lead Poisoning Prevention program for fiscal year 2012 alone will jeopardize the health of families and nearly 450,000 children living in homes nationwide where exposure to lead, rodent infestation, and other risk factors is likely. We support funding for NCEH at \$181.66 million for fiscal year 2013.

Since 2002, the mission of the National Environmental Public Health Tracking Network has been to provide information that communities can use to improve their health; the information will come from a nationwide network that brings together health and environmental data. The program currently operates in 23 States and one city. TFAH recommends \$43 million for the Tracking Network to expand the program to link environmental and health data to identify problems and effective solutions that will reduce the burden of chronic disease. This level of funding would

enable CDC to fund at least five additional grantees. An additional \$5 million over the fiscal year 2012 level would enable the program to add at least three States to the existing network. However, the current level of funding is not sufficient to fill the health and environmental data gap that is preventing our full understanding of how our health is affected by the environment.

For over 30 years, the Environmental Health Laboratory of NCEH has been performing biomonitoring measurements—direct measurements of people’s exposure to toxic substances in the environment. TFAH recommends a funding increase of \$2 million from fiscal year 2012 levels to enable the Division of Laboratory Sciences to work with the clinical laboratory community to create a standardized measurement process for several cardiovascular disease biomarkers. A reference method for these specific biomarkers would improve diagnosis of disease and create a tremendous return on investment for Federal and State healthcare programs.

Public Health Emergency Preparedness.—The State & Local Preparedness & Response Capability program at the Centers for Disease Control and Prevention is the only Federal program that supports the work of health departments to prepare for and respond to all types of disasters, including bioterror attacks, natural disasters, and infectious disease outbreaks. The centerpiece of the program is the Public Health Emergency Preparedness (PHEP) Cooperative Agreements. PHEP grants support all 50 States, as well as major cities and territories, to develop 15 core public health capabilities identified by CDC, including in the areas of biosurveillance, community resilience, countermeasures, mitigation, incident management, information management, and surge management. TFAH recommends providing \$761.1 million for State and Local Preparedness and Response Capability, equivalent to the fiscal year 2010 allocation. Recent and proposed cuts mean that our Nation may be less prepared than it was just a few years ago, including the potential loss of as many as 1,500 highly trained frontline public health preparedness workers, reducing the number of high-level laboratories, defunding academic and research centers, and eroding training, exercise, planning, epidemiology, and surveillance capacity. Preparedness is dependent on maintaining a well-trained public health workforce, and inconsistent funding results in serious gaps in our ability to respond to new health threats.

In the event of a major disease outbreak or bioterror attack, the public health and healthcare systems would be severely overstretched. TFAH recommends \$426 million for fiscal year 2013 for Hospital Preparedness Program (HPP), equivalent to the fiscal year 2010 allocation. The HPP, administered by the Assistant Secretary for Preparedness and Response (ASPR), provides funding and technical assistance to prepare the health system to respond to and recover from a disaster. The program, which began in response to 9/11, has evolved from one focused on equipment and supplies held by individual hospitals to respond to a terrorist event to a system-wide, all-hazards approach. Funding for HPP must be maintained to retain and build on the progress made in hospitals’ ability to respond to a disaster.

Pandemic Influenza and Medical Countermeasures Enterprise.—The 2011 H1N1 flu outbreak demonstrated how rapidly a new strain of flu can emerge and spread around the world. In 2011, CDC confirmed reports from several States of the first human-to-human transmission of a novel H3N2v influenza virus, illustrating how quickly the virus can mutate and spread. Funding for research, prevention, and response cannot simply be provided after a pandemic emerges. TFAH recommends \$160 million for CDC’s seasonal and pandemic influenza program, equivalent to the fiscal year 2012 allocation, to ensure preparedness for this deadly infectious disease. In fiscal year 2013, CDC will use the funding to continue to protect the public against seasonal flu, track the H3N2 variant, monitor changes in the deadly H5N1 virus, work to reduce ongoing racial and ethnic disparities in adult vaccine demand, and plan for deploying new advances in vaccine formulations and diagnostics.

The Biomedical Advanced Research and Development Authority (BARDA), within the office of the Assistant Secretary for Preparedness and Response was established in 2006 to jumpstart a new cycle of innovation in vaccines, diagnostics, and therapeutics, which would not be developed in the private market, in order to combat emerging health threats. BARDA provides incentives and guidance for research and development of products to counter bioterrorism and pandemic flu and manages Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents. TFAH recommends \$547 million for BARDA for fiscal year 2013 to continue development and acquisition of medical products key to America’s biodefense strategy.

The President’s fiscal year 2013 request also includes funding for a new medical countermeasure strategic investment (MCMSI) firm, as proposed in the 2011 review. TFAH recommends \$50 million to launch the MCM Strategic Investor to provide

business and financial resources to biotech firms working to bring medical countermeasures into production.

Global Disease Detection.—Through integrated disease surveillance, prevention and control activities, CDC's Global Disease Detection (GDD) program aims to recognize infectious disease outbreaks faster, improve the ability to control and prevent outbreaks, and to detect emerging microbial threats, in support of the International Health Regulations. In collaboration with host countries and the World Health Organization, CDC has established seven GDD Regional Centers, which strengthen our capacity to detect and respond to infectious disease outbreaks before they reach American shores, such as respiratory syndromes, diarrheal diseases, food-borne illnesses, and zoonotic diseases. TFAH recommends a \$6 million increase for the GDD Program in fiscal year 2013, which would add at least two new Regional Centers, and enhance capacity at two existing Regional Centers. This increase would broaden our geographic coverage by establishing new developing Centers in West Africa or South America. According to CDC, additional cuts to the program could result in the closure of existing Regional Centers and diminished capacity at other Regional Centers. Establishing a Center requires years of negotiation, training, and nurturing of partnerships between CDC and local health and governmental officials. Closing a Center could result in that nation or region remaining closed to CDC for years to come.

Conclusion

Investing in disease prevention is the most effective, common-sense way to improve health. Hundreds of billions of dollars are spent each year via Medicare, Medicaid, and other Federal healthcare programs to pay for healthcare services once patients develop an acute illness, injury, or chronic disease and present for treatment in our healthcare system. A sustained and sufficient level of investment in public health and prevention is essential to reduce high rates of disease and improve health in the United States. Mr. Chairman, thank you again for the opportunity to submit testimony on the urgent need to enhance Federal funding for public health programs which can save countless lives and protect our communities and our Nation.

PREPARED STATEMENT OF THE AIDS INSTITUTE

The AIDS Institute, a national public policy research, advocacy, and education organization, is pleased to comment in support of critical HIV/AIDS and Hepatitis programs as part of the fiscal year 2013 Labor, Health and Human Services, Education and Related Agencies appropriation measure. We thank you for your support over the years, and hope you will adequately fund them in the future in order to provide for and protect the health of many Americans.

HIV/AIDS remains one of the world's worst health pandemics. According to the Centers for Disease Control (CDC), more than 620,000 people have died of AIDS and there are 50,000 new infections each year in the United States. An all-time high of approximately 1.2 million people in the United States are living with HIV/AIDS. Persons of minority races and ethnicities are disproportionately affected, as well as low income people, with nearly 90 percent of those infected relying on publicly funded healthcare.

The vast majority of the discretionary programs supporting domestic HIV/AIDS efforts are funded through your Subcommittee. We are keenly aware of current budget constraints and competing interests for limited dollars, but programs that prevent and treat HIV are inherently in the Federal interest as they protect the public health. The AIDS Institute, working in coalition with others, has developed funding request numbers for each of these programs. We ask that you do your best to adequately fund them at the requested level.

National HIV/AIDS Strategy

The Obama administration is implementing a comprehensive National HIV/AIDS Strategy (NHAS) that seeks to reduce new HIV infections, increase access to care and improve health outcomes for people living with HIV, as well as reduce HIV-related health disparities. The Strategy sets ambitious goals and seeks a more coordinated national response with a focus on communities where HIV is most prevalent and on programs that work. In order to attain the goals, additional investment in key areas will be needed and health reform must be implemented.

Centers for Disease Control and Prevention-HIV Prevention and Research

Fiscal year 2012: \$786.2 million

Fiscal year 2013 community request: \$1,311.2 million

The United States allocates only 3 percent of its domestic HIV/AIDS spending on prevention. Investing in prevention today will save money tomorrow. Preventing one infection will save approximately \$355,000 in future lifetime medical costs. Preventing all the new 50,000 cases in just 1 year would translate into an astounding \$18 billion in lifetime medical costs.

The CDC is focused on carrying out several goals of the NHAS. Specifically, (1) lowering the annual number of new infections by 25 percent; (2) reducing the transmission rate by 30 percent; and (3) increasing from 79 to 90 the percentage of people living with HIV who know their serostatus. In order to address the needs of affected populations and the increased number of people living with HIV, CDC needs additional funding. While an increase of more than \$500 million would be needed to achieve the goals of the NHAS, The AIDS Institute supports an increase of at least \$40.2 million over fiscal year 2012, as proposed by the President.

With this funding, the CDC will be able to implement its new, high-impact approach to HIV prevention, based on the combination of scientifically proven, cost-effective, and scalable interventions directed to the right populations in the right areas. Funds will also expand HIV testing.

Included in the President's CDC HIV budget proposal is \$10 million to restore a 25 percent cut to HIV Division of Adolescent and School Health (DASH) programs. The CDC reports that young people aged 13–29 accounted for 39 percent of all new HIV infections in 2009. The AIDS Institute strongly supports the restoration of these funds.

Ryan White HIV/AIDS Programs

Fiscal year 2012: \$2,392.2 million

Fiscal year 2013 community request: \$2,875.0 million

The centerpiece of the Government's response to caring for and treating low-income people with HIV/AIDS is the Ryan White HIV/AIDS Program. It now serves 577,000 low-income, uninsured, and underinsured people. In fiscal year 2012, all but one part of the Program experienced cuts in appropriated dollars. This is occurring at a time of increased need and demand. Consider the following:

- Caseloads are increasing. People with HIV are living longer due to lifesaving medications, and each year there are 50,000 new infections with increased testing programs identifying thousands of new people infected with HIV. As unemployment rates climb, people are losing their employer-sponsored health coverage.

- Recent research has proven that HIV treatment also serves as HIV prevention.

In 2011, a landmark study found that successful anti-retroviral treatment of HIV reduced the risk of transmitting the virus to others by up to 96 percent.

- There are significant numbers of people with HIV in the United States who are not in care and receiving life-saving AIDS medications. Recent CDC analysis reveals that only 41 percent of the 1.2 million people living with HIV in the United States are retained in HIV care and only 28 percent have a suppressed viral load.

