DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2012

WEDNESDAY, MARCH 30, 2011

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

The subcommittee met at 10:03 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senator Harkin, Reed, Pryor, Mikulski, Brown, Shelby, Johnson, Kirk, 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 Labor, Health and Human Services Appropriations Subcommittee will come to order.

We welcome back Madam Secretary to the subcommittee. I want to first start by commending you for the outstanding work that you are doing to implement our healthcare reform law. It has been just 1 year since President Obama signed the Affordable Care Act into law, and already millions of Americans are reaping major benefits. Those benefits include very strong consumer protections. No longer can large health insurers use technicalities to cancel your policy if you get sick or impose lifetime limits on your benefits. No longer can children be denied coverage because of a preexisting health condition. Americans have greater access to preventative care than ever before, and of course, young adults can now stay on their parents' plan until age 26.

In the past year, your Department has also awarded the first grants from the Prevention and Public Health Fund, a new fund that will not only improve the health of the American people but also help bend the cost curve on healthcare. This fund is already being used to help Americans stop smoking, as well as to reduce obesity and prevent costly chronic diseases like diabetes.

Your plan for fiscal year 2011 expands on all of this work and adds an investment in childhood immunization which data shows saves about $6.30 for every dollar that we spend.

Your Department is implementing these reforms with great skill and dedication, and I thank you for your leadership.

I also want to assure you that as chairman of both this Appropriations subcommittee and the authorizing committee, the HELP Committee, your Department will continue to receive the resources you need to implement the Affordable Care Act. The American people will not allow the hard-earned protections and benefits in this law to be taken away. And neither will we.

Reforming healthcare is not only the right thing to do, it will save taxpayers money and reduce the deficit by $210 billion in the first decade and more than $1 trillion in the next. And those are not my estimates. They are from the nonpartisan Congressional Budget Office.

I am well aware that some opponents of healthcare reform say they intend to use the Labor, HHS appropriations bill, our bill, as a vehicle for defunding the Affordable Care Act. That will not happen.

Our topic today is the President's fiscal year 2012 budget request for the Department of Health and Human Services. Unfortunately, as we all know, Congress still has not closed the books on fiscal year 2011. That uncertainty makes it harder than usual to evaluate the President's request. For example, the House has proposed major reductions to key programs like community health centers, Head Start, and the National Institutes of Health. We do not yet know the outcome of negotiations to complete a budget for fiscal year 2011, but one of the things I want to cover in this hearing is what the impact of those potential cuts would be, that is, on community health centers, Head Start, and the National Institutes of Health (NIH).

Overall, the President's proposed budget for fiscal year 2012 is a good start. It is a tight budget. Total funding for the Department is almost flat compared with fiscal year 2010, but it does include some significant increases for key priorities like NIH, child care, Head Start, and of course, rooting out fraud and waste in Medicare and Medicaid.

I also applaud the administration for proposing a new early learning challenge fund which is intended to improve the quality of early childhood education programs. The money for this new fund would go through the Education Department, but HHS would be a partner in that effort.

However, some provisions in the President's budget are a cause for concern. I recognize that we are operating under significant fiscal constraints, but I am greatly disappointed by the proposed 50 percent cut to the community services block grant program. This funding is critically important for community initiatives that provide a safety net for millions of low-income people across the country, and I will do whatever I can to oppose that cut in any bill that comes out of this subcommittee.

I am also concerned by the proposed $2.5 billion cut to the Low-Income Home Energy Assistance Program, as well as the small but important $30 million cut—that would be a 72 percent cut—to the Child Traumatic Stress Network.

But as I said, overall the budget is a good start.

Madam Secretary, I look forward to hearing your testimony.

First, before I yield to Senator Shelby for his opening remarks, I have received statements from the full committee chairman, Senator Inouye and the vice chairman, Senator Cochran. Their statements will be inserted into the record at this point.

[The statements follow:]

PREPARED STATEMENT OF CHAIRMAN DANIEL K. INOUYE

Secretary Sebelius, given the unique geographic challenges in Hawaii it is imperative that we continue to work together to address the healthcare needs of our population. I would like to take this opportunity to thank you for your support in addressing the medical needs of the people in Hawaii. I will provide questions for the record.

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for chairing this hearing to review the President's fiscal year 2012 budget for the Department of Health and Human Services. We are pleased to welcome the Secretary of Health and Human Services, Kathleen Sebelius to her third appearance before our Subcommittee, and we look forward to working with her to support our Nation's investment in healthcare, social services programs, medical research and disease prevention.

I am pleased that your budget includes a $745 million increase for the National Institutes of Health. These additional dollars are essential if we are to continue to make scientific discoveries in cancer, autism, heart disease and the many other maladies that plague so many Americans.

This subcommittee will be challenged to balance the competing needs of the programs contained in your $79 billion budget. We look forward to working with you to maintain our commitment to fiscal restraint while providing much needed increases for high priority programs.

I am very sorry I cannot stay for the duration of this important hearing due to another hearing that requires my attention, but I am submitting questions for the record and I look forward to a response.

Senator HARKIN. Senator Shelby.

STATEMENT OF SENATOR RICHARD C. SHELBY

Senator SHELBY. Thank you, Mr. Chairman.

Welcome, Secretary Sebelius.

I look forward to hearing your testimony today on the 2012 budget request.

In this austere economic environment, Congress is struggling with difficult budget decisions. We all understand the valuable role that healthcare plays in the lives of our citizens, and we all want to make healthcare more affordable, more accessible, and on the cutting edge of scientific discoveries.

However, in times of economic uncertainty when every Department should be exercising fiscal restraint, I am disappointed that the administration has not significantly reduced healthcare spending. In fact, on top of the 9 percent increase in the entire Department of Health and Human Services' budget request, the 2012 bill includes $4.2 billion in mandatory spending for the Affordable Care Act, ACA. This is $4.2 billion that, due to Senate rules, this subcommittee cannot reduce or rescind. It is simply more spending for another entitlement program.

One of the most troubling aspects of the ACA is the Community Living Assistance Services and Supports (CLASS) Act. The CLASS Act we call it. The CLASS Act is a new voluntary Federal insurance program. Its goal is twofold: to provide a cash benefit to individuals with either a functional or equivalent cognitive limitation

that become too disabled to work and to create a voluntary insurance program for healthy individuals looking to hedge against the risk of needing long-term care in the future. However, the CLASS Act's poor design attempts to accomplish these two incompatible goals with a single program. The result will be that the cost of serving disabled workers will push premiums to unacceptably high levels for those looking to purchase insurance, and they will decline to buy. I think this will quickly push the program to insolvency.

The Congressional Budget Office predicts the CLASS Act will "add to budget deficits by amounts on the order of tens of billions of dollars." The Department of Health and Human Services actuary states and says, "There is a very serious risk that the program will be unsustainable." Even you, Madam Secretary, testified at the Senate Finance Committee hearing early this year and said, "The bill as written is totally unsustainable."

In addition to the $4.2 billion included in mandatory spending for the ACA, the budget submission includes $450 million in discretionary funding. Specifically, the budget proposes to spend $120 million on the financially unsustainable CLASS Act, $236 million for health insurance exchange operations, $38 million for healthcare.gov, and $28 million to help consumers navigate the private insurance market. Secretary Sebelius, we fundamentally disagree on the implementation of the ACA. However, one area of the ACA we should agree on is that $38 million to fund one website is unacceptable.

Further, I am concerned that many important programs, such as the Community Health Center Fund, are moved to the mandatory side of the ledger and funded under the ACA. The question is, what happens if the ACA is repealed and agencies' baseline funding levels are too low to cover the cost of these programs?

Finally, as we continue to review the 2012 budget, I believe we need to ensure that our entire Nation, not just population-rich urban areas, is reaping the benefits of healthcare programs. There are numerous consolidations in the budget that eliminate formula-funded grants which will result in the redirection of critical Federal funds from smaller, rural States to urban areas. I think we must continue to make certain that programs that are deemed competitive actually allow all States to compete on a level playing field.

Mr. Chairman, the level of Federal spending, I believe, is unsustainable. We must make steps to reduce the deficit that burdens our Nation today and will continue to in the future. Every Federal program should be reviewed to ensure it is working effectively and efficiently and is a valuable use of taxpayer dollars. However, I remain cautious about arbitrary or across-the-board cuts to agencies and programs simply to score a political point. Congress needs to carefully examine programs to ensure that we are sustaining those that are effective and cutting those that are not.

In particular, one of the most results-driven aspects of our entire Federal budget I believe is the National Institutes of Health. Research conducted at NIH reduces disabilities, prolongs life, and is an essential component to the health of all Americans. NIH programs consistently meet their performance and outcome measures, as well as achieve their overall mission.

For example, in February, NIH research led to the announcement of a very promising cystic fibrosis therapy that targets the genetic defect that causes cystic fibrosis as opposed to only addressing its symptoms. The preliminary success of this drug, for instance, underscores the importance of the NIH whose innovative work on human genetics and other areas of basic science could potentially lead to treatments and even cures for some of our most devastating diseases.

Mr. Chairman, I look forward to working with you to craft a bill that balances the needs of our healthcare system with our fiscal realities.

Senator HARKIN. Thank you very much, Senator Shelby.

Now we will turn to our distinguished Secretary of Health and Human Services. Kathleen Sebelius became the 21st Secretary of the Department of Health and Human Services on April 29, 2009. Prior to that, of course, in 2003 she was elected as Governor of Kansas and served in that capacity until her appointment as the Secretary.

Prior to her election as Governor, the Secretary served as the Kansas State insurance commissioner.

She is a graduate of Trinity Washington University and the University of Kansas.

I believe this will make the Secretary's fourth appearance before this subcommittee since her appointment.

Madam Secretary, we welcome you again. Your statement will be made a part of the record in its entirety, and please proceed as you so desire.

SUMMARY STATEMENT OF HON. KATHLEEN SEBELIUS

Secretary SEBELIUS. Thank you, Mr. Chairman. Chairman Harkin, Ranking Member Shelby, members of the subcommittee, I need to do a special shout out to my fellow Kansan, Senator Moran, who is a new member of your subcommittee, Mr. Chairman. But I had the privilege of working with the Senator for years on Kansas business and now look forward to working with him in his new capacity here in the Senate.

It is good to be with you and discuss the President's 2012 budget for the Department of Health and Human Services.

In the President's State of the Union Address, he outlined a vision of how the United States can win the future by out-educating, out-building, and out-innovating the world so we give every family and business the chance to thrive.

Our 2012 budget is a blueprint for putting that vision into action. It makes investments for the future that will grow our economy and create jobs.

But the budget recognizes we cannot build lasting prosperity on a mountain of debt. Years of deficits have put us in a position where we need to make some tough choices. In order to invest for the future, we need to live within our means.

In developing our budget, we looked closely at every program in our Department. We cut waste when we found it, and when programs were not working well enough, we redesigned them to put a new focus on results. And, in some cases, we cut programs that would not have been cut in better budget times.

Now, I look forward to answering your questions on the budget, but first I want to share some of the highlights that fall under the jurisdiction of this subcommittee which oversees more than $72 billion of our Department's $80 billion budget.

Last week, as the chairman said, was the 1-year anniversary of the Affordable Care Act. Over the last 12 months, we have worked around the clock with partners in Congress and States to deliver on the promise of the law to the American people.

Thanks to the new law, children are no longer denied coverage because of their preexisting health conditions. Families have new protections under the Patient's Bill of Rights. Businesses are beginning to get some relief from soaring healthcare costs, and seniors have lower cost access to prescription drugs and preventive care.

We are building on this first year's progress by supporting innovative new models of care that will improve patient safety and quality while reducing the burden of rising health costs on families, businesses, cities, and States.

We are also making new, important investments in our healthcare workforce and community health centers to make quality, affordable care available to millions more Americans and create hundreds of thousands of new jobs across the country.

To make sure America continues to lead the world in innovation, our budget also increases funding for the National Institutes of Health. New frontiers of research like cell-based therapies and genomics have the promise to unlock transformative treatments and cures for diseases ranging from Alzheimer's to cancer to autism. Our budget will allow the world's leading scientists to pursue these discoveries while keeping America at the forefront of biomedical research.

And because we know, Mr. Chairman, there is nothing more important to our future than the healthy development of our children, our budget includes significant increases in funding for child care and Head Start. Science shows that success in school is significantly enhanced by high quality early learning opportunities, which makes these some of the wisest investments we can make in America's future.

But the budget does more than provide additional resources. We are also aiming to raise the bar on quality by supporting key reforms to transform the Nation's child care system into one that fosters healthy development and gets children ready for school. The budget proposes a new early learning challenge fund, a partnership with the Department of Education that helps promote State innovation in early education. These initiatives, coupled with the quality efforts already underway in Head Start, are an important part of the education agenda that will help every child reach their academic potential and make America more competitive.

Our budget also recognizes that at a time when so many Americans are making every dollar count, we need to do the same. That is why we are providing new support for President Obama's unprecedented push to stamp out waste, fraud, and abuse in the healthcare system, an effort that well more than pays for itself. Last year, we returned a record $4 billion to taxpayers. The key part of this effort is empowering seniors to recognize and report fraud, and we have appreciated the support of Congress and espe-

cially Senator Harkin for the Senior Medicare Patrol Program, which is one of our best tools for doing that.

In addition, the budget includes a robust package of legislative proposals to root out waste and abuse within Medicare and Medicaid. These proposals enhance prepayment scrutiny, expand auditing, increase penalties for improper actions, and strengthen CMS' ability to implement corrective actions. We address State activities that increase Federal spending. Over 10 years, on the conservative side, they will deliver at least $32 billion in savings.

Across our entire Department, Mr. Chairman, we have made eliminating waste, fraud, and abuse a top priority, but we know that is not enough. Over the last few months, we have also gone through our Department's budget, program by program, to find additional savings and opportunities where we can make our resources go further.

The President's 2012 budget makes tough choices and smart, targeted investments today so that we can have a stronger, healthy, and more competitive America tomorrow. That is what it takes to win the future and that is what we are determined to do.

PREPARED STATEMENT

Again, thank you, Mr. Chairman, for having me here today and I look forward to our discussion.

[The statement follows:]

PREPARED STATEMENT OF KATHLEEN SEBELIUS

Chairman Harkin, Senator Shelby, and Members of the Subcommittee, thank you for the invitation to discuss the President's fiscal year 2012 budget for the Department of Health and Human Services (HHS).

In President Obama's State of the Union address he outlined his vision for how the United States can win the future by out-educating, out-building and out-innovating the world so that we give every family and business the chance to thrive. His 2012 budget is the blueprint for putting that vision into action and making the investments that will grow our economy and create jobs.

At the Department of Health and Human Services this means giving families and business owners better access to healthcare and more freedom from rising health costs and insurance abuses. It means keeping America at the cutting edge of new cures, treatments and health information technology. It means helping our children get a healthy start in life and preparing them for academic success. It means promoting prevention and wellness to make it easier for families to make healthy choices. It means building a healthcare workforce that is ready for the 21st century health needs of our country. And it means attacking waste and fraud throughout our department to increase efficiency, transparency and accountability.

Our 2012 budget does all of this.

At the same time, we know that we can't build lasting prosperity on a mountain of debt. And we can't win the future if we pass on massive debts to our children and grandchildren. We have a responsibility to the American people to live within our means so we can invest in our future.

For every program we invest in, we know we need to cut somewhere else. So in developing this budget, we took a magnifying glass to every program in our department and made tough choices. When we found waste, we cut it. When we found duplication, we eliminated it. When programs weren't working well enough, we reorganized and streamlined them to put a new focus on results. When they weren't working at all, we ended them. In some cases, we cut programs we wouldn't in better fiscal times.

The President's fiscal year 2012 budget for HHS totals $891.6 billion in outlays. The budget proposes $79.9 billion in discretionary budget authority for fiscal year 2012, of which $72.4 billion is within the jurisdiction of the Labor, Health and Human Services, Education, and Related Agencies Subcommittee.

The Department's discretionary budget is slightly below the 2010 level. Within that total we cover the increasing costs of ensuring the safety of our food supply,

providing medical care to American Indians and Alaska Natives, managing our entitlement programs, investing in early childhood, and advancing scientific research. We contribute to deficit reduction and meet the President's freeze to non-security programs by offsetting these investments with over $5 billion in targeted reductions. These reductions are to real programs and reflect tough choices. In some cases the reductions are to ineffective or outdated programs and in other areas they are cuts we would not have made absent the fiscal situation.

The budget proposes a number of reductions and terminations in HHS.

—The budget cuts the Community Services Block Grant in half, a $350 million reduction, and injects competition into grant awards.

—The budget cuts the Low Income Home Energy Assistance Program by $2.5 billion bringing it back to the 2008 level appropriated prior to energy price spikes.

—The budget eliminates subsidies to Children's Hospitals Graduate Medical Education focusing instead on targeted investments to increase the primary care workforce.

—The budget reduces the Senior Community Services Employment Program by $375 million, proposes to transfer this program from the Department of Labor to HHS, and refocuses the program to train seniors to help other seniors.

The budget also stretches existing resources through better targeting.

—The budget redirects and increases funding in CDC to reduce chronic disease. Rather than splitting funding and making separate grants for heart disease, diabetes, and other chronic diseases, the budget proposes one comprehensive grant that will allow States to address chronic disease more effectively.

—The budget redirects prevention resources in SAMHSA to fund evidence-based interventions and better respond to evolving needs. States and local communities will benefit from the additional flexibility while funds will still be competed and directed toward proven interventions.

These are the two goals that run throughout this budget: making the smart investments for the future that will help build a stronger, healthier, more competitive, and more prosperous America, and making the tough choices to ensure we are building on a solid fiscal foundation.

The budget documents are available on our website. But for now, I want to share an outline of the budget, including the areas of most interest to this Committee, and how it will help our country invest in, and win, the future.

That starts with giving Americans more freedom in their healthcare choices, so they can get affordable, high-quality care when they need it.

TRANSFORM HEALTHCARE

Expanding Access to Coverage and Making Coverage More Secure.—The Affordable Care Act expands access to affordable coverage to millions of Americans and strengthens consumer protections to ensure individuals have coverage when they need it most. These reforms create an important foundation of patients' rights in the private health insurance market and put Americans in charge of their own healthcare. As a result, we have already implemented historic private market reforms including eliminating pre-existing condition exclusions for children; prohibiting insurance companies from rescinding coverage and imposing lifetime dollar limits on coverage; and enabling many adult children to stay on their parent's insurance plan up to age 26. The Affordable Care Act also established new programs to lower premiums and support coverage options, such as the Pre-Existing Condition Insurance Plans Program and the Early Retiree Reinsurance Program. The Act provides Medicare beneficiaries and enrollees in most private plans access to certain covered preventative services free of charge. Medicare beneficiaries also have increased access to prescription drugs under Medicare Part D by closing the coverage gap, known as the "donut hole," by 2020 so that seniors no longer have to fear being unable to afford their prescriptions. The Act also provides for an annual wellness visit to all Medicare beneficiaries free of charge.