Specifically, The AIDS Institute requests the following:

Part A provides medical care and vital support services for persons living with HIV/AIDS in the metropolitan areas most affected by HIV/AIDS. We request an increase of \$118.2 million, for a total of \$789.5 million.

Part B Base provides essential services including diagnostic, viral load testing and viral resistance monitoring, and HIV care to all 50 States, DC, Puerto Rico, and the territories. We are requesting an \$80.7 million increase, for a total of \$502.9 million.

The AIDS Drug Assistance Program (ADAP) provides life-saving HIV drug treatment to more than 209,000 people, or about 46 percent of the HIV positive people in care in the United States. The majority of whom are people of color (65 percent) and very poor (75 percent are at or below 200 percent of the Federal poverty level). ADAPs are experiencing unprecedented growth. Over the course of fiscal year 2011, HRSA reports that nearly 15,000 new people were added to the program.

At the same time, State budgets have been stretched and the Federal contribution to the program as a percentage has dropped resulting in a crisis situation. According to NASTAD, State funding for ADAPs increased 11.5 percent between fiscal year 2010 and fiscal year 2011, and drug company rebates grew 18.43 percent to \$618.9 million.

Because of a lack of funding, there are currently 3,097 people in 10 States on waiting lists, thousands more have been removed from the program due to lowered eligibility requirements, and drug formularies have been reduced. The AIDS Institute is very appreciative of the \$15 million increase to ADAP in fiscal year 2012, but it is far from what is currently required to meet the growing demand.

Recognizing the current ADAP crisis, on World AIDS Day, December 1, 2011, President Obama announced a transfer of \$35 million from existing health programs to ADAP. The President proposes to continue that funding into fiscal year 2013 as part of his budget as well as an increase of \$66.7 million for a total of \$1 billion. While this is short of the actual need of \$1,123.3 million, The AIDS Institute strongly supports this increase.

Part C provides early medical intervention and other supportive services to 255,000 people at 345 directly funded clinics. Recognizing the shortage of resources for providing healthcare, on World AIDS Day 2011, President Obama redirected \$15 million to Part C Programs. The President is requesting to continue this funding in his fiscal year 2013 budget and increase it by \$15 million. While still short of the actual total need of \$286 million, The AIDS Institute supports this request.

Part D provides care to more than 90,000 women, children, youth, and families living with and affected by HIV/AIDS at 700 sites. This family centered care promotes better health, prevents mother-to-child transmission, and brings hard-to-reach youth into care. We are disappointed that the President has proposed cutting Part D programs by \$7.6 million and ask that you reject this request. Rather, The AIDS Institute supports a \$10.1 million increase, for a total of \$87.3 million.

Part F includes the AIDS Education and Training Centers (AETCs) program and the Dental Reimbursement program. We are requesting a \$7.7 million increase for the AETC program, for a total of \$42.2 million, and a \$5.5 million increase for the Dental Reimbursement program, for a total of \$19 million.

National Institutes of Health-AIDS Research

Fiscal year 2012: \$3.07 billion

Fiscal year 2013 community request: \$3.5 billion

The NIH conducts research to better understand HIV and its complicated mutations, discover new drug treatments, develop a vaccine and other prevention programs such as microbicides, and ultimately develop a cure. This research has already helped in the development of many highly effective new drug treatments, however as neither a cure nor a vaccine exists, and patients continue to build resistance to medications, additional research must be carried out. We ask the Committee to fund critical AIDS research at the community requested level of \$3.5 billion.

Comprehensive Sexuality Education

Since the vast majority of HIV infection occurs through sex, age appropriate education on how HIV is transmitted and how one can prevent transmission is critical. It is for this reason The AIDS Institute supports the funding of the Teen Pregnancy Prevention Initiative for a total of \$130 million. Additionally, we oppose funding of abstinence only education programs, which have proven to be ineffective.

Minority AIDS Initiative

The AIDS Institute supports increased funding for the Minority AIDS Initiative (MAI), which funds services nationwide that address the disproportionate impact that HIV has on communities of color. For fiscal year 2013, we are requesting a total of \$610 million.

Policy Riders

The AIDS Institute is opposed to using the appropriations process as a vehicle to repeal or prevent the implementation of current law or ban funding for certain activities or organizations. This includes implementation of the Affordable Care Act. We urge you not to prevent the implementation of programs, such as syringe exchange programs, which are scientifically proven to prevent HIV and Hepatitis. The AIDS Institute was disappointed the Federal funding ban was reinstated in fiscal year 2012, and appreciates that this language was not included in the President's budget.

Viral Hepatitis

There are more than 5.3 million people in the United States infected with viral hepatitis, but hepatitis prevention at the CDC is funded at only \$29.8 million. This is insufficient to provide basic health services or to implement the HHS Viral Hepatitis Action Plan. While the President's fiscal year 2013 budget flat funds overall CDC Hepatitis programs at \$29.7 million, it does include \$10 million allocated from the Prevention and Public Health Fund in fiscal year 2012 to continue as appropriated dollars in fiscal year 2013. For fiscal year 2013, we request an increase of \$30.1 million for a total of \$59.8 million.

The AIDS Institute asks that you give great weight to our testimony as you develop the fiscal year 2013 appropriation bill. Should you have any questions or com-

ments, feel free to contact Carl Schmid, Deputy Executive Director, The AIDS Institute, cschmid@theaidsinstitute.org.

Thank you very much.

PREPARED STATEMENT OF THE ENDOCRINE SOCIETY

The Endocrine Society is pleased to submit the following testimony regarding fiscal year 2013 Federal appropriations for biomedical research, with an emphasis on appropriations for the National Institutes of Health (NIH). The Endocrine Society is the world's largest and most active professional organization of endocrinologists representing more than 15,000 members worldwide. Our organization is dedicated to promoting excellence in research, education, and clinical practice in the field of endocrinology. The Society's membership includes thousands of researchers who depend on Federal support for their careers and their scientific advances.

A half century of sustained investment by the United States Federal Government in biomedical research has dramatically advanced the health and improved the lives of the American people. The NIH specifically has had a significant impact on the United States' global preeminence in research and fostered the development of a biomedical research enterprise that was at one time unrivaled throughout the world. However, the dominance of the U.S. research enterprise is being sorely tested with the consistently low funding increases allotted to the NIH since 2003. Just one small example of this is the dramatic increase in the percentage of manuscripts from investigators in Europe and Asia that are published in our own journals.

While funding for basic research in the United States appears to be slowing down, other countries are ramping up funding. China, for instance, plans to increase investment in basic research by 26 percent per year, and European countries will increase funding for basic research over the next 7 years by 40 percent.¹ The countries of China, Ireland, Israel, Singapore, South Korea and Taiwan collectively increased their research and development (R&D) investments by 214 percent between 1995 and 2004. The United States increased its total R&D investments by 43 percent during the same period.²

Although some would argue that the investment of other countries in R&D will benefit the United States through the subsequent discoveries, innovation is one of the keys to the economic growth and stability of our country. As President Obama stated, "The key to our success—as it has always been—will be to compete by developing new products, by generating new industries, by maintaining our role as the world's engine of scientific discovery and technological innovation. It's absolutely essential to our future." Unfortunately, the President's fiscal year 2013 budget request for the NIH does not reflect this commitment.

The relative lack of support for funding the biomedical research enterprise has consequences for our economy. Funding from the NIH supported more than 432,000 jobs and generated more than \$62.1 billion in economic activity last year. More than 80 percent of its budget directly funds "extramural" research performed by 325,000 scientists at more than 3,000 institutions in all 50 States and the District of Columbia.³ While the number of jobs supported is impressive, it is unfortunately a decline from 2010, when the money spent by NIH extramurally supported 487,900 jobs, approximately 55,000 more jobs than in 2011. This is a direct illustration of the impact that lack of sustained investment in the agency is beginning to have.

In addition to creating jobs, funds from NIH grants put money back into the local and State economies through salaries and purchase of equipment, laboratory supplies, and vendor services. On average, for each dollar of taxpayer investment, NIH grants generate \$2.21 in economic activity. As an example, UCLA generates almost \$15 in economic activity for each dollar, resulting in a \$9.3 billion impact on the region. The estimated economic impact of Baylor on the surrounding community is more than \$358 million, generating more than 3,300 jobs.⁴

Although the NIH has a significant impact on our local, State, and national economies, its primary purpose is to improve the health of the American people. Each year, the NIH funds thousands of research grants, facilitating the discovery of methods of prevention, treatment, and cure for debilitating diseases that negatively impact the health of the Nation's citizens and fuel rising healthcare costs. Nearly half

¹Dr. Francis Collin's Testimony to House Appropriations Subcommittee. March 20, 2012

²The Task Force on the Future of American Innovation. *Measuring the Moment: Innovation, National Security, and Economic Competitiveness*.

³United for Medical Research. *NIH's Role in Sustaining the U.S. Economy; A 2011 Update*. March 20, 2012.

⁴Federation of American Societies for Experimental Biology. *NIH Advocacy Slides: California, Texas*.

of all Americans have a chronic medical condition, and these diseases now cause more than half of all deaths worldwide. Deaths attributed to chronic conditions could reach 36 million by 2015 if the trend continues unabated. In order to prevent and treat these diseases, and save the country billions in healthcare costs, significant investment in biomedical research will be needed.

During a time of economic instability, investment in biomedical research makes sense because it leads to cures and treatments for debilitating diseases while at the same time generating significant economic activity for the local community.

The Endocrine Society remains deeply concerned about the future of biomedical research in the United States without sustained support from the Federal Government. The Society strongly supports increased Federal funding for biomedical research in order to provide the additional resources needed to enable American scientists to address the burgeoning scientific opportunities and maintain the country's status of the preeminent research enterprise. The Endocrine Society recommends that NIH receive at least \$32 billion in fiscal year 2013. This funding recommendation represents the minimum investment necessary to avoid further loss of promising research and global preeminence, while allowing the NIH's budget to keep pace with biomedical inflation.

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

On behalf of The Humane Society of the United States (HSUS) and the Humane Society Legislative Fund (HSLF), and our joint membership of more than 11 million supporters nationwide, we appreciate the opportunity to provide testimony on our top NIH funding priorities for the Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittee in fiscal year 2013.

BREEDING OF CHIMPANZEES FOR RESEARCH

The HSUS requests that no Federal funding be appropriated for the breeding of chimpanzees for research purposes. The National Institutes of Health has had a moratorium on the breeding of federally owned and federally supported chimpanzees in place since 1995, but evidence shows that Government supported breeding still continues. However, given the lack of necessity for chimpanzees as models for human disease, the exorbitant costs of maintaining chimpanzees in laboratories, and the ethical issues surrounding the use of chimpanzees, there is no justification for the breeding of additional chimpanzees, who have a lifespan of up to 60 years, for research; therefore, Federal funds should not be used for this purpose.