Beginning in 2014, State-based health insurance Exchanges will create affordable, quality insurance options for many Americans who previously did not have health insurance coverage, had inadequate coverage, or were vulnerable to losing the coverage they had. Exchanges will make purchasing private health coverage easier by providing eligible consumers and small businesses with "one-stop-shopping" where they can compare a range of plans. New premium tax credits and cost-sharing reductions will also increase the affordability of coverage and care. The Affordable Care Act will also extend Medicaid insurance to millions of low-income individuals who were previously not eligible for coverage, granting them access to affordable healthcare.

Ensuring Access to Quality, Culturally Competent Care for Vulnerable Populations.—The budget includes $3.3 billion for the Health Centers Program, including $1.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund, to expand the capacity of existing health center services and create new access points. The infusion of funding provided through the Affordable Care Act, combined with the discretionary request for fiscal year 2012, will enable health centers to serve 900,000 new patients and increase access to medical, oral, and behavioral health services to a total of 24 million patients.

Reducing Health Care Costs.—New innovative delivery and payment approaches will lead to both more efficient and higher quality care. For example, provisions in the Affordable Care Act designed to reduce healthcare acquired conditions and preventable readmissions will both improve patient outcomes and reduce unnecessary health spending. The Innovation Center, in coordination with private sector partners whenever possible, will pursue new approaches that not only improve quality of care, but also lead to cost savings for Medicare, Medicaid, and CHIP. Rate adjustments for Medicare providers and insurers participating in Medicare Advantage will promote greater efficiency in the delivery of care. Meanwhile, new rules for private insurers, such as medical loss ratio standards and enhanced review of premium increases, will lead to greater value and affordability for consumers.

Combating Healthcare Associated Infections.—HHS will use measures related to heathcare-associated infections (HAIs) for hospital value-based purchasing beginning in fiscal year 2013, as called for in the Affordable Care Act. The fiscal year 2012 budget includes $86 million—of which $20 million is funded in the Prevention and Public Health Fund Prevention Trust Fund—to the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and the Office of the Secretary to reduce healthcare-associated infections. In fiscal year 2012, HHS will continue research on health-care associated infections and tracking infections through the National Healthcare Safety Network. HHS will also identify and respond to new healthcare-associated infections by conducting outbreak and epidemiological investigations. In addition, HHS will implement, and ensure adherence to, evidence-based prevention practices to eliminate healthcare-associated infections. HHS activities, including those that the Innovation Center sponsors, will further the infection reduction goals of the Department's Action Plan to Prevent Healthcare-Associated Infections. HHS has made progress in reducing HAIs. For instance, in 2009, an estimated 25,000 fewer central line-associated blood stream infections (CLABSIs) occurred among patients in ICUs in the United States than in 2001 (a 58 percent reduction). Progress in reducing CLABSIs highlights the preventability of these infections, and HHS will continue to support HAI prevention in collaboration with States and facility partners.

Health Services for 9/11 Terrorist Attacks.—To implement the James Zadroga 9/11 Health and Compensation Act, the fiscal year 2012 budget includes $313 million in mandatory funding to provide medical monitoring and treatment to responders of the September 11, 2001 terrorist attacks and initial health evaluations, monitoring, and treatment to others directly affected by the attacks. In addition to supporting medical monitoring and treatment, HHS will use funds to establish an outreach program for potentially eligible individuals, collect health data on individuals receiving benefits, and establish a research program on health conditions resulting from the terrorist attacks.

ADVANCE SCIENTIFIC KNOWLEDGE AND INNOVATION

Accelerating Scientific Discovery to Improve Patient Care.—The budget includes $32 billion for the National Institutes of Health (NIH), an increased investment of $745 million over the fiscal year 2010 enacted level, to support innovative basic and clinical research that promises to deliver better health and drive future economic growth. In fiscal year 2012, NIH estimates it will support a total of 36,852 research project grants, including 9,158 new and competing awards.

Recent advances in the biomedical field, including genomics, high-throughput biotechnologies, and stem cell biology, are shortening the pathway from discovery to revolutionary treatments for a wide range of diseases, such as Alzheimer's, cancer, autism, diabetes, and obesity. The dramatic acceleration of our basic understanding of hundreds of diseases; the establishment of NIH-supported centers that can screen thousands of chemicals for potential drug candidates; and the emergence of public-private partnerships to aid the movement of drug candidates into the commercial development pipeline are fueling expectations that an era of personalized medicine is emerging where prevention, diagnosis, and treatment of disease can be tailored to the individual and targeted to be more effective. To help bridge the divide between basic science and therapeutic applications, NIH plans to establish in fiscal

year 2012 the National Center for Advancing Translational Sciences (NCATS), of which one component would be the new Cures Acceleration Network. With the creation of NCATS, the National Center for Research Resources will be abolished and its programs transferred to the new Center or other parts of NIH.

Advancing Patient-Centered Health Research.—The Affordable Care Act created the Patient-Centered Outcomes Research Institute to fund research and get relevant, high quality information to patients, clinicians and policy-makers so that they can make informed healthcare decisions. The Patient-Centered Outcomes Research Trust Fund will fund this independent Institute, and related activities within HHS. In fiscal year 2012, the budget includes $620 million in AHRQ, NIH and the Office of the Secretary, including $30 million from the Trust Fund, to invest in core patient-centered health research activities and to disseminate research findings, train the next generation of patient-centered outcomes researchers, and improve data capacity.

Advancing Health Information Technology.—The budget includes $78 million, an increase of $17 million, for the Office of the National Coordinator for Health Information Technology (ONC) to accelerate health information technology (health IT) adoption and promote electronic health records (EHRs) as tools to improve the health of individuals and transform the healthcare system. The increase will allow ONC to assist healthcare providers in becoming meaningful users of health IT.

ADVANCE THE HEALTH, SAFETY, AND WELL-BEING OF THE AMERICAN PEOPLE

Enhancing the Quality of Early Care.—The budget provides $6 billion in combined discretionary and mandatory funding for child care. These resources will enable 1.7 million children to receive child care services. The Administration also supports reforms to the child care program to serve more low-income children in safe, healthy, and nurturing child care settings that are highly effective in promoting early learning; supports parental employment and choice by providing information to parents on quality; promotes continuity of care; and strengthens program integrity and accountability Additionally, the President's budget includes $8.1 billion for Head Start, which will allow us to continue to serve 968,000 children in 2012. The Administration is also working to implement key provisions of the Head Start Reauthorization, including requiring low-performing programs to compete for funding, that will improve program quality. These reforms and investments at HHS, in conjunction with the Administration's investments in the Early Learning Challenge Fund, are key elements of the broader education agenda designed to help every child reach his or her academic potential and improve our Nation's competitiveness.

Preventing and Treating HIV/AIDS.—The budget supports the goals of the National HIV/AIDS Strategy to reduce HIV incidence, increase access to care and optimize health outcomes for people living with HIV, and reduce HIV-related health disparities. The request focuses resources on high-risk populations and allocates funds to State and local health departments to align resources to the burden of the epidemic across the United States. The budget includes $2.4 billion, an increase of $85 million, for HRSA's Ryan White program to expand access to care for persons living with HIV/AIDS who are otherwise unable to afford healthcare and related support services. The budget also includes $858 million for domestic HIV/AIDS Prevention in CDC, an increase of $58 million, which will help CDC decrease the HIV transmission rate; decrease risk behaviors among persons at risk for acquiring HIV; increase the proportion of HIV infected people who know they are infected; and integrate services for populations most at risk of HIV, sexually transmitted diseases, and viral hepatitis. In addition, the budget proposes that up to one percent of HHS discretionary funds appropriated for domestic HIV/AIDS activities, or approximately $60 million, be provided to the Office of the Assistant Secretary for Health to foster collaborations across HHS agencies and finance high priority initiatives in support of the National HIV/AIDS Strategy. Such initiatives would focus on improving linkages between prevention and care, coordinating Federal resources within targeted high-risk populations, enhancing provider capacity to care for persons living with HIV/AIDS, and monitoring key Strategy targets.

Addressing the Leading Causes of Death and Disability.—Chronic diseases and injuries represent the major causes of morbidity, disability, and premature death and 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 includes $705 million for a new competitive 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 the leading causes of death. Because many 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. In addition, the allocation of the $1 billion available in the Prevention Fund will improve health and restrain the growth of healthcare costs through a balanced portfolio of investments. The fiscal year 2012 allocation of the Fund builds on existing investments and will align with the vision and goals of the National Prevention and Health Promotion Strategy under development. For instance, the CDC Community Transformation Grants create and sustain communities that support prevention and wellness where people live, learn, work and play through the implementation, evaluation, and dissemination of evidence-based community preventive health activities.

Preventing Substance Abuse and Mental Illness.—The budget includes $535 million within the Substance Abuse and Mental Health Services Administration (SAMHSA) for new, expanded, and refocused substance abuse prevention and mental health promotion grants to States and Tribes. To maximize the effectiveness and efficiency of its resources, SAMHSA will deploy mental health and substance abuse prevention and treatment investments more thoughtfully and strategically. SAMHSA will use competitive grants to identify and test innovative prevention practices and will leverage State and Tribal investments to foster the widespread implementation of evidence-based prevention strategies through data driven planning and resource dissemination.

Supporting Older Adults and their Caregivers.—The budget includes $57 million, an increase of $21 million over fiscal year 2010, to help seniors live in their communities without fear of abuse, and includes an increase of $96 million for caregiver services, like counseling, training, and respite care, to enable families to better care for their relatives in the community. The budget also proposes to transfer an Older Americans Act program that provides community service opportunities and job training to unemployed older adults from the Department of Labor to HHS. As part of this move, a new focus will be placed on developing professional skills that will enable participants to provide services that allow fellow seniors to live in their communities as long as possible.