Further basis of our request can be found below.

Background Information and Costs

In 1995, the National Institutes of Health implemented a moratorium on the breeding of federally owned and supported chimpanzees, due to a "surplus" of chimpanzees and the excessive costs of lifetime care of chimpanzees in laboratory settings.¹ The cost of maintaining chimpanzees in laboratories is exorbitant, up to \$66 per day per chimpanzee; more than \$1 million per chimpanzee over an individual's approximately 60-year lifetime. Breeding of additional chimpanzees into laboratories will only perpetuate and increase the burdens on the Government in supporting and managing the chimpanzee research colony.

The breeding moratorium was extended indefinitely in 2007. As a result, none of the federally owned chimpanzees should have given birth or sired infants since 1995. However, there is evidence that at least one laboratory has used millions of Federal dollars in recent years to support breeding of Government owned chimpanzees. According to records provided by the New Iberia Research Center (NIRC) and the National Institutes of Health, at least 132 infants were born to a federally owned mother and/or federally owned father at NIRC between January 2000 and November 2011.

Some of the infants born at NIRC to federally owned parents were used to fulfill a multi-year, multi-million dollar contract that the laboratory has with an institute within NIH to provide NIH researchers with "4 to 12 disease free infants per year." This contract is scheduled to end in fiscal year 2012 and this language will ensure that it is not renewed.

In 2010, the Senate Committee on Appropriations included report language asking NIH to look into allegations that 123 infants had been born to at least one federally owned parent between 2000 and 2009 at NIRC. NIH responded that they had

¹ NRC (National Research Council) (1997) *Chimpanzees in research: strategies for their ethical care, management and use*. National Academies Press: Washington, DC.

could not find evidence that it was happening to the extent that had been alleged and they believed NIRC was compliant with the moratorium. However, in an article in the journal *Nature* in November 2011, the director of NIRC admitted that he did not dispute the allegations and is, in fact, breeding federally owned chimpanzees.²

Chimpanzees Are Not Necessary for Most Current Research

In December 2011, the Institute of Medicine (IOM) and National Research Council released a report entitled “Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity”. The report found that chimpanzees are “largely unnecessary” for research and, further, could not identify any current area of research for which chimpanzees are essential. The report also called for a sharp reduction in the use of chimpanzees in biomedical and behavioral research and noted that the “current trajectory indicates a decreasing scientific need for chimpanzee studies due to the emergence of non-chimpanzee models and technologies.”³

It is also important to note that even in the decade prior to IOM’s findings, the vast majority of chimpanzees were not being used in any studies but, rather, were being warehoused at taxpayer expense. A main reason for implementing the breeding moratorium in the first place was due to a “surplus” of chimpanzees after it turned out that chimpanzees were not ideal models for HIV/AIDS.⁴

Given the obvious downward trend of chimpanzee research, it makes little sense to invest limited research resources into any further breeding.

Concerns Regarding Chimpanzee Care in Laboratories

A 9 month undercover investigation by The HSUS at University of Louisiana at Lafayette New Iberia Research Center (NIRC)—the largest chimpanzee laboratory in the world—revealed some chimpanzees living in barren, isolated conditions and documented more than 100 alleged violations of the Animal Welfare Act at the facility regarding conditions for and treatment of chimpanzees. The U.S. Department of Agriculture (USDA) and NIH’s Office of Laboratory Animal Welfare (OLAW) launched formal investigations into the facility and NIRC paid an \$18,000 stipulation for violations of the Animal Welfare Act.

Aside from the HSUS investigation, inspections conducted by the USDA demonstrate that basic chimpanzee standards are often not being met. Inspection reports for other federally funded chimpanzee facilities have reported violations of the Animal Welfare Act in recent years, including the death of a chimpanzee during improper transport, housing of chimpanzees in less than minimal space requirements, inadequate environmental enhancement, and/or general disrepair of facilities. These problems add further argument against the breeding of even more chimpanzees into this system.

Ethical and Public Concerns About Chimpanzee Research

Chimpanzee research raises serious ethical issues, particularly because of their extremely close similarities to humans in terms of intelligence and emotions. Americans are clearly concerned about these issues: 90 percent believe it is unacceptable to confine chimpanzees individually in Government-approved cages (as we documented during our investigation at NIRC); 71 percent believe that chimpanzees who have been in the laboratory for over 10 years should be sent to sanctuary for retirement⁴; and 54 percent believe that it is unacceptable for chimpanzees to “undergo research which causes them to suffer for human benefit.”⁵

We respectfully request the following bill or committee report language:

“No funds made available in this Act, or any prior Act, may be used for grant agreements or contracts with facilities defined in 7 U.S.C. § 2132(e) if those agreements or contracts allow or encourage the breeding of chimpanzees.”

We appreciate the opportunity to share our views for the Labor, Health and Human Services, Education and Related Agencies Appropriations Act for Fiscal Year 2013. We hope the Committee will be able to accommodate this modest request that will save the Government a substantial sum of money, benefit chimpanzees, and allay some concerns of the public at large. Thank you for your consideration.

²Wadman, Meredith. (2011). Lab bred chimps despite ban. *Nature*, Vol 479, Pages 453–454.

³Institute of Medicine and National Research Council. (2011). *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*. National Academies Press: Washington, DC.

⁴2006 poll conducted by the Humane Research Council for Project Release & Restitution for Chimpanzees in laboratories.

⁵2001 poll conducted by Zogby International for the Chimpanzee Collaboratory.

ALTERNATIVES TO THE USE OF CHIMPANZEES IN PROPHYLACTIC HEPATITIS C VACCINE
EFFICACY RESEARCH

In their December 2011 report entitled “Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity”, the Institute of Medicine found that chimpanzees are “largely unnecessary” for current research and pointed to several available alternatives to the use of chimpanzees. The efficacy testing of a prophylactic hepatitis C vaccine, once developed, is the only area for which the committee wasn’t able to reach consensus as to whether chimpanzees are necessary for this purpose. However, the committee pointed to several alternatives which are currently in development that could eliminate any need for chimpanzees in this type of research. Given the financial and ethical costs of maintaining chimpanzees in laboratories, coupled the serious doubts about the necessity of chimpanzees for such research, The Humane Society of the United States believes development of alternatives for this purpose should be an urgent priority for the National Institutes of Health. Not only would this ensure better use of limited research funds, but will also serve to move scientific innovation forward.

We respectfully request the following committee report language.

“The Committee supports the immediate implementation and prioritization of the development of non-chimpanzee alternatives for hepatitis C prophylactic vaccine efficacy studies—as supported by the recent IOM report entitled “Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity.”

HIGH THROUGHPUT SCREENING, TOXICITY PATHWAY PROFILING, AND BIOLOGICAL
INTERPRETATION OF FINDINGS

NATIONAL INSTITUTES OF HEALTH—OFFICE OF THE DIRECTOR

In 2007, the National Research Council published its report titled “Toxicity Testing in the 21st Century: A Vision and a Strategy.” This report catalyzed collaborative efforts across the research community to focus on developing new, advanced molecular screening methods for use in assessing potential adverse health effects of environmental agents. It is widely recognized that the rapid emergence of omics technologies and other advanced technologies offers great promise to transform toxicology from a discipline largely based on observational outcomes from animal tests as the basis for safety determinations to a discipline that uses knowledge of biological pathways and molecular modes of action to predict hazards and potential risks.

In 2008, NIH, NIEHS and EPA signed a memorandum of understanding⁶ to collaborate with each other to identify and/or develop high throughput screening assays that investigate “toxicity pathways” that contribute to a variety of adverse health outcomes (e.g., from acute oral toxicity to long-term effects like cancer). In addition, the MOU recognized the necessity for these Federal research organizations to work with “acknowledged experts in different disciplines in the international scientific community.” Much progress has been made, including FDA joining the MOU, but there is still a significant amount of research, development and translational science needed to bring this vision forward to where it can be used with confidence for safety determinations by regulatory programs in the Government and product stewardship programs in the private sector. In particular, there is a growing need to support research to develop the key science-based interpretation tools which will accelerate using 21st century approaches for predictive risk analysis. We believe the Office of the Director at NIH can play a leadership role for the entire U.S. Government by funding both extramural and intramural research.

We respectfully request the following committee report language, which is supported by The HSUS, HSLF, The Procter & Gamble Company, and the American Chemistry Council.

“NIH Director

“The Committee supports NIH’s leadership role in the creation of a new paradigm for chemical risk assessment based on the incorporation of advanced molecular biological and computational methods in lieu of animal toxicity tests. NIH has indicated that development of this science is critical to several of its priorities, from personalized medicine to tackling specific diseases such as cancer and diabetes. The Committee encourages NIH to continue to expand its extramural support for the use of human biology-based experimental and computational approaches in health research to further define toxicity and disease pathways and develop tools for their integration into evaluation strategies. Extramural and intramural funding should be

⁶ <http://www.genome.gov/pages/newsroom/currentnewsreleases/ntpncgepamou121307finalv2.pdf>.

made available for the evaluation of the relevance and reliability of Tox21 methods and prediction tools to assure readiness and utility for regulatory purposes, including pilot studies of pathway-based risk assessments. The Committee requests NIH provide a report on associated funding in fiscal year 2013 for such activity and a progress report of Tox21 activities in the congressional justification request, featuring a 5-year plan for projected budgets for the development of Tox21 methods, including prediction models, and activities specifically focused on establishing scientific confidence in them for regulatory. The Committee also requests NIH prioritize an additional (1–3 percent) of its research budget within existing funds for such activity.”

PREPARED STATEMENT OF THE TRI-COUNCIL FOR NURSING

The Tri-Council for Nursing, comprising the American Association of Colleges of Nursing, the American Nurses Association, the American Organization of Nurse Executives, and the National League for Nursing, respectfully requests \$251 million for the Nursing Workforce Development programs authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.) in fiscal year 2013.

The Tri-Council is a long-standing nursing alliance focused on leadership and excellence in the nursing profession. As the Nation looks toward restructuring the healthcare system by focusing on expanding access, decreasing cost, and improving quality, a significant investment must be made in strengthening the nursing workforce, a profession which the U.S. Bureau of Labor Statistics (BLS) projects a growth of 26 percent by 2020.