Pandemic and Emergency Preparedness.—While responding to the H1N1 influenza pandemic has been the focus of the most recent pandemic investments, the threat of a pandemic caused by H5N1 or other strains has not diminished. HHS is currently implementing pandemic preparedness activities in response to lessons learned from the H1N1 pandemic in order to strengthen the Nation's ability to respond to future health threats. Balances from the fiscal year 2009 supplemental appropriations are being used to support recommendations from the HHS Medical Countermeasure Review and the President's Council of Advisors on Science and Technology. These multi-year activities include advanced development of influenza vaccines and the construction of a new cell-based vaccine facility in order to quickly produce vaccine in the United States, as well as development of next generation antivirals, rapid diagnostics, and maintenance of the H5N1 vaccine stockpile.

The HHS Medical Countermeasure Review described a new strategy focused on forging partnerships, minimizing constraints, modernizing regulatory oversight, and supporting transformational technologies. The request includes $665 million for the Biomedical Advanced Research and Development Authority, to improve existing and develop new next-generation medical countermeasures and $100 million to establish a strategic investment corporation that would improve the chances of successful development of new medical countermeasure technologies and products by small and new companies. The budget includes $70 million for FDA to establish teams of public health experts to support the review of medical countermeasures and novel manufacturing approaches. Additionally, NIH will dedicate $55 million to individually help shepherd investigators who have promising, early-stage, medical countermeasure products. Finally, the budget includes $655 million for the Strategic National Stockpile to replace expiring products, support BioShield acquisitions, and fill gaps in the stockpile inventory.

STRENGTHEN THE NATION'S HEALTH AND HUMAN SERVICE INFRASTRUCTURE AND WORKFORCE

Strengthening the Health Workforce.—A strong health workforce is key to ensuring that more Americans can get the quality care they need to stay healthy. The budget includes $1.3 billion, including $315 million in mandatory funding, within HRSA, to support a strategy which aims to promote a sufficient health workforce that is deployed effectively and efficiently and trained to meet the changing needs of the American people. The budget will initiate investments that will expand the capacity of institutions to train over 4,000 new primary care providers over 5 years.

Health Workforce Diversity.—As part of these health workforce investments, the budget also includes $163 million at HRSA for Health Workforce Diversity programs to improve the diversity of the Nation's health workforce and improve care to vulnerable populations. This funding will support training programs and scholarship opportunities to students from disadvantaged backgrounds enrolled in health professions and nursing programs.

Expanding Public Health Infrastructure.—The fiscal year 2012 budget supports State and local capacity so that health departments are not left behind. Specifically, the budget requests $73 million, of which $25 million is funded in 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 an effective, prepared, and sustainable health workforce to meet emerging public health challenges. In addition, the budget requests $40 million in the Prevention Fund to support CDC's Public Health Infrastructure Program. This program will increase the capacity and ability of health departments to meet national public health standards in areas such as information technology and data systems, workforce training, and regulation and policy development.

INCREASE EFFICIENCY, TRANSPARENCY, AND ACCOUNTABILITY OF HHS PROGRAMS

Strengthening Program Integrity.—Strengthening program integrity is a priority for both the President and myself. The budget includes $581 million in discretionary funding, a $270 million increase over fiscal year 2010, to expand prevention-focused, data-driven, and innovative initiatives to improve CMS program integrity. The budget request also supports the expansion up to 20 Strike Force cities to target Medicare fraud in high risk areas and other efforts to achieve the President's goal of cutting the Medicare fee-for-service error rate in half by 2012. The proposed 10 year discretionary investment yields $10.3 billion in Medicare and Medicaid savings, a return of about $1.5 for every dollar spent. In addition, the budget includes a robust package of program integrity legislative proposals to expand HHS program integrity tools and produce $32.3 billion in savings over 10 years. We appreciate the support of Congress, particularly Chairman Harkin, on efforts to fight Medicare fraud. I look forward to working with the Subcommittee on this issue.

In addition, the Affordable Care Act provides unprecedented tools to CMS and law enforcement to enhance Medicare, Medicaid, and Children's Health Insurance Program (CHIP) program integrity. The Act enhances provider screening to stop fraudsters from participating in these programs in the first place, gives the Secretary the authority to implement temporary enrollment moratoria for fraud hot spots, and increases law enforcement penalties. Additionally, the continued implementation of the Secretary's Program Integrity Initiative seeks to ensure that every program and office in HHS prioritizes the identification of systemic vulnerabilities and opportunities for waste and abuse, and implements heightened oversight.

Implementing the Recovery Act.—The American Recovery and Reinvestment Act provides $138 billion to HHS programs as part of a government-wide response to the economic downturn. HHS-funded projects around the country are working to achieve the goals of the Recovery Act by helping State Medicaid programs meet increasing demand for health services; supporting struggling families through expanded child care services and subsidized employment opportunities; and by making long-term investments in health information technology (IT), biomedical research and prevention and wellness efforts. HHS made available a total of $118 billion to States and local communities through December 31, 2010; recipients of these funds have in turn spent $100 billion by the same date. Most of the remaining funds will support a signature Recovery Act program to provide Medicare and Medicaid incentive payments to hospitals and eligible healthcare providers as they demonstrate the adoption and meaningful use of electronic health records. The first of these Medicaid incentive payments were made January 5, 2011. More than 23,000 grantees and contractors of HHS discretionary programs have to submit reports on the status of their projects each calendar quarter. These reports are available to the public on Recovery.gov. For the quarter ending December 31, 2010, 99.6 percent of the required recipient reports were filed timely. Recipients that do not comply with reporting requirements are subject to sanction.

CONCLUSION

This budget is about investing our resources in a way that pays off again and again. By making smart investments and tough choices today, we can have a stronger, healthier, more competitive America tomorrow. This testimony reflects just some of the ways that HHS programs improve the everyday lives of Americans.

Under this budget, we will continue to work to make sure every American child, family, and senior has the opportunity to thrive. And we will take responsibility for our deficits by cutting programs that were outdated, ineffective, or that we simply could not afford. But, we need to make sure we're cutting waste and excess, not making across the board, deep cuts in programs that are helping our economy grow and making a difference for families and businesses. We need to move forward responsibly, by investing in what helps us grow and cutting what doesn't.

My department can't accomplish any of these goals alone. It will require all of us to work together. I look forward to working with you to advance the health, safety, and well-being of the American people. Thank you for this opportunity to speak with you today. I look forward to our conversation.

Senator HARKIN. Thank you very much, Madam Secretary.

We will start a round of 5-minute questions and recognize people in order of appearance at the subcommittee. So I will start, and then Senator Shelby, then we will go by order of appearance at the subcommittee.

HEAD START

Madam Secretary, I want to focus on early childhood programs, the impact of H.R. 1, the House-proposed bill, which would cut over $1 billion from Head Start and the child care programs. This would go well beyond whatever we did in the Recovery Act. It actually would cut the funding below the level where they stood prior to the Recovery Act.

I just visited a Head Start center in Iowa, talked to parents there and the Head Start program people and the teachers, and the impact in my own State would be pretty severe. They estimate about 1,800 kids in Iowa would lose their Head Start program.

Can you just tell us for the subcommittee what do you see as the impact of H.R. 1 on Head Start, what changes are you making to Head Start to ensure that children receive high quality services, and just a little bit about the early learning challenge fund and the purpose of it?

Secretary SEBELIUS. Mr. Chairman, I share your interest and focus on early childhood education as being an investment that pays huge dividends in the long run. If H.R. 1 were to become the law, the budget for Head Start would be cut about $1.1 billion below 2010 funding, and we think about 218,000 children across the country who are currently being served would lose those slots both in Head Start and in Early Head Start.

The President, by contrast, has proposed an increase in Head Start, feeling that that is an investment that is important to make. Even though our budget is flat-lined, he has chosen to make an increase in that area, or recommend an increase.

We have looked across the range of programs at Head Start and since studies have been done to indicate there has not been enough progress made as children become school-eligible and continue on in school, we are relooking at all kinds of features with the Department of Education in terms of school readiness. The programs are currently being upgraded and updated in great collaboration and partnership with the Department of Education.

We are also, Mr. Chairman, recompeting the 25 lowest-performing quadrant of the programs, feeling that automatic ongoing funding has not provided an incentive to update and upgrade the quality.

Senator HARKIN. By the way, I commend your Department and your leadership in that area.

Secretary SEBELIUS. Well, I think parents need to be assured that whatever out-of-home placement they choose for their child, whether it is a child care setting or Head Start or a school-based early education program, that the same goals are in place. And that is really what the early learning challenge grant is about.

States—and I will take some credit for what we did in Kansas—are frankly a bit ahead in this. A lot of States have been very innovative in early child care and early education opportunities, putting all the placement folks at the table and insisting that the same kind of quality standards be in place.

The early learning challenge grant would be a partnership with HHS and Department of Education who together run the scope of the child care programs and make sure that we are putting incentives in place to drive higher quality because children who enter school less prepared than their peers, often, by the third grade, are so far behind that they will never catch up. We know that having not only developmentally ready children but educationally ready children is a way to really open those doorways of opportunity, and that is what the focus has been.

Senator HARKIN. Thank you, Madam Secretary.

COMMUNITY HEALTH CENTERS

My last question—I am running out of time—has to do with community health centers. I happen to think the community health center has been one of the great underpinnings of our health system in America, 1,100 of them nationwide providing the kind of healthcare that low-income people need when they walk in that door. Could you explain the impact of the proposed cuts in H.R. 1, what that would do, and how many patients we might lose?