Notwithstanding the economic challenges facing our Nation today, the BLS projects there will be 712,000 new nursing jobs created between 2010 and 2020. This workforce growth is expected to continue as the demand for nursing care in traditional acute care settings and the expansion of non-hospital settings such as home care and long-term care accelerates. The BLS projections further explain the need for 495,500 replacements in the nursing workforce, bringing the total number of job openings for nurses due to growth and replacements to 1.2 million by 2020.

As our Nation regains its economic foothold, the Tri-Council urges the Subcommittee to focus on the larger context of building the nursing capacity needed to meet the increasing healthcare demands of our Nation's population. Starting on January 1, 2011, baby boomers began turning 65 at the rate of 10,000 a day. With them comes the increased demand for healthcare and services of an aging population, which will swell the pressure on the healthcare system, especially when coupled with near epidemic growth in childhood obesity, diabetes, and other chronic diseases experienced among our country's populations.

Moreover, the acute nurse faculty shortage is a primary reason why schools of nursing across the country turn away thousands of qualified applications each year. The demand for nurses and the faculty who educate them is a serious impediment to improving the health of America. Nurses continue to be the largest group of healthcare providers whose services are directly linked to quality and cost-effectiveness. The Tri-Council is grateful to the Subcommittee for its past commitment to Title VIII funding and respectfully asks for a continued long-term investment that will build the nursing workforce necessary to deliver the quality, affordable care envisioned in health reform.

A PROVEN SOLUTION: NURSING WORKFORCE DEVELOPMENT PROGRAMS

The Nursing Workforce Development programs, authorized under Title VIII of the Public Health Service Act (42 U.S.C. 296 et seq.), have helped build the supply and distribution of qualified nurses to meet our Nation's healthcare needs since 1964. Over the last 48 years, the original programs as well as newly added and expanded programs have addressed all aspects of supporting the workforce—education, practice, retention, and recruitment. They have bolstered nursing education at all levels; from entry-level preparation through graduate study, and provide support for institutions that educate nurses for practice in rural and medically underserved communities. A description of the Title VIII programs and their impact are included below.

—Advanced Nursing Education (ANE) Grants (Sec. 811) support the preparation of registered nurses (RNs) in master's and doctoral nursing programs. The ANE grants help prepare our Nation's nurse practitioners, clinical nurse specialists, nurse midwives, nurse anesthetists, nurse educators, nurse administrators, nurses in executive practice, public health nurses, and other nursing specialists requiring advanced nursing education. In fiscal year 2010, these grants supported the education of 7,863 students.

- Advanced Education Nursing Traineeships (AENT) assist graduate nursing students by providing full or partial reimbursement for the costs of tuition, books, program fees, and reasonable living expenses. Funding for the AENTs supports the education of future nurse practitioners, clinical nurse specialists, nurse midwives, nurse anesthetists, nurse educators, nurse administrators, public health nurses, and other nurse specialists requiring advanced education.
- Nurse Anesthetist Traineeships (NAT) supports the education of students in nurse anesthetist programs. In some States, certified registered nurse anesthetists are the sole anesthesia providers in almost 100 percent of rural hospitals. Much like the AEN Traineeships, the NAT provides full or partial support for the costs of tuition, books, program fees, and reasonable living expenses.
- In fiscal year 2010, the AEN Traineeship and the NAT supported 12,325 nursing students.
- Nursing Workforce Diversity Grants (Sec. 821) prepare students from disadvantaged backgrounds to become nurses. This program awards grants and contract opportunities to schools of nursing for a variety of clinical training facilities to address nursing educational needs for not only disadvantaged students but also racial and ethnic minorities underrepresented in the nursing profession. In fiscal year 2010, the program supported 10,361 students.
- Nurse Education, Practice, Quality and Retention Grants (Sec. 831 and Sec. 831A) help schools of nursing, academic health centers, nurse-managed health centers, State and local governments to strengthen nursing education programs. In fiscal year 2010, this program supported 4,860 undergraduate nursing students.
- Nurse Loan Repayment and Scholarship Program (Sec. 846, Title VIII, PHSA) provides grants to students that pay up to 85 percent of a student's loan in return for at least 3 years of service in a designated health shortage area or in an accredited school of nursing. In fiscal year 2010, the Nurse Loan Repayment and Scholarship Programs supported 1,304 nurses and nursing students.
- Nurse Faculty Loan Program (Sec. 846A, Title VIII, PHSA) provides up to 85 percent of loan cancellation if the student agrees to a 4-year teaching commitment in a school of nursing. In fiscal year 2010, these grants supported the education of 1,551 future nurse educators.
- Comprehensive Geriatric Grants (Sec. 855, Title VIII, PHSA) provide support to nursing students specializing in care for the elderly. These grants may be used to educate RNs who will provide direct care to older Americans, develop and disseminate geriatric curriculum, prepare faculty members, and provide continuing education.

Our Nation is faced with a growing healthcare crisis that must be addressed on many fronts. Nurses are an important part of the solution to the crisis of cost, burden of disease, and access to quality care. To meet this challenge, funding of proven Federal programs such as Title VIII will help ease the demand for RNs. The Tricouncil respectfully requests your support of \$251 million for the Title VIII Nursing Workforce Development Programs in fiscal year 2013.

PREPARED STATEMENT OF THE SOCIETY FOR HEALTHCARE EPIDEMIOLOGY OF AMERICA AND THE ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY

The Society for Healthcare Epidemiology of America (SHEA) and the Association for Professionals in Infection Control and Epidemiology (APIC) thank you for this opportunity to submit testimony on Federal efforts to eliminate preventable healthcare-associated infections (HAIs). HAIs are among the leading causes of preventable death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths annually according to the CDC's most recent official estimates. In addition to the substantial human suffering, HAIs contribute \$28 to \$33 billion in excess healthcare costs each year.

The good news is that some HAIs are on the decline as a result of recent advances in the understanding of how to prevent certain infections. In particular, bloodstream infections associated with indwelling central venous catheters, or "central lines," are largely preventable when healthcare providers use the CDC infection prevention recommendations in the context of a performance improvement collaborative. Over the past decade, the Agency for Healthcare Research and Quality (AHRQ) has funded numerous projects targeting HAI prevention that have led to the successful reduction of central line-associated blood stream infections (CLABSIs) in hospital intensive care units (ICUs). Healthcare professionals have reduced these infections in

ICU patients by 58 percent since 2001, which represents up to 27,000 lives saved. In spite of this notable progress, there is a great deal of work to be done toward the goal of HAI elimination.

To build and then sustain these winnable battles against HAIs, we urge you, in fiscal year 2013, to support the CDC Coalition's request for \$7.8 billion for the CDC's "core programs." We are concerned about the President's fiscal year 2013 budget proposal that would reduce the CDC's budget authority by \$664 million, for a total reduction of \$1.4 billion since fiscal year 2010. At the same time, the administration and the Congress increasingly rely on the Prevention and Public Health Fund and funding transfers from other agencies to backfill the cuts to CDC's budget authority. We believe that the Congress should prioritize funding for the activities and programs supported by CDC that are essential to protect the health of the American people.

We especially want to highlight our support for the \$27.5 million in the President's budget for the CDC's National Healthcare Safety Network (NHSN). These funds are critically needed to ensure high-quality monitoring of HAI prevalence as well as antibiotic usage in the U.S. Collection of accurate, timely, and complete data is necessary to measure the true extent of the problem, develop evidence-based HAI prevention strategies and monitor their effectiveness. In addition, consistent, high quality, scientifically sound and validated data are necessary to be reported at the State and Federal level to ensure that accurate data are available to evaluate the HHS National Action Plan to Prevent HAIs progress as well as to support transparency to the public, allowing for fair comparisons between facilities. Such data are critical to understanding patterns of HAI prevalence, which help public health and healthcare practitioners better coordinate prevention efforts and measure reduction in HAIs. Since NHSN is the only system with this capability, the majority of States have adopted it for legislatively mandated public reporting and most inpatient facilities reimbursed by Medicare are required to report specified HAIs via NHSN. Data from other care settings and additional infection types are being phased in. Thus, the number of facilities, types of facilities and number of infection indicators are growing exponentially.

Despite the system's importance in our Nation's efforts to monitor and prevent HAIs, funding for NHSN has been flat since fiscal year 2010. Without additional funding, increasing the number of facilities reporting into NHSN from 3,000 in 2010 to an expected 16,500 in 2013 will exceed the capacity of the system. The requested funding for NHSN will allow CDC to modernize the NHSN information technology platform to enhance electronic data collection, reduce the burden of data collection and allow facilities, States and Federal agencies to focus on infection prevention and control. The NHSN serves as the foundation for prevention and the development of innovative, evidence-based HAI prevention strategies. Federal resources are required to ensure accurate, timely, and complete data are reported to NHSN and become available to the public. We urge you to support the requested funding level for NHSN to allow the CDC, States and other Federal agencies to use this tool to carry out their mission to ensure the public's health, assure and improve the quality of care and enhance patient safety.

CDC's Antimicrobial Resistance activities are included within the Emerging and Zoonotic Infectious Disease programs' proposed budget. SHEA and APIC commend the CDC for creating an expert advisory group on antimicrobial resistance. Continued support for the Emerging Infections Program (EIP) is also critical as the HAI component engages a network of State health departments and their academic medical center partners to help answer important questions about emerging HAI threats, advanced infection tracking methods and antibiotic resistance in the United States. Ensuring the effectiveness of antibiotics well into the future is vital for the Nation's public health, particularly at this time when our current therapeutic options are dwindling and research and development of new antibiotics is lagging. As bacteria and other micro-organisms are becoming more resistant to antimicrobials, it is essential that the CDC maintains the ability to monitor organism resistance in healthcare as it is one of the most pressing problems and greatest challenges that healthcare providers will confront during the coming decade.

It is critical that antimicrobial stewardship programs are adopted in all settings where antimicrobials are used. SHEA and APIC applaud the CDC for its Get Smart for Healthcare campaign, which aims to optimize antibiotic use by encouraging adherence to appropriate prescribing guidelines in hospitals and long-term care facilities and we encourage its continued support. We also strongly support the NHSN's Antibiotic Use Module. Launched in May 2011, it is the first effort in the United States to define national data on antibiotic use in healthcare institutions. Because single payer systems have the advantage of making it easier to track antimicrobial

resistance, the United States stands at a disadvantage to European countries in this regard.

SHEA and APIC are strongly supportive of the CDC Prevention Epicenters Program, a collaboration of CDC's Division of Healthcare Quality Promotion (DHQP) and five academic medical centers that conduct innovative infection control and prevention research to address important scientific questions regarding the prevention of HAIs, antibiotic resistance and other adverse healthcare events. The Epicenters Program is funded through the NHSN and has provided a unique forum in which academic leaders in healthcare epidemiology can partner directly with each other and with CDC subject matter experts. The resultant emphasis on multicenter collaborative research projects, through which investigators work together as a group, allows for research that in many cases, would not have been possible for a single academic center. The knowledge gained through the Epicenters Program has been highly valuable to the field, and has resulted in more than 150 publications in peer-reviewed journals on a wide range of HAI prevention topics.

Existing HAI prevention strategies are limited by the current state of science, and as a result cannot prevent all HAIs even when fully implemented. As we strive to eliminate all preventable HAIs, we need to identify the gaps in our understanding of what is actually preventable. This distinction is critical to help guide subsequent research priorities and to help set realistic expectations. SHEA and APIC believe in the importance of conducting basic, epidemiological and translational studies to fill basic and clinical science gaps. While health services research (i.e., successful implementation of strategies already known or suspected to be beneficial) may provide some immediate short-term benefit, to achieve further success, a substantial investment in basic science, translational medicine, and epidemiology is needed to permit effective and precise, interventions that prevent HAIs. Moreover, experts in the field (Epidemiologists and Infection Preventionists), in collaboration with CDC and AHRQ, should be engaged in order to further define and prioritize the research agenda.

SHEA and APIC strongly support the proposed investment of \$34 million by AHRQ in fiscal year 2013 to reduce and prevent healthcare-associated infections (HAIs). This total includes \$11.6 million in HAI research grants to improve the prevention and management of HAIs and \$22.4 million in HAI contracts including nationwide implementation of Comprehensive Unit-based Safety Program (CUSP). AHRQ-funded projects related to HAI prevention involve the implementation of CUSP, which is based on an Intensive Care Unit Safety Reporting System developed by the Johns Hopkins University Quality and Safety Research Group, Baltimore, Maryland. SHEA and APIC are very pleased that AHRQ is expanding the CUSP program to all 50 States, extending its reach to other settings in addition to ICUs, and broadening the focus to address other types of infections, such as catheter-associated urinary tract infections (CAUTIs). Our organizations are participating in the CUSP-CAUTI initiative through identification of expert members to serve on a national network of clinical faculty working to improve patient safety through dissemination of educational modules across the Nation.

Despite the fact that HAIs are among the top 10 annual causes of death in the United States, support for basic, translational and epidemiological HAI research has not been a priority of the National Institutes of Health (NIH). The reality is that scientists studying these infections receive relatively less funding than colleagues in many other disciplines. The limited availability of Federal funding to study HAIs has the effect of steering young investigators interested in pursuing research in this area toward other, better-funded fields. This severely hampers the HAI clinical research enterprise at a time when it should be expanding. The current convergence of scientific, public and legislative interest in reducing rates of HAIs can provide the necessary momentum to address and answer important questions in HAI research and move our discipline to the next level of evidence-based patient safety. SHEA and APIC urge your support of increased NIH funding for basic, translational and implementation research proportionate to the clinical significance of HAIs.

Although we are pleased that HHS' Office of the Assistant Secretary for Health (OASH) has expressed support for the implementation of HAI-related reforms through the overall OASH budget, we believe having dedicated funding of \$5 million for the HAI Action Plan is the best way to ensure that this critical initiative is adequately resourced. SHEA and APIC members have been actively engaged in this partnership for HAI prevention under the leadership of HHS Assistant Secretary for Health, Dr. Howard Koh and Deputy Assistant Secretary for Healthcare Quality, Dr. Don Wright. The development of the HAI Action Plan and the funding to support these activities has been critical to the effort to build support for a coordinated Federal plan to prevent infections. Additionally, we believe strongly that the CDC

is the agency with the necessary expertise to define appropriate metrics through which the HAI Action Plan can best measure its efforts.

SHEA and APIC also request that the Subcommittee approve \$16.1 million for the Centers for Medicare and Medicaid Services (CMS) surveys of ambulatory surgical centers (ASCs) as part of the budget request addressing direct survey costs. This funding will allow the CMS to continue the enhanced survey process—developed jointly with the CDC—to target infection control deficiencies in ASCs every 4 years. We believe this enhanced survey process is a good way of ensuring that basic infection prevention practices are followed, thus avoiding potential outbreaks due to unsafe practices.

We thank you for the opportunity to submit testimony and greatly appreciate this subcommittee's assistance in providing the necessary funding for the Federal Government to have a leadership role in the effort to eliminate HAIs.

About SHEA.—SHEA has helped define best practices in healthcare epidemiology worldwide since its founding in 1980. The Society works to achieve the highest quality of patient care and healthcare personnel safety in all healthcare settings by applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues. SHEA is a growing organization, strengthened by its membership of 2,200 in all branches of medicine, public health, and healthcare epidemiology. SHEA members are committed to implementing evidence-based strategies to prevent HAIs and improve patient safety, and have scientific expertise in evaluating potential strategies to accomplish this goal.

About APIC.—APIC's mission is to create a safer world through prevention of infection. The association's more than 14,000 members direct infection prevention programs that save lives and improve the bottom line for hospitals and other healthcare facilities. APIC advances its mission through patient safety, implementation science, competencies and certification, advocacy, and data standardization.

PREPARED STATEMENT OF THE UNIVERSITY OF NORTH DAKOTA AND NORTH DAKOTA STATE UNIVERSITY

On behalf of the University of North Dakota and North Dakota State University, thank you for the opportunity to submit our written testimony regarding the fiscal year 2013 funding for the National Institutes of Health (NIH) Institutional Development Award (IDeA) program. We respectfully request your support of no less than \$310 million for this critically important program. We further request that the Subcommittee gives serious consideration to legislative language which would direct that future NIH budgets include funding for the IDeA program that reaches no less than 1 percent of the total NIH budget. IDeA was authorized by the 1993 NIH Revitalization Act (Public Law 103–43) and funds only merit-based, peer reviewed research that meets NIH research objectives in the 23 IDeA States and Puerto Rico.

The States eligible for IDeA funding are defined as “all States/commonwealths with a success rate for obtaining NIH grant awards of less than 20 percent over the period of 2001–2005 or received less than an average of \$120 million per year during that time period.” Currently this includes 23 States and Puerto Rico—nearly half of the States. Funding from this critical capacity-building program has been a key part of the growth in research capacity and impact at the two North Dakota research universities in recent years.

Funding for the IDeA program in fiscal year 2012 was \$276.48 million. The total budget for NIH in fiscal year 2012 was \$30.86 billion; thus in fiscal year 2012, the IDeA program—funding competitively awarded biomedical research in nearly half the Nation—comprised only 0.89 percent of the entire NIH budget. The IDeA program exists because the 23 eligible States overall receive less than 20 percent of NIH's extramural funding. The proposed reduction in the President's fiscal year 2013 budget request of \$51 million represents a staggering 18 percent cut to the budget of the IDeA program, but represents only 0.16 percent of the entire proposed NIH budget. Making such a serious, disproportionate cut to a program designed to aid small, rural States is manifestly unfair. This program is small in the overall scheme of things at NIH, but huge for the States that compete for these funds. Our requested funding level of \$310 million represents only 1 percent of the President's total fiscal year 2013 budget request for NIH.

Our State, North Dakota, has benefited immensely from the competitive funding available through the IDeA program in the form of COBRE (Center for Biomedical Research Excellence) and INBRE (IDeA Networks of Biomedical Research Excellence) grants, and we anticipate submitting a joint proposal in September of this year for an IDeA Program Infrastructure for Clinical and Translational Research (IDeA CTR) grant.

At the University of North Dakota, we have been awarded funding for two phases of a COBRE grant supporting research on neurodegenerative diseases. We have been notified informally that we can expect funding for Phase III, the final phase of a COBRE project, during fiscal year 2012. North Dakota has one of the largest populations of the extremely old in the Nation (second only to Florida in the percentage of its citizens over 85 years of age), and high rates of neurodegenerative diseases such as Alzheimer's, Parkinson's, and multiple sclerosis. As an example of the impact of this funding and the research capacity it has built, externally funded research at the University of North Dakota's School of Medicine and Health Sciences has grown substantially. Prior to COBRE funding, in fiscal year 2002, the SMHS received about \$12 million in external funding; by fiscal year 2011, this had increased to \$20.5 million, an increase of 71 percent. In 2010, when UND developed a new strategic plan for research, neuroscience was identified as an existing strength on which to build further.

Thus, the neurobiology COBRE grant is achieving its intended purpose of expanding our research capacity and our ability to compete for Federal funding. That research is directed at problems of direct interest to our citizenry, but also to the rest of the United States.

The University of North Dakota has submitted a proposal for an additional COBRE grant on the topic of epigenetics. Epigenetics is the study of how environmental factors influence the expression of our genes; in many cases these changes in gene expression can then be inherited by the next generation. Although possible funding for this COBRE grant application has not yet been determined, we believe that the submitted grant is a highly competitive one that addresses a burgeoning area of research interest and importance.

North Dakota State University has received COBRE grants to fund research at its Center for Protease Research and the Center for Visual and Cognitive Neuroscience. COBRE funding supported important chemical and biological research at the Center for Protease Research relating to the roles played by enzymes that break down proteins in cancer and asthma.

COBRE funding at NDSU's Center for Visual and Cognitive Neuroscience facilitated research illuminating and ameliorating conditions such as disordered perception, cognition, emotion, attention and executive function which are hallmarks of debilitating and costly disease syndromes (e.g. ADHD, ARMD, agnosia, amblyopia, autism, depression, dementia, dyslexia, hemi neglect, multiple sclerosis, Parkinson's disease, PTSD, and schizophrenia).

COBRE funding has contributed to the success that both NDSU's Centers have achieved in obtaining competitive grants from private sources and a variety of Federal agencies. Additionally, the COBRE grants led to the publication of NDSU's research findings in international, refereed publications and have aided in the recruitment of new faculty and increased enrollments in related graduate and undergraduate programs.

Another critically important IDEa program is INBRE, which provides funding to build the biomedical workforce through activities ranging from outreach to elementary school children to creating opportunities for undergraduates to engage in research. This program has provided support for undergraduate students at 2- and 4-year colleges in North Dakota to participate in research during the summer at their home institutions. This program includes two tribal colleges and serves between 70 and 100 students each year. Another program at the University of North Dakota serves about 60 undergraduates per year and applications routinely exceed the number of slots that are available. These programs are critical for keeping students in the pipeline for the STEM (science, technology, engineering, and math) workforce. Studies have repeatedly shown that engaging undergraduates in original research is a powerful tool for retaining students in college so that they graduate in a timely way.