Secretary SEBELIUS. The billion dollars that would be, again, cut from the community health center funding below 2010 would serve—we are calculating that about close to 3 million of the people currently served in community health centers would lose that opportunity, and 10 million who are looking forward to having access to community health centers would also not have those sites available. Along with the health center sites themselves are the healthcare providers, doctors, nurses, nurse practitioners, mental health professionals. So, with the Recovery Act, the Affordable Care Act, and the budget investments, the community health center footprint is scheduled to go from serving about 20 million Americans to serving 40 million Americans in the most underserved areas, rural and urban, throughout the country.

Senator HARKIN. Thank you very much, Madam Secretary.

Senator Shelby.

CLASS ACT

Senator SHELBY. Secretary Sebelius, the CLASS Act attempts to address an important public policy concern, that is, the need for non-institutional long-term care, but it is viewed by many experts as financially unsound. The President's Fiscal Commission recommended reform or repeal of the CLASS Act. You stated to health advocacy groups—and I will quote you—that "it would be irrespon-

sible to ignore the concerns about the CLASS program's long-term sustainability in its current form."

The President's budget proposal includes a request of $120 million for the CLASS Act which would be the first discretionary appropriation for the program. If you are unable to certify that it will be sustainable absent a massive taxpayer infusion of funds, why should Congress want to appropriate the requested $120 million in taxpayer funds for a program that a lot of the experts project will fail? And what will prevent the Department from subsidizing this alleged self-sustaining program with taxpayer funds once it is implemented and then fails? Is that a concern of yours?

Secretary SEBELIUS. Senator, the law as written has some pretty clear directions that we have to be able to certify before benefits would become available to promote to the public for their voluntary enrollment that the program is not only sustainable short-term but sustainable long-term. It needs a 20-year and a 75-year actuarial projection of sustainability.

There also is a very clear directive in the law that prohibits any taxpayer dollars being spent to subsidize what may be a program that is on shaky financial ground.

So those are the two guardrails that we are looking at very closely.

We are working with actuaries. In fact, the head actuary from GenWorth, who has probably the biggest footprint in this space, has become our chief actuary on the CLASS modeling program. But looking at the flexibility that we have, frankly, to look at work requirements, premium indexing, and enrollment—three of the elements that are really critical to making sure you have a solvent program in the future, if indeed only the disabled community enrolls—this program is immediately insolvent in a fiscal manner because there will not be enough income to pay for the benefits.

The money that you have referred to in the budget, which is being requested as an initial outreach and enrollment feature, is designed to make sure we have a solvent program, which means you need to reach into a younger, healthier population, market benefits——

Senator SHELBY. In other words, it is taxpayers' money you are asking for here. Right? $120 million.

Secretary SEBELIUS. It is budgeted money that could make the CLASS program sustainable into the future. Yes, sir.

Senator SHELBY. The budget proposal for the CLASS Act also includes $93.5 million in new Federal spending for, "information and education to ensure that an adequate number of individuals would enroll in the program." While I do not agree myself with Congress appropriating $120 million for an insolvent program, it makes even less sense to me to spend $93.5 million of that funding to promote a program that we know is structured currently to fail.

How do you justify, Madam Secretary, spending such a large sum of money on promotion efforts, given you will be promoting a program that is not quite defined?

Secretary SEBELIUS. Well, again, Senator, we would not promote a program that could not be sustained, and I am prohibited by law from doing that. So it is our intent to—and we are engaged in extensive outreach to look at the elements of the program that need

to be adjusted in order to make sure it is sustainable. I have just mentioned three of them: the work requirements, the premium indexing issues, and the outreach efforts.

The outreach is absolutely essential to engage the employer community and engage citizens who right now—frankly, most think that Medicare provides long-term care, which it does not. Most think that that is a benefit that they have to look forward to, and there really is no private market opportunity right now for the kind of residential assistance that most people want and need.

Senator HARKIN. We will do other rounds.

Senator SHELBY. I will come back.

Senator HARKIN. We have a lot of people here. I want to make sure everyone gets a chance.

I will recognize in order now Senator Pryor, Senator Johnson, Senator Moran, Senator Reed, Senator Brown, and Senator Mikulski. Senator Pryor.

WASTE, FRAUD AND ABUSE

Senator PRYOR. Thank you, Mr. Chairman.

And thank you, Madam Secretary, for being here.

Let me follow up on something that we actually talked about 1 year ago in this subcommittee, and we were talking about waste, fraud, and abuse. You had a request in I think for $110 million to do a 2-year process, I guess you can say, to try to get all the Medicare payment data sets in one system. And I understand we have had some budget issues in the meantime, but I am curious about where you are in that process. I guess you got some of the money appropriated, but tell me where you are in that process?

Secretary SEBELIUS. Well, Senator, there is a broad-based effort underway to put together what is called in the private market "predictive modeling," the kind of data checks that credit card companies use to find if there is an aberrant billing pattern. So, if 10 flat screen TVs end up on your credit card, you are likely to get a call saying did you purchase 10 flat screen TVs before they actually send the money out the door. We have never had that ability with Medicare data in five or six different systems and not integrated.

We are building that database. We are well down the line to modeling now what we can do, and with the Affordable Care Act, we were given new tools to actually be much more nimble in stopping payments before they go out the door. So the opportunity to go from the old "pay and chase" model, where the money went out and then we tried to put back together the scheme of the crooks and find them at some point, to actually stopping that from ever happening in the first place, using the very effective tools that the private sector has used for years, is well underway and we hope to be up and running. We do have a request in the budget that would continue not only that but the strike force opportunities and building that data system, enforcing scrutiny as providers come into the system, all of which we think will be very effective. Last year alone, Senator, we got about a 7 to 1 return on dollars out/dollars in, which I think just gives a prelude to what could be effective in terms of building some firewalls at the very front end.

Senator PRYOR. Great. At one point you had, I think, a deadline of trying to get this up and running at least in some measure maybe at the end of 2011. Are you still on track there?

Secretary SEBELIUS. I think we have been a little bit frozen in terms of our capabilities of moving ahead. So there are some new assets in the Affordable Care Act that we are continuing to mobilize. We are still working on 2010 assumptions in our budget, and as you know, one of the things that the House continuing resolution would do to our budget is take an additional $500 million out of CMS administrative overhead, reducing us to a level that is about 2006. So we are a little uncertain what the funding would be, but this is definitely a program that well pays for itself.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

Senator PRYOR. In the President's budget, it eliminates funding to children's hospitals for graduate medical education. And I am concerned about that because pediatricians really are the primary care providers for our children. So when I see something like that, it makes me concerned that, in effect, we are going to harm the ability to train physicians to be primary care physicians for children.

So what assurance can you give me today that this budget is not going to harm our ability to train more qualified pediatricians?

Secretary SEBELIUS. Well, I share your concern, Senator, and can assure you that in rosier budget times this would not have been a proposal to take that $317 million out of the budget. There are some exclusive children's hospitals that have that funding. I would tell you that there is $40 million in our block grant for maternal and child health that trains pediatricians and pediatric residents across the country, as well as Medicaid training of about $3.89 billion, again some of which comes to pediatricians. So this is not the sole source of funding for pediatricians. But I share your concerns that primary care docs and particularly those who deal with children are critical.

Senator PRYOR. And I do not have time to ask the question, but there is a Government Accountability Office (GAO) report that came out this month. It is GAO–11–318SP, and it looks for opportunities to reduce potential duplication in Government programs, save tax dollars, and enhance revenue. And I notice that your Department is mentioned in here many, many times on ways that hopefully we can save money and stop duplication. We do not have time to really ask because other Senators are waiting, but I hope you will look at that——

Secretary SEBELIUS. We are.

Senator PRYOR [continuing]. And take their recommendations to heart.

Secretary SEBELIUS. Thank you.

Senator HARKIN. Thank you, Senator Pryor.

And now we will turn to Senator Johnson. I want to welcome our new member to the committee and the subcommittee. As a matter of fact, I was just checking with my staff. This may be a unique situation where we have two Senators from the same State on the same subcommittee on the Appropriations Committee. So welcome to the subcommittee, Senator Johnson.

Senator JOHNSON. Well, thank you, Mr. Chairman. It is a privilege to serve on the subcommittee with you.

Madam Secretary, it was a pleasure meeting you earlier.

I want to center on the Affordable Care Act or law I guess. First of all, obviously your background is pretty impressive, being a health commissioner and Governor of the State. You obviously understand health insurance pretty deeply.

Have you ever purchased, though, a healthcare plan for a group of individuals, other than the State? I mean for 50 employees, 100 employees.

Secretary SEBELIUS. Yes, sir. I ran the State health insurance program which was the largest covered group in Kansas for 90,000 covered lives. We negotiated 10 or 12 various competitive plans, kind of the exchange that we are looking to set up in States around the country. It is exactly that model.

Senator JOHNSON. Again, that is a very large group, obviously. Just so you understand my background, I am an accountant by training, a business owner for the last 31 years, and I have been buying healthcare for the people that work with me for 31 years. So I understand fee-for-service. I understand a self-insured plan where you are buying inspector general coverage and specific coverage. I know about PPO's and HMO's. Obviously, with the background with my daughter, having to seek out the best surgical technique for her, I always made sure that the employees that worked with me had that exact same freedom in a fee-for-service type of plan to be able to go anywhere in the country to do that. So basically what I do is I bring the perspective of a business owner, a business manager who will be making the kind of decisions on healthcare coverage under this Affordable Care Act.

So from my standpoint, this is a very complex bill, 2,700 pages. We have another 6,200 pages, what I was reading, in terms of additional regulations that have been written since that point in time. So I try and simplify things. I am trying to look at the bigger picture. And so I would like to start by just asking some basic questions we can kind of agree on some figures here because I am a very reality-based guy. I want to look at facts and figures.

So is it true that about 163 million people in America get their healthcare through an employer-sponsored plan? Is that about the correct number?

Secretary SEBELIUS. I think it is about 180 million.

Senator JOHNSON. The Congressional Budget Office (CBO) has issued a study, a report that claims that under the healthcare law now, that by 2016 the average cost of a family plan will be in excess of $15,000. Is that pretty much your——

Secretary SEBELIUS. I assume that is accurate.

Senator JOHNSON. It is. We will stipulate that.

Is it also true that under the healthcare law now, if an employer with more than 50 employees does not provide, I guess, affordable coverage, the penalty to that employer will be $2,000 per employee?

Secretary SEBELIUS. It is an employer responsibility. If that employee qualifies for the taxpayer subsidy that is in the bill, then there is, yes, a payment into the fund so that that cost is not shift-

ed on to other taxpayers who are, indeed, providing coverage for their employees and paying for the subsidy.

Senator JOHNSON. So the CBO has also estimated now that they are thinking—it is starting, I think, at 2.6 million rising to about 3.6 million employees will lose their coverage, will be dropped from their employer-sponsored care into the Government exchange. Is that about the right figure?

Secretary SEBELIUS. Well, I know there were all sorts of studies done by all kinds of people, sir, during the course of the debate, and I think before we have a framing of a plan and the opportunity to look at how affordable these plans are, one of the directives, as you know, with the State-based plan is that it be affordable coverage. So I think there is not at all a firm number on how many employers will or will not do what they are voluntarily doing now.

Senator JOHNSON. But that is how this thing has been scored dollar-wise in terms of the cost estimate. Around 3 million people.

The average subsidy, according to CBO, per person in those exchanges will rise from about $4,500 to over $7,000 by the year 2021. Is that largely correct?

Secretary SEBELIUS. The average subsidy—it is based on an income level to——

Senator JOHNSON. Per person. I understand, but what has been budgeted is almost $7,000 by the year 2021. My concern is taking a look at the big picture here. I think we have grossly underestimated the number of employees that will lose their employer coverage plan under this healthcare act, be put in the exchanges under extremely high subsidy levels. If I am right, if my fears come true, we could be looking at tens of millions of people put in the exchanges at the tune of $5,000 to $7,000 in subsidies. We could be doubling, tripling, quadrupling the cost of this healthcare bill. Rather than $150 billion, it could be easily one-half a trillion dollars per year. That is my concern.

Secretary SEBELIUS. Well, Senator, I think, as you know and as a business person participating in the market, the market is entirely voluntary now for employers. I think the most cynical view is that employers will just dump all their employees, discontinue employee benefits, and I guess move people into some other option. I don't share that kind of cynical view. I think the voluntary marketplace, in fact, is going to be far more attractive. A lot of small business owners who now are paying 18 to 20 percent more for identical coverage to large business owners will have, for the first time, affordable options within an exchange to purchase coverage. I think that the opportunity for individuals, entrepreneurs, farm families, and others who right now are on the edge of the market or often outside the market will have affordable options. And I think the large employers who we talked to who will not see much difference in their choices, except they will stop paying the approximately $1,000 per policy tax for everyone who is accessing the healthcare system without affordable coverage that gets shifted onto everybody who has coverage.

I guess I think that while there is a scenario that says everybody would voluntarily walk out of the market and dump their employees, I think just the opposite is going to happen. We have not seen that in the one State that is really up and running—in Massachu-

setts. Employers have not dropped their coverage, have not dumped employees. They, in fact, are continuing, and Massachusetts is now at about a 97 percent coverage rate. So I think that is an encouraging at least precursor of what may be coming.

Senator JOHNSON. Thank you.

Senator HARKIN. Thank you, Senator.

Senator Moran.

Senator MORAN. Mr. Chairman, thank you.

Senator HARKIN. Again, welcome to the subcommittee. Senator Moran and I have done a lot of work in the past on farm issues. Now we can work on health issues.

RURAL ACCESS HOSPITALS

Senator MORAN. I look forward to continuing that working relationship, and I am honored to serve Kansas in the United States Senate by the side of my colleagues here today and honored to have my former Governor with us this afternoon so that I can ask a few questions.

Secretary, my thoughts for questioning you today really revolve around some pretty significant Kansas issues related to healthcare and your role. And they are, of course, related to the issue of healthcare in a rural setting.

The IPAB at the moment fails to account for critical access hospitals. Congress carved out exceptions to the payment mechanism that we have in place but did not carve out critical access hospitals, and I would like your reaction to that related to that because I am fearful that if that carve-out does not occur and decisions are made by those policymakers not responsible to rural America, those critical access hospitals could easily be a target for reduced spending which in my view causes the demise of access to healthcare in rural America.

Related to that is the budget item for providing the doc fix. In so many instances today, our rural hospitals are now employing physicians. And they do that out of necessity. The ability to track a physician to a rural community is restricted, is limited. And so in many instances, our rural hospitals pay the salaries of physicians. Their ability to do that will be greatly damaged if we lose the ability to be reimbursed as we are currently as critical access hospitals. But it is compounded by the problem that in the 29.5 percent reduction in payments to physicians under Medicare, if we do not put a doc fix in place. So we have the circumstance in which many hospitals will have declining revenues and increasing costs. Of course, a hospital has little viability if there are not physicians in that community admitting patients to those hospitals.

So my question is—I have only been in the Senate 2 months, but I have learned that I have to ask more than one question in the one question in the 5 minutes that I am allowed. But my two questions that are related to each other is what is the plan for the carve out for critical access hospitals and what is the administration's plan in regard to the so-called doc fix, the sustainable growth rate problem that we face. There is a fix in the President's budget for the next couple of years, but nothing beyond that. And it is significant amounts of dollars that we need to figure out how we are

going to pay and I very much would welcome your input on both those items.

Secretary SEBELIUS. Well, thank you, Senator, for those questions. I do want to tell the chairman that you are not only an expert now on rural agricultural issues but rural health issues because Senator Moran started when he was a Kansas senator working on rural health issues and has continued that interest. So I look forward to the opportunity to work on some of these enormous challenges.

The rural access hospitals, as you know, Senator, are paid at a different rate. So they are paid, I think it is now, 101 percent of costs, and that does not change with anything with IPAB. The other hospitals are negotiated rates. And so I think that the lack of a carve out was due to the fact that there is a different payment structure.

But I share your concern that somehow being focused on by recommendations in the future with the Independent Payment Advisory Board is precarious territory. And I would look forward to working with you on how to look at that structure going forward. But I do think the differential in the payment rates was one of the areas that the drafters of the Affordable Care Act looked at.

In terms of the sustainable growth rate and the ability to pay Medicare providers adequately and commit to that payment into the future, I think it is one of the most significant looming issues. As you know, it well predates the Affordable Care Act. This has been a discussion for the last decade. The President has, as you said, in his budget proposed about a 2½ year offset for the fix going forward.

But there is no doubt that we need, on a very bipartisan basis, to sit down and look at what is the long-term ability to make sure that doctors do not have this looming crisis. I have now been in my job slightly longer than you have been in yours, but I can tell you that it is certainly the single most raised topic by physicians dealing with Medicare. And I do think it is something that while we have proposed offsets for the next couple of years, we need to at least have a 10-year or permanent fix which could be part of the ongoing deficit conversations or into the future. But there is no question that that has to be solved long term.

I would tell you, though, also that the Affordable Care Act has a couple of features that are particularly focused on rural areas where Medicare providers are paid. Starting this year, an enhanced rate for serving in underserved areas where there are access issues that are particularly addressed in terms of not only the health service corps, but nurse practitioners, and nurse-provided health centers, that are again, targeted for rural and underserved areas that I think also are going to be critically important as you look at healthcare delivery because it is not only affordable, it is available healthcare.

Senator HARKIN. Thank you very much, Senator.

Senator MORAN. Thank you, Mr. Chairman.

Senator HARKIN. And now Senator Reed.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Senator REED. Thank you very much, Mr. Chairman.

Thank you, Madam Secretary, for your service.

Let me begin also by thanking you for the investment in the budget for health professions. We had a chance to talk about the need for primary care physicians and nurse practitioners, and the budget represents a good step forward. I know we have to do more, but thank you for what you have done.

I want to focus quickly on two areas. One was alluded to by the chairman. That is the cuts in LIHEAP. When the budget was being prepared, prices in the oil markets were a little tamer. They are now seemingly out of control. I know there have been some long-term reductions, at least moderation in the natural gas market, but up our way we depend heavily on heating oil and together with the 12 percent unemployment rate, we are anticipating a huge, huge crisis next winter in terms of heating. And so these LIHEAP cuts are going to be very difficult to bear.

Can you talk about how you got to this recommendation? And two, is there any way going forward that you have the flexibility to adapt to these increased prices?

Secretary SEBELIUS. Well, again, Senator, you and I have had this conversation, and I know that you are not only concerned, but have been a real leader in the low energy assistance area. What this budget does—and again, I can assure you this is not an easy choice for anyone—is return the LIHEAP funding to the historic traditional levels. The LIHEAP budget more than doubled in fiscal year 2009 and continued that in 2010 and 2011. This goes back to what was the historic rate. And it cuts $2.5 billion which is a very significant cut in the LIHEAP funding. I would not say that I have flexibility, if it is moving money from somewhere else into LIHEAP, probably not unless the direction of the Congress is aimed in that area.