A major emphasis has been on outreach programs to Native American students, the minority group that is most under-represented in the fields of science, engineering, and math. Between 25 and 35 Native American students in grades 7–12 participate each year in a program that uses traditional Native American tools to teach science. As many as 40 students from tribal colleges are funded each year to visit UND and learn about opportunities to transfer to the university and complete their 4-year degrees. INBRE provides support for transfer students from tribal colleges through the Pathway program, a 6-week summer program that prepares participants for advanced coursework in science. Pathway students can also receive tuition waivers from the university. INBRE funding is also provided to support the American Indian Health Research Forum on the UND campus each year; this forum attracts attendees from across the Nation.

We expect to submit a joint proposal from the two North Dakota research universities this fall to help us develop a joint center for clinical and translational research. The basic science departments in our School of Medicine and Health Sciences have grown as a result of COBRE and INBRE programs. Like other States, we need to move the results of that research to patients' bedsides. If we are successful in competing for a CTR grant, we will be able to build the necessary infrastructure that we need to do so.

North Dakota, with a population of 672,591 according to the 2010 Census, is the smallest of all the IDeA States. Yet, our School of Medicine and Health Sciences graduates a disproportionately large number of primary care physicians who practice in rural areas, and 20 percent of all Native American physicians in the United States are graduates of the University of North Dakota. This medical school is clearly making important contributions to healthcare for underserved populations. Like all medical schools, it must have a healthy research program underpinning its training of physicians, and funding from the IDeA program is critical to the health of that program and to building research capacity for the future.

The IDeA States produce STEM graduates at the same per capita rate as States with larger populations and larger research portfolios. The students from IDeA States need and deserve the same exposure to research as students in larger States. If the proposed reductions in the President's fiscal year 2013 budget request for the IDeA program are not rejected, North Dakota and other small, mostly rural States, will receive a major setback in their efforts to increase their capacity to undertake biomedical research and to train the next generation of scientists who are critical for the health of our Nation and our economy.

The IDeA program is absolutely critical not only for the University of North Dakota and North Dakota State University, but also for the biomedical research capacity and capability of research institutions nationwide. We sincerely appreciate the Subcommittee's ongoing support of the IDeA program and request that you give full consideration to our recommendations and fiscal year 2013 request of no less than \$310 million for the National Institutes of Health IDeA program. We further request that the Subcommittee considers legislative language directing that future NIH budgets include funding for the IDeA program that reaches no less than 1 percent of the total NIH budget.

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PREPARED STATEMENT OF THE US HEREDITARY ANGIOEDEMA ASSOCIATION

Thank you for the opportunity to present the views of the US Hereditary Angioedema Association (US HAEA) regarding the importance of Hereditary Angioedema (HAE) public awareness activities and research.

The US HAEA is a nonprofit patient advocacy organization founded in 1999 to help those suffering with HAE and their families to live healthy lives. The Association's goals were, and remain, to provide patient support, advance HAE research and find a cure. The US HAEA provides patient services that include referrals to HAE knowledgeable healthcare providers, disease information and peer-to-peer support. US HAEA also provides research funding to scientific investigators to increase the HAE knowledge base and maintains an HAE patient registry to support groundbreaking research efforts. Additionally, US HAEA provides disease information materials and hosts forums to educate patients and their families, healthcare providers, and the general public on HAE.

HAE is a rare and potentially life-threatening inherited disease with symptoms of severe, recurring, debilitating attacks of edema (swelling). HAE patients have a defect in the gene that controls a blood protein called C1-inhibitor, so it is also more specifically referred to as C1-inhibitor deficiency. This genetic defect results in production of either inadequate or nonfunctioning C1-inhibitor protein. Because the defective C1-inhibitor does not adequately perform its regulatory function, a biochemical imbalance can occur and produce an unwanted peptide—called

bradykinin—that induces the capillaries to release fluids into surrounding tissues, thereby causing swelling.

People with HAE experience attacks of severe swelling that affect various body parts including the hands, feet, face, airway (throat) and intestinal wall. Swelling of the throat is the most life-threatening aspect of HAE, because the airway can close and cause death by suffocation. Studies reveal that more than 50 percent of patients will experience at least one throat attack in their lifetime.

HAE swelling is disfiguring, extremely painful and debilitating. Attacks of abdominal swelling involve severe and excruciating pain, vomiting, and diarrhea. Because abdominal attacks mimic a surgical emergency, approximately one-third of patients with undiagnosed HAE undergo unnecessary surgery. Untreated, an average HAE attack lasts between 24 and 72 hours, but some attacks may last longer and be accompanied by prolonged fatigue.

The majority of HAE patients experience their first attack during childhood or adolescence. Most attacks occur spontaneously with no apparent reason, but anxiety, stress, minor trauma, medical, surgical, and dental procedures, and illnesses such as colds and flu have been cited as common triggers. ACE Inhibitors (a blood pressure control medication) and estrogen-derived medications (birth control pills and hormone replacement drugs) have also been shown to exacerbate HAE attacks.

HAE's genetic defect can be passed on in families. A child has a 50 percent chance of inheriting the disease from a parent with HAE. However, the absence of family history does not rule out the HAE diagnosis; scientists report that as many as 25 percent of HAE cases today result from patients who had a spontaneous mutation of the C1-inhibitor gene at conception. These patients can also pass the defective gene to their offspring. Worldwide, it is estimated that this condition affects between 1 in 10,000 and 1 in 30,000 people.

Public Awareness at the Centers for Disease Control and Prevention

HAE patients often suffer for many years and may be subject to unnecessary medical procedures and surgery prior to receiving an accurate diagnosis. Raising awareness about HAE among healthcare providers and the general public will help reduce delays in diagnosis and limit the amount of time that patients must spend without treatment for a condition that could, at any moment, end their lives.

Once diagnosed, many individuals are able to piece together a family history of mysterious deaths and episodes of swelling that previously had no name. In some families, over many years, this condition has come to be accepted as something that must simply be endured. Increased public awareness is crucial so that these patients understand that HAE often requires emergency treatment and disabling attacks no longer need to be passively accepted. While HAE cannot yet be cured, intelligent use of available treatments can help patients lead a productive life.

In order to prevent deaths, eliminate unnecessary surgeries, and improve patients' quality of life, it is critical that CDC pursue programs to educate the public and medical professionals about HAE in fiscal year 2013.

Research Through the National Institutes of Health

In years past, HAE research was conducted at the National Institutes of Health (NIH) through the National Institute of Allergy and Infectious Diseases, the National Institute of Neurological Disorders and Stroke, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, National Center for Research Resources, and the National Institute on Diabetes and Digestive and Kidney Diseases. However, NIH has not engaged in HAE-specific research since 2009, and there is no longer any Federal research as it relates to HAE.

As it may provide greater opportunities for HAE research, we applaud the recent establishment of the National Center for Advancing Translational Sciences (NCATS) at NIH. Housing translational research activities at a single Center at NIH will allow these programs to achieve new levels of success. Initiatives like the Cures Acceleration Network are critical to overhauling the translational research process and overcoming the challenges that plague treatment development. In addition, new efforts like taking the lead on drug repurposing have the potential to speed access to new treatments, particularly to patients who struggle with rare or neglected diseases. As a rare disease community, HAE patients may also benefit from the Therapeutics for Rare and Neglected Diseases (TRND) program, housed at NCATS, as well coordination with the Office of Rare Diseases Research (ORDR). We ask that you support NCATS and provide adequate resources for the Center in fiscal year 2013.

In order to reinvigorate HAE research at NIH, it is vital that NIH receive increased support in fiscal year 2013. US HAEA recommends an overall funding level of \$32 billion for NIH in fiscal year 2013 and the inclusion of recommendations em-

phasizing the importance of HAE research to learn more about this rare disease and new pathways for appropriate treatment.

Thank you for the opportunity to present the views of the HAE community.

PREPARED STATEMENT OF THE U.S. SOCCER FOUNDATION

Thank you Chairman Harkin, Ranking Member Shelby, and Members of the subcommittee, for the opportunity to submit this testimony. I am Ed Foster-Simeon, the president and chief executive officer of the U.S. Soccer Foundation (USSF). As the Congress works on priorities for fiscal year 2013 Federal appropriations, I would like to respectfully urge that the subcommittee prioritize the Social Innovation Fund, an account in the Federal Corporation for National and Community Service, which is under the subcommittee's jurisdiction.

The U.S. Soccer Foundation, the major charitable arm of soccer in the United States, was established in 1994. Thanks to support from donors, our corporate partners, and countless youth development organizations, the Foundation has provided more than \$55 million in grants, financial support, and loans to help fund programs and projects in all 50 States. Thousands of individuals have benefited from the Foundation's support, and the need continues to grow.

The U.S. Soccer Foundation seeks to improve the health and well-being of children in urban economically disadvantaged areas using soccer as a vehicle for youth development and social change. Specifically, our goal is ensure that children in underserved communities have easy and affordable access to high-quality out-of-school programs that improve health and social outcomes among this vulnerable population. We accomplish this through our innovative program: Soccer for Success, a free afterschool sports-based youth development program designed to address such national priorities as childhood obesity and juvenile delinquency. I will discuss this program further in my testimony, after detailing the urgent needs we are working to address and the Federal resource that provides tremendous support to these efforts.

There is a great need for the expansion of multi-faceted youth development programs across the United States. First, childhood obesity rates have increased sharply in the United States over the past 30 years. Today, nearly one-third of children and adolescents are overweight or obese (White House Task Force on Childhood Obesity). The rate of childhood obesity is even more alarming among children growing up in economically disadvantaged communities. We can reverse this pattern by providing children with more opportunities to be physically active and by educating them on the importance of developing and maintaining active, healthy lifestyles. In many urban communities, however, there is a lack of suitable recreation facilities and organized programming. Our urban soccer programs provide inner-city children with safe havens to play, stay active, and engage with positive adult role models and mentors who help them develop important life skills.

Second, additional resources must be dedicated to address the needs of America's at-risk youth. The statistics are alarming. According to the U.S. Census Bureau's 2012 statistical abstract, more than 1.5 million juveniles were arrested in 2009, including more than 69,000 for a violent crime. As reported in the National Youth Gang Survey, more than 28,000 gangs were active in larger cities (55.6 percent), suburban counties (23.3 percent), smaller cities (18.3 percent), and rural counties (2.7 percent) among U.S. jurisdictions in 2009. According to the U.S. Department of Health and Human Services (HHS), at-risk youth across low-income urban communities not only have a higher chance of being obese, but are more likely than youth from middle- or upper-class families to join a gang, get in a fight or steal something worth more than \$50.