So again, I do not think there is an easy answer for this. It was traditionally the level of funding before there was a dramatic increase, but will it leave a lot of people who have relied on that help and support for the last couple of years in much more difficult circumstances? No question.

Senator REED. Well, just to reemphasize the point, we are looking at over 11 percent unemployment in my State. That was one of the reasons I think for the increase, the recognition of the difficult times. But the new factor is not a stable but potentially accelerating price for particularly heating oil, and we will have to revisit this again, unfortunately, I think, as we go forward, Madam Secretary.

IMMUNIZATION—SECTION 317 FUNDS

Let me switch to a second area in the remaining time I have, and that is the section 317 funds for immunization. Immunization is such a critical part of healthcare. We do not have to state the benefits. When children are immunized, they are protected and they save tremendous amounts of—billions of dollars in avoided health care problems.

The 317 funds as proposed—there seems to be a tradeoff now between the 317 funds and the prevention trust fund which was incorporated in the new healthcare act. The prevention trust fund is designed, at least in your proposal, for infrastructure improve-

ments, but that will take away money from the actual acquisition of the vaccines that are necessary. Unfortunately, what we have seen in Rhode Island is a slippage in coverage for children. We have gone down from almost 90 percent to less than that. I have less than a moment for you to comment on that.

Secretary SEBELIUS. Well again, Senator, this is a critical area, and Chairman Harkin already mentioned it. What the budget proposes is the same funding level that we have had in the 317 program, and then, as you noted, an additional $100 million that would be spent out of the prevention fund for what are more likely to be sort of one-time investments whether it is school vaccination clinics or outreach efforts that States can employ.

One of the challenges, as you well know, is that not only in Rhode Island but in States across the country, the health staff, the infrastructure to distribute vaccines, to do outreach to have kids vaccinated across the country has been severely hampered in cuts. So we are really trying to calibrate our resources and make them flexible to States, and I think that additional $100 million for fiscal year 2011 is a critical component. Up to 50 percent could be used for vaccination purchase or for actually immunizing kids. And we think States can use that to really make sure that they are filling the holes in their own strategies.

Senator REED. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Reed.

Senator Brown.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

Senator BROWN. Thank you, Mr. Chairman.

I wanted to mention that I appreciate Senator Pryor's concern about children's GME. I also am concerned. I know Senator Harkin is. For 10 years, he and I have worked on this issue and it began when I was at Akron Children's Hospital some years ago and saw that we had no way with the squeeze of managed care to fund particularly children's pediatric specialist training. I appreciate your answer. I appreciate just about everything you do. But I think that these other ways of funding graduate medical education for children for training pediatricians is far too inadequate. So I hope that you will revisit this issue as it comes forward.

Thank you for coming to Columbus on the patient safety issue. My State has done some remarkable things in patient safety in hospitals, and I think that is going to bring a lot of cost savings that I think opponents to the healthcare bill have not recognized. None of that was scored as we know, the work that Senator Mikulski did and Senator Harkin and others. But that kind of preventive care, that kind of patient safety, everything from the Pronovost checklist to so much else will clearly help us restrain healthcare costs that the opponents to healthcare really barely addressed. And I am really proud to have been part of that.

MAKENA, KV PHARMACEUTICAL

Two issues I want to bring up. One is a conversation that we had last week on the Makena, KV Pharmaceutical. For my colleagues who do not know the background, a drug, a progesterone, that was administered once a week for 20 weeks at a cost of about $10 a

shot for high-risk pregnant women who had typically had a low birth weight or a preterm birth in their past, was making such a difference in cutting the rate of low birth weight babies.

This drug company, KV Pharmaceutical, out of St. Louis that really spent some money to do the clinical trials, although the Government had done them 7 or 8 years earlier and paid for it, raised their price once they got FDA approval from $10 a shot, $200 for the whole regimen of treatment, to $1,500 a shot, or $30,000 for the regimen of treatment, which will mean terribly high costs and burden for those women, for Medicaid, for insurance companies, for businesses and will also clearly result in an increased number of low birth weight babies.

So I just wanted you, if not in the hearing today, to recommend administrative or legislative strategies that we can employ to do something about this. We have tried, frankly, to embarrass the company. We have tried to look at the Food and Drug Administration (FDA) when Dr. Hamburg testified to our subcommittee not too long ago to another subcommittee here about that. And we are looking for answers legislatively, administratively. If you would speak to that.

Secretary SEBELIUS. Well, Senator, as you know, the FDA is really prohibited from considering price in terms of drug approval, which I think is an appropriate policy.

Having said that, one of the things that the company has done is to actively notify pharmacists that the FDA will be enforcing a noncompounding rule. We have put out a statement today saying that is not the case. The FDA will not be conducting any enforcement action over the opportunity for pharmacists to continue to do what they have been doing, which is compounding this treatment and having it available to patients throughout the country unless there is some specific safety issue, which has not come to our attention yet. And we are continuing to work on what other options we may have, but we wanted pharmacists throughout the country to understand that in spite of the drug company's warning, that is not really the policy of the Food and Drug Administration.

PEDIATRIC CANCER

Senator BROWN. Thank you. And we will continue on that.

A low birth weight baby in the first year of life costs on the average $51,000, putting aside the human cost to the child, to the baby, the family, and everyone else. And we know what that is going to do to costs of Government, and I would hope that people very bipartisanly would go to work on this.

Last point, Mr. Chairman, in the brief time I have. There is no comprehensive pediatric cancer registry, which makes it difficult to compare State by State statistics. Ohio is, unfortunately, home to what we think of as five different sorts of cancer clusters. There is one in Clyde, Ohio where many children have been afflicted and several died. Caroline Pryce Walker, named after Ohio Congresswoman Deborah Pryce's daughter, Childhood Cancer Act was signed into law in 2008. It authorizes $30 million annually over 5 years for pediatric cancer clinical trials. I would just ask you to work with us on this whole Clyde, Ohio cancer cluster. The cause has not been determined. We are looking to HHS to work with

other agencies to research this and other kinds of cancer clusters around the country.

Secretary SEBELIUS. Well, Senator, I would welcome that opportunity because this question has come up a couple of times in committee and I know you are trying to parse your way through. But again, one of the very troubling features of H.R. 1 in the House would have a huge detrimental effect on NIH trials because not only does it cut a significant amount of resources, $1.6 billion, but it also has a lot of language that would micromanage trials. And we feel that many of the clinical trials now underway dealing with cancer, dealing with autism, dealing with others would have to stop taking any additional patients immediately if that language were to be adopted. So just to put a little warning on the radar screen.

Senator HARKIN. Senator Mikulski.

Senator MIKULSKI. Thank you, Mr. Chairman.

Madam Secretary, I really just want to welcome you to the subcommittee. Before I go to my questions, I just want you to know I think you are doing a great job. You have one of the largest, most complex agencies within our Federal Government, and we want to salute you on what you are doing and also the fact that you are even in public service. Someone with your background could certainly be in the private sector. One of those insurance companies would snap you up in a minute and multiply your salary over and over again.

Secretary SEBELIUS. Maybe not.

IMPACT OF A FEDERAL GOVERNMENT SHUTDOWN

Senator MIKULSKI. Well, maybe not now.

But anyway, I just wanted to say that, because I think there is a lot of intensity involved in these hearings.

This is a very quiet hearing, and I am surprised because we are on the brink of a shutdown. Whether you call it a shutdown or a slowdown, we are on the brink I think of a catastrophic situation. And we are only 10 days away from it. My question to you as Secretary of HHS is the implications and the operational consequences if we go to a shutdown. With the people who work at HHS, could you tell me how many work at HHS, and in the event of a shutdown, how many would be deemed nonessential and how many would be possibly furloughed?

Secretary SEBELIUS. Senator, I am not sure I can give you the precise numbers right now. We do have a look-back to 1995 when a shutdown occurred and have looked at some of the services and operations that were slowed down or even stopped. It has a pretty widespread effect on healthcare delivery and human service availability throughout the country because we do touch lives each and every day.

Senator MIKULSKI. Well, let me jump in. I have major iconic agencies from the Federal Government and beneficiaries in my State. And they are also globally recognized and globally envied. They have names like the National Institutes of Health, the Food and Drug Administration, beneficiaries of HHS funds, Nobel Prize winning institutions like Johns Hopkins, important institutions like the University of Maryland.

Let us go to NIH. If there was a shutdown, could you tell me the consequences on NIH either both in terms of the employees who would be nonessential, what would be the impact on clinical trials, what would be the impact on grant beneficiaries like at Johns Hopkins?

Secretary SEBELIUS. Well again, Senator, I hesitate to give you specifics because I do not have them here. I can tell you there are conversations going on, and our best indication is the look-back.

But having said that, we know that critical trials are underway. Research goes on day in and day out. Thousands of people are affected not only on the campuses that you referred to but certainly in grant programs throughout this country which provide jobs and economic opportunity.

Senator MIKULSKI. If there is a shutdown, would grant beneficiaries continue to get their funds?

Secretary SEBELIUS. Dubious. I do not know what the funding cycle would be.

Senator MIKULSKI. I think this is really a big deal. So if you are in the midst of a clinical trial, whether it is cancer or autism, even if we looked at the "A" words, AIDS, autism, arthritis.

Secretary SEBELIUS. I can tell you, having met with Dr. Collins as recently as 3 days ago, he currently, because of the uncertainty just of the 2011 budget and the numbers he has to work with, has given information to grantees all over the country that he cannot assure them that ongoing funding is available, and has given a very cautionary note about what they should do in the future. So we are operating under extremely uncertain territory right now.

Senator MIKULSKI. Well, how will you proceed?

Secretary SEBELIUS. We continue to be hopeful that there will be a resolution which will give us at least a framework for the remainder of this fiscal year which, as you know, we are halfway through. But certainly we have given great notice to all of our 11 agency directors and everyone throughout the Department that we are operating on 2010 estimates but to prepare for the possibility of significant differences.

Let me just give you a snapshot outside of NIH.

Senator MIKULSKI. Go to any agency. I mean, I raised it——

Secretary SEBELIUS. We are two-thirds of the way through a school year with Head Start. If indeed there were to be a cut right now, we are not sure the programs even have enough money to make that cut. So, there would be programs that would be shut down immediately across the country because they literally do not have enough in their budgets to take the possible cuts. So we are trying to model scenarios that are very difficult to try and administer.

Senator MIKULSKI. Well, Madam Secretary, I know my time is up.

But, Mr. Chairman, you know, there is this belief that somehow or another a shutdown will only occur in Washington with people who ostensibly are overpaid or the lights will go out on the Washington Monument. I am terrified that the lights will go out at Johns Hopkins, the University of Maryland. I am concerned that the lights will go out in my Head Start programs in the rural parts of my State where they are needed. So, Mr. Chairman, I think we

might have to ask Senator Inouye. We need to have maybe an all-hands-on-deck hearing on what are the consequences to this.

Anyway, I exceeded my time. Thank you.

Thank you very much, Madam Secretary.

Senator HARKIN. Thank you, Senator.

Senator Kirk.

Senator KIRK. Thank you.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

With all respect, I hope we can reject the administration's proposal to zero out children's graduate medical education. And you just head about that as well. I think for, obviously, like Children's Memorial Hospital in Chicago, La Rabida, et cetera, I hope we go with regular order on this because the current system—I do not have faith that the proposal would adequately provide the trained physician needs in pediatrics. And I hope the subcommittee goes in that direction.

Senator HARKIN. I can assure the gentleman that I share his concern.

Senator KIRK. Thank you.

WASTE, FRAUD, AND ABUSE IN MEDICARE

I would say, Madam Secretary, you have about a $580 million request to root out Medicare waste, fraud, and abuse, and you are running around an 8 to 1 ratio of dollars provided to dollars saved, which is good.

Another thing that with Ranking Member Shelby and the chairman that we are working on is to upgrade the very outdated Medicare card. This is the Medicare card as it currently exists, and it has none of the standard upgrades that is available on ID's that are available today.

Now, the Department has funded a pilot project for DME equipment in Indianapolis, but it is totally outdated. It is only providing a mag swipe which for $30 can be completely counterfeited and I think does not represent the technology that is used by the Federal Government.

This is a common access card of the U.S. military, and 20 million of these have been issued at a cost of approximately $8 each. What I just saw, because I was alert and had a lot of coffee at the time, is Transportation Security Administration (TSA) agents have common access cards. So that whole 70,000-man agency now has this. The critical thing is not just the enhanced bar code, the optical variable ink, the picture, the signature, and the chip, but it is all on the back as well.

As far as I know, the Department of Defense (DOD) reports not a single CAC card has been counterfeited, whereas this card is pretty easy to counterfeit and the Social Security card being almost no barrier to counterfeit.

We have agreed to team up and look at how we can use what is commonly available, and I am hoping you take a look at—and I would ask you to reach out to Secretary Gates and his team because I think if we had legislation that went forward to say to seniors, if you want to protect your ID and help root out waste, fraud, and abuse, for an $8 fee you can get an enhanced Medicare card.

And I hope we do not reinvent the wheel. I hope that in fact we reinvent nothing. We just expand the CAC card to 40 million seniors.

But I wonder if you could explore that.

Secretary SEBELIUS. Well, Senator, I would love to have our team work with you on this issue. I do know that there has been concern that DOD's card is generations ahead of what we are looking at. It is, as you might understand, a slightly different universe. They have a closed network system. We have about 1 million providers. So, it is a challenge of different proportions. But we do have a new administrator who is specifically charged with program integrity at CMS, a position never created before. He is helping to build the new system and look at ways—and I would love to ask him to follow up with you and your staff because we would love to take a look at what you are talking about.

Senator KIRK. I am going to be very much in train with the chairman and ranking minority here. But I think that a lot of seniors in this age of identity theft would be pretty reassured.

Secretary SEBELIUS. Well, and we are trying, among other things, to establish the fraudulent card database, because it is not only seniors losing their card, but it is providers. So we have got the challenge on both fronts. But I agree with you. Things that could prevent that in the front end are what we are looking at. So, I will have Dr. Budetti follow up with you right away. Thank you.

Senator KIRK. Thank you, Mr. Chairman.

Senator HARKIN. I will exercise a little chairman's prerogative here. I will just back up to what Senator Kirk said. Senator Kirk brought this up when Mr. Budetti testified here a few weeks ago. So it would be good for you to contact him and have him start closing this loop. I concur wholeheartedly with Senator Kirk. I think this is something that we just have not paid much attention to and we should. I hope we can close the loop on this this yearμ—

Secretary SEBELIUS. You bet.

Senator HARKIN [continuing]. And move head on it very aggressively.

Secretary SEBELIUS. It sounds like a great bipartisan proposal. All for it.

Senator HARKIN. Actually a great proposal.

Madam Secretary, we will start a second round here of questions for 5 minutes.

CLASS ACT

The CLASS Act was raised by my good friend, Senator Shelby. I remember when we discussed this in the healthcare debate and in developing the legislation. I can tell you, as the chief sponsor of the Americans with Disabilities Act, now in its 21st year, and the chief sponsor of the Americans with Disabilities Act amendments which were just signed into law by President Bush in 2008, I was very concerned about the CLASS Act and how it would work. Too many people in our country simply have no recourse, have no way of setting aside some funds really for a possible disability that could happen to them or for long-term care as they grow older.

Right now, one out of six people who reach the age of 65 will spend more than $100,000 on long-term care. Yet, only about 8 to

10 percent of Americans have private long-term care insurance coverage. Medicaid now pays more than $110 billion—$110 billion—annually for long-term care for both the elderly and the disabled.

So I was one of those. I was very cautiously supportive of the CLASS Act. I was concerned about whether it would work or not and how viable it would be. That is why we put into the legislation the language that would give authority to you, to the Secretary, to change the program to make sure that it is financially solvent.

So again, I guess my question to you, Madam Secretary, is simply that. Are you confident enough that under the legislation you have the authority to make any changes in the program to make it financially solvent in the long term?

Secretary SEBELIUS. Yes, Mr. Chairman, I do think that the concern about actuarial solvency in the future is one that is very real, and I have stated that on earlier occasions. Both as an insurance commissioner working on solvency issues but also setting up the framework for what an HMO has to have in reserve and how you model that into the future is something that I take very seriously. And I think the legislation is very clear that we cannot turn the switch on in this program unless we can effectively demonstrate through actuarial models that this is a solvent program.

Part of the challenge—and Senator Shelby referred to this earlier—is what the outreach looks like and what the take-up rate is. If the premiums are too high, the take-up rate will be very low and only accessed by those who desperately need it. If indeed there is a broader education effort—and I have to tell you part of the education effort is directly tied to the fact that most Americans believe that Medicare covers long-term care. That is a commonly held belief and often not until they get close to needing long-term care is there a realization that really the only program covering long-term care is Medicaid and that is only if your income is eligible.

So part of the outreach which would have to be done early on and again to younger, healthier workers is the opportunity to set aside some income. And again, we are not talking about competing on long-term care insurance policies. That market would stay in place. This is really for a range of residential services. What we also know is that people want to age in place. They want opportunities to have assistance to stay in their own homes for a longer period of time, to have care around areas that they may not be able to do as readily as they could have years ago and not have a nursing home as the only option.

But it would need a broad take-up rate, competitively priced policies, and if that cannot be modeled successfully, we will not turn the switch on.

Senator HARKIN. Thank you very much, Madam Secretary.

Senator Shelby.

CHRONIC DISEASE GRANT PROGRAM

Senator SHELBY. Madam Secretary, the President's budget proposes the elimination of the preventative health services block grant and proposes a new consolidated chronic disease grant program at the Centers for Disease Control and Prevention (CDC). The budget justification in my understanding says this new grant program will not be a formula grant structure but, rather, it will

be competitive. Rural areas and States without capacity will be, I believe, disproportionately affected by competition.

I am concerned that the new chronic disease grant program will create a scenario where the rich get richer and the poor get poorer. What are your plans to ensure that State health departments have the capacity to compete for funds at the Centers for Disease Control?

Secretary SEBELIUS. Well, Senator, I——

Senator SHELBY. Is that a concern of yours?

Secretary SEBELIUS. I share the concern that often some of the, I would say, more underserved areas are also those with the higher levels of chronic disease. So the worst of all worlds would be to have a situation where the revenue does not follow the disease patterns.

The new CDC proposal is to consolidate a series of separately funded disease programs. Not only does the budget propose an increase in funding—about $72 million above what the current level is—but I would suggest gives States the flexibility of really directing these resources to their target areas. Every State would get resources. Let me make that clear. This is not 100 percent of the funds are competed for and there could be losers and winners. So every State would have a level of funding, and over and above that, there would be some additional competition, but it would very much tie I think the disease profiles in often some of the most underserved areas to the resources.

But we have heard this proposal was greatly informed by State health officers who asked us—often they are dealing with heart disease and diabetes and three or four chronic conditions that have the same underlying causes. And so rather than having that funding channeled through separate silos, they said give us the flexibility of really addressing our State profile, our situations in a more strategic manner. So that information with the State health officers is part of what informed this proposal to have a chronic disease