Further, MENTOR/National Mentoring Partnership estimates that 18 million young people—nearly one-half of the population between the ages of 10 and 18—live in situations which put them at-risk of “not living up to their potential.” They also identified a total of 3 million youth currently benefiting from a formal mentoring relationship. This leaves as many as 15 million American youth in want or need of mentors which comprise what MENTOR calls the “mentoring gap”. To meet this need and overcome one of the biggest barriers in the mentoring field, which is difficulty in mentor recruitment and retention, alternatives to the classic “one-to-one” mentoring model must be considered, utilized, and leveraged.

By leveraging Social Innovation Fund dollars, the U.S. Soccer Foundation is expanding its Soccer for Success program to address these national issues and reduce mentoring wait lists by utilizing a group mentoring model.

According to the Corporation for National and Community Service, the Social Innovation Fund leverages a modest investment of public funds to significantly expand

the most promising, evidence-based nonprofit programs serving low-income communities. Each Social Innovation Fund dollar must be matched by at least three private and non-Federal funders. The proposed \$50 million investment will bring an additional \$150 million to promising, locally driven programs with evidence of compelling results—including the Foundation’s programs.

The Social Innovation Fund program clearly has wide-ranging impact. Currently, there are more than 200 organizations benefiting from the Social Innovation Fund, operating in more than 100 cities in 31 States and our Nation’s capital. This national footprint will expand after all of the 2011 sub-grants have been awarded. Under consistent and effective program evaluation, the Social Innovation Fund is an excellent example of the Federal dollar being used to propagate best practices and ensure greatest impact.

The U.S. Soccer Foundation is a 2011 recipient of a \$2 million, 2-year Social Innovation Fund award that is enabling us to reach 12,000 children, 3 days a week, 24 weeks a year, through Soccer for Success—our sports-based after school youth development program. Soccer for Success is an evidence based program that promotes healthy lifestyles and works to reduce childhood obesity and juvenile delinquency rates among at-risk youth in underserved urban communities by providing exercise, nutritional education, and mentoring by positive adult role models in a safe environment.

the U.S. Soccer Foundation is matching the \$2 million Social Innovation Fund award dollar for dollar. Each sub-grantee is matching their award dollar for dollar with private, non-Federal dollars. The result is that each Federal taxpayer dollar awarded is being leveraged 3-to-1.

The following is a list of the 13 community-based organizations selected as Social Innovation Fund sub-grantees who will implement Soccer for Success in the upcoming school year. This list includes the number of children anticipated to be served:

SIF Soccer for Success Organizations	City/State	Grant (2-year award)	No. of children served
Brotherhood Crusade	Los Angeles, California	\$600,000	1,600
Boys & Girls Club of Camden County	Camden, New Jersey	200,000	840
Boys & Girls Club of Metro Atlanta	Atlanta, Georgia	200,000	670
Colorado Fusion Soccer Club	Denver, Colorado	300,000	1,125
DC Scores	Washington, DC	220,000	650
El Monte CBI	El Monte, California	270,000	1,080
Independent Health Foundation	Buffalo, New York	320,000	700
Think Detroit PAL	Detroit, Michigan	300,000	950
Widener University	Chester, Pennsylvania	230,000	1,000
Boys & Girls Club of Trenton	Trenton, New Jersey	200,000	1,000
YMCA of Greater Dayton	Dayton, Ohio	320,000	1,000
Houston Parks & Recreation Department	Houston, Texas	240,000	1,000
Washington Youth Soccer Association	Seattle, Washington	200,000	800
Total	3,600,000	12,415

These 13 organizations demonstrated through a rigorous selection process the strong organizational capacity needed to manage the grant and implement the program. They serve the desired population—children growing up in economically disadvantaged urban communities—have the ability to match the funds awarded dollar for dollar, have an effective cost model for program implementation, and have strong partnerships and funding prospects for long-term sustainability.

Before I end, let me share with you a story about the impact youth development programs like Soccer for Success can have in addressing national priorities. Celeste Amaya, a 10-year old girl in our Los Angeles program, weighed 145 when she began our program. Soccer for Success’ physical activity and nutritional lessons component has helped her drop nearly 16 lbs. “I eat the same food, but it was the amount of food”, she says, about cutting back on portion size. “A lot of the clothes [that I had outgrown] fit me now,” she shared. Celeste recently weighed in at 129 lbs. Soccer for Success has not only made a difference in Celeste’s life, but also has helped the entire family become more active. Celeste’s mother says that when her daughter’s doctor warned her that her overweight child could develop diabetes, the whole family became determined to get in shape. “We do everything together”, says Mrs. Amaya. While her mom gets exercise by walking around the soccer field with some of the other parents, as part of Soccer for Success Los Angeles’ parent engagement component, Celeste’s father helps the Soccer for Success mentors coach Celeste and the other children. Celeste’s little sister also participates in Soccer for Success. Due

to the funding we received from the Social Innovation Fund, we will be able to leverage each Federal dollar and continue making this type of impact, while changing the lives of more than 12,000 youth like Celeste.

In conclusion, we respectfully ask you to support \$70 million in funding for the Social Innovation Fund which is the level at which it is authorized in the Serve America Act. At a time when the Federal Government seeks to leverage every taxpayer dollar to greatest effect, the Social Innovation Fund provides a critical mechanism for identifying innovative, cost-effective, evidence-based programs like Soccer for Success—programs that make a real difference in lives of the Nation’s most vulnerable children. Every child should have a chance to play, to be a teammate, to build self-confidence and to live a healthy and active life. Funding from the Social Innovation Fund helps to further this vision.

Thank you once again for the opportunity to provide testimony to your subcommittee in support of this important program. Your attention and assistance are greatly appreciated.

PREPARED STATEMENT OF THE UNITED TRIBES TECHNICAL COLLEGE

For 43 years, United Tribes Technical College (UTTC) has provided postsecondary career and technical education, job training and family services to some of the most impoverished, high risk Indian students from throughout the Nation. We are governed by the five tribes located wholly or in part in North Dakota. We are not part of the North Dakota State college system and do not have a tax base or State-appropriated funds on which to rely. We have consistently had excellent retention and placement rates and are a fully accredited institution. Section 117 Carl Perkins Act funds represent about one-half of our operating budget and provide for our core instructional programs. The requests of the United Tribes Technical College Board for fiscal year 2013 is for Department of Education programs as follows:

- \$10 million for base funding authorized under section 117 of the Carl Perkins Act for the Tribally Controlled Postsecondary Career and Technical Institutions program (20 U.S.C. section 2327). This is \$1.8 million over the fiscal year 2012 level and the President’s request. These funds are awarded competitively and are distributed via formula;
- \$30 million as requested by the administration and the American Indian Higher Education Consortium for title III–A (section 316) of the Higher Education Act (Strengthening Institutions program). This is \$5 million over fiscal year 2012 enacted;
- Maintain Pell Grants at the \$5,635 maximum award level; and
- Support the proposed Community College to Career Fund.

AUTHORIZATION

United Tribes Technical College began operations in 1969. We realized that in order to more effectively address the unique needs of Indian people to acquire the academic knowledge and skills necessary to enter the workforce we needed to expand our curricula and services. We were scraping by with small amounts of money from the Bureau of Indian Affairs, and so decided to work for an authorization in the Department of Education. That came about in 1990 when the Carl Perkins Act was reauthorized and it included specific authorization for what is now called the Tribally Controlled Postsecondary Career and Technical Institutions program (Section 117). The Perkins Act has been reauthorized twice since then—in 1998 and in 2006, with the Congress each time continuing the section 117 Perkins program.

SOME IMPORTANT FACTS ABOUT UNITED TRIBES TECHNICAL COLLEGE

We have:

- A dedication to providing an educational setting that takes a holistic approach toward the full spectrum of student needs—educational, cultural, and necessary life skills.
- Renewed unrestricted accreditation from the North Central Association of Colleges and Schools for the period July 2011 through July 2021, including authority to offer all of our full programs online.
- Services including a Child Development Center, family literacy program, wellness center, area transportation, K–8 elementary school, tutoring, counseling and housing.
- A semester completion rate of 82 percent.
- A graduate placement rate of 83 percent (placement into jobs and higher education).

- A projected return on Federal investment of 20–1 (2005 study).
- more than 30 percent of our graduates move on to 4 year or advanced degree institutions.
- A current student body from 63 tribes who come mostly from high-poverty, high-unemployment tribal nations in the Great Plains; many students have dependents.
- 76 percent of undergraduate students receive Pell Grants.
- 21 2 year degree programs, 12 certificates, and 3 bachelor degree programs (elementary education; business administration; and criminal justice).
- An expanding curricula to meet job-training needs for growing fields including law enforcement and health information technology. We have new short-term training programs for welding technology (in particular demand in North Dakota because of the oil boom), electrical, energy auditing, and Geographic Information System technology.
- A dual enrollment program targeting junior and senior high school students, providing them an introduction to college life and offering high school and college credits.
- A critical role in the regional economy. Our presence brings at least \$34 million annually to the economy of the Bismarck region.
- A workforce of 360 people.
- An award-winning annual powwow which last year had participants from 60+ tribes and international indigenous dance groups, drawing more than 10,000 spectators.

FUNDING REQUESTS

Section 117 Perkins Base Funding.—Funds requested under section 117 of the Perkins Act above the fiscal year 2012 level are needed to: maintain 100-year-old education buildings and 50-year-old housing stock for students; upgrade technology capabilities; provide adequate salaries for faculty and staff (who have not received a cost of living increase for the past year and who are in the bottom quartile of salary for comparable positions elsewhere); and fund program and curriculum improvements.

Acquisition of additional base funding is critical as UTTC has more than tripled its number of students within the past 8 years while actual base funding, including Interior Department funding, have not increased commensurately (increased from \$6 million to \$8 million for the two programs combined). Our Perkins funding provides a base level of support while allowing the college to compete for desperately needed discretionary contracts and grants leading to additional resources annually for the college's programs and support services.

Title III-A (Section 316) Strengthening Institutions.—Among the Title III-A statutorily allowable uses is facility construction and maintenance. We are constantly in need of additional student housing, including family housing. We would like to educate more students but lack of housing has at times limited the admission of new students. With the completion this year of a new Science, Math and Technology building on our south campus on land acquired with a private grant, we urgently need housing for up to 150 students, many of whom have families.

While UTTC has constructed three housing facilities using a variety of sources in the past 20 years, approximately 50 percent of students are housed in the 100-year-old buildings of the old Fort Abraham Lincoln, as well as in housing that was donated by the Federal Government along with the land and Fort buildings in 1973. These buildings require major rehabilitation. New buildings for housing are actually cheaper than trying to rehabilitate the old buildings.

Pell Grants.—We support maintaining the Pell Grant maximum amount to at least a level of \$5,635. As mentioned above, 76 percent of our students are Pell Grant-eligible. This program makes all the difference in the world of whether these students can attend college.

Community College to Career Fund.—We support the proposed Community College Career Fund, and understand that tribally controlled colleges will be eligible applicants. UTTC is ready with training—campus-based and online—to help meet the needs of high-demand businesses.

GOVERNMENT ACCOUNTABILITY OFFICE REPORT

As you know, the Government Accountability Office in March 2011 issued two reports regarding Federal programs which may have similar or overlapping services or objectives (GAO-11-318SP of March 1 and GAO-11-474R of March 18). Funding from the Bureau of Indian Education (BIE) and the Department of Education's Perkins Act for Tribally Controlled Postsecondary Career and Technical Institutions

were among the programs listed in the supplemental report of March 18. The GAO did not recommend defunding these or other programs; in some cases consolidation or better coordination of programs was recommended to save administrative costs. We are not in disagreement about possible consolidation or coordination of the administration of these funding sources so long as funds are not reduced.

Perkins funds represent about 46 percent of UTTC's core operating budget. The Perkins funds supplement, but do not duplicate, the BIE funds. It takes both sources of funding to frugally maintain the institution. Even these combined sources do not provide the resources necessary to operate and maintain the college and thus we actively seek alternative funding to assist with academic programming, deferred maintenance of our physical plant and scholarship assistance, among other things.

We reiterate that UTTC and other tribally chartered colleges are not part of State educational systems and do not receive State-appropriated general operational funds for their Indian students. The need for postsecondary career and technical education in Indian country is so great and the funding so small, that there is little chance for duplicative funding.

There are only two institutions targeting American Indian/Alaska Native career and technical education and training at the postsecondary level—United Tribes Technical College and Navajo Technical College. Combined, these institutions received less than \$15 million in fiscal year 2012 Federal operational funds (\$8 million from Perkins; \$7 million from the BIE). That is a modest amount for two campus-based institutions which offer a broad (and expanding) array of programs geared toward the educational, job-training, and cultural needs of their students.

UTTC offers services that are catered to the needs of our students, many of whom are first-generation college attendees and many of whom come to us needing remedial education and services. Our students disproportionately possess more high risk characteristics than other student populations. We also provide services for the children and dependents of our students. Although BIE and section 117 funds do not pay for remedial education services, we make this investment through other sources of funding to help ensure that our students succeed at the postsecondary level.

Perkins funds are central to the viability of our core postsecondary educational programs. Very little of the other funds we receive may be used for core career and technical educational programs; they are highly competitive, often one-time supplemental funds.

Thank you for your consideration of our requests.

PREPARED STATEMENT OF THE UNIVERSITY OF VIRGINIA

This testimony is submitted for the record on behalf of the University of Virginia, a nonprofit public institution of higher education located in Charlottesville, Virginia. The University sustains the ideal of developing, through education, leaders who are well-prepared to help shape the future of the nation. In fiscal year 2011 the University received research awards totaling more than \$338 million from all sources (Federal and State agencies, industry and private foundations). Of this amount, \$241 million, or 71 percent, came from Federal grants and contracts.

As Vice President for Research and on behalf of UVa, I urge the Committee to support \$32 billion for the National Institutes of Health (NIH) in fiscal year 2013. We are aware of the difficult budgetary decisions facing the Congress and the administration in the coming years, yet Federal investments in scientific and engineering research remain critical to spurring innovation, driving the economy, and developing the knowledge and technologies to tackle current and future health challenges. According to the Science Coalition, more than half of our economic growth in the United States since World War II can be traced to science-driven technological innovation. The platform for this innovation has been scientific and engineering research conducted at universities and supported by the Federal Government through agencies such as NIH.

Ground-breaking discoveries to better diagnose and treat debilitating human diseases and improve the health and quality of life of our citizens would not be possible without the foundational work of basic research. Universities conduct most of the basic research in this country and NIH is the critical funder of basic biomedical research. NIH continues to be the largest source of Federal research funding at UVa, providing more than \$144 million in competitive grants to researchers at UVa in fiscal year 2011 alone. Funding from NIH has allowed faculty and students at UVa to conduct ground-breaking research to transform our understanding of and develop new treatments for diabetes, asthma, cardiovascular disease, and Alzheimer's disease, among many other conditions, while also furthering our fundamental knowledge of biology, health, and development from childhood to old age.

Considering the tight budget conditions that the country faces, it is imperative to make strategic investments in critical areas of science and biomedical research that will produce technological innovation and societal benefit. For example, continued support for the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is critical to advancing the next generation of technologies that can be used to address a myriad of health challenges. Researchers at UVa are already making substantial advances on a wide array of new technologies for applications such as molecular imaging and tissue engineering.

NIH is also at the forefront of efforts to ensure that basic research is transformed into products and knowledge that improve everyday life and power our innovation economy. UVa appreciates NIH's commitment to funding programs that support commercialization such as the new National Center for Advancing Translational Sciences (NCATS). UVa also urges support for a newly created pilot program to fund proof-of-concept research that will enable universities to more effectively commercialize new technologies and propel the creation of successful small businesses. Modeled after the Coulter Process and authorized in the Small Business Innovation Research (SBIR) and the Small Business Technical Transfer (STTR) Reauthorization Act of 2011, the program will allow NIH to award competitive grants of up to \$1 million to universities and other research institutions, which then would award grants to investigators for activities such as prototype development, market research, or developing an intellectual property strategy and/or business development plan. We look forward to seeing how NIH will implement this new program and urge the Congress to encourage NIH to support proof-of-concept funds to advance commercialization.

At UVa we are devoting significant institutional resources to the process of bringing discoveries to the marketplace and have experienced considerable success. For instance, UVa and the Coulter Foundation have recently teamed to create the UVa Coulter Translational Research Partnership to foster collaborations between clinicians and biomedical engineers at UVa in order to advance translational research which will result in new technologies to improve patient care and human health. An independent audit has shown that our proof-of-concept funds have led to a 7:1 return on investment after 5 years and a 42:1 return on investment for the top 10 percent of portfolio projects. We attribute UVa's success in proof-of-concept research to the now nationally well-known Coulter process, involving a very diverse review board, in-person final review sessions, milestone-driven projects, quarterly reporting that is simple yet effective in re-directing projects, the "will to kill" projects or re-direct funds if insurmountable obstacles occur, and excellent networking to the venture capital and private sector. The key differentiators of this process as we employ it at UVa versus most prior proof-of-concept funding mechanisms is the in-person diligence on the involved people and ideas, dedicated project manager, the diverse composition of the board, the urgency of quarterly reviews, and will to re-direct funds as results emerge.

Conclusion

I would like to thank the Committee for your support of biomedical research in these tough budgetary times. While we understand that funding is greatly constrained, I hope that you will choose to support a strategic increase for the National Institutes of Health to spur innovation, strengthen our technology and economic base, train the next generation of scientists and engineers, and improve our health. Further investment in discovery science and commercialization will help create the new discoveries and technologies needed for long-term economic growth.

I thank you for your consideration of these important issues.

PREPARED STATEMENT OF THE DEPARTMENT OF MINES, MINERALS AND ENERGY, COMMONWEALTH OF VIRGINIA

We are writing in opposition to the fiscal year 2013 budget request for the Mine Safety and Health Administration (MSHA), which is part of the U.S. Department of Labor. In particular, we urge the subcommittee to reject MSHA's proposed reduction of \$5 million for grants to States for safety and health training of our Nation's miners pursuant to Section 503(a) of the Mine Safety and Health Act of 1977.

Over the past several years, MSHA's budget request for State's Grants was approximately \$9 million, which approached the statutorily authorized level of \$10 million, but still did not consider inflationary and programmatic increases being experienced by the States. This drastic change in funding the State's Grants programs will certainly have negative impacts on the availability and quality of mine safety training. Without full funding of the State's Grants programs, the Federal required

safety training for miners will suffer. This situation will be further exacerbated by the new statutory, regulatory and policy requirements that grow out of the various reports and recommendations pending the Upper Big Branch mine disaster investigation. We therefore urge the subcommittee to restore funding to the statutorily authorized level of \$10 million for State's grants so that States can meet the training needs of miners and fully and effectively carry out State responsibilities under Section 203(a) of the Act.

While we can appreciate MSHA's desire to realign its resources to focus on inspection and enforcement activities, one of the most effective ways to ensure miner health and safety in the first place is through comprehensive and high quality training. MSHA Assistant Secretary Main specifically spoke of this in a recent letter to State's Grant recipients wherein he stated: "As in the past, we are reaching out to grantees, recognizing the positive impact you have in delivering training to miners. I am asking that you incorporate, as appropriate training on these types of fatal accidents as well as measures needed to prevent them. Increased training and awareness is necessary if we are to prevent these types of deaths".

Certainly, we can all agree that high quality, effective training plays a critical role in preventing miner deaths, injuries and illness across the Nation. Comprehensive, up-to-date training is the most effective means for preparing miners to recognize and correct unsafe acts and unsafe conditions in the workplace. Unsafe acts and unsafe conditions have been proven to contribute significantly to accidents and injuries. Training enhances the capability of miners to recognize potential hazards in the workplace and to follow safe work procedures.

The Virginia State's Grants training program has contributed significantly to training approximately 5,400 miners, annually, for the past 5 years. Our training program also develops miner training programs, mine safety videos, mine and equipment examination record books, among other useful resources. These programs and materials are distributed to industry, independent and college trainers and mine officials to enhance their capability to provide on-target, up-to-date, effective training for miners.

The DMME has been in the forefront of providing this training in Virginia for over 40 years and is best positioned to continue that work into the future. The Federal Government's relatively modest investment of money in supporting the States to coordinate this training has certainly paid huge dividends in protecting lives and preventing injuries/illnesses for our miners. The VA-DMME State's Grants programs play a particularly critical role in providing quality mine safety training and providing special assistance to small mine operators. Our State's grant program provides these services at a cost well below what it would cost the Federal Government to do so.

Without the training programs that are funded/provided by the VA-DMME State's grants program, pursuant to the funding that we receive from MSHA, mine safety training responsibilities and costs will shift to mine operators. Mine operators will be compelled to comply with MSHA-required miner training by obtaining training services from any available resource. Quality, effective training for our most valuable resource—the miner—will be diminished, especially for miners employed at small mines (50 or less employees). In addition, some training services now funded/provided by the VA-DMME State's grants program will be significantly reduced or eliminated.

In conclusion, the everyday miner in the workplace will be the greatest loser if this proposed funding reduction is imposed upon the VA-DMME State's Grant training program.

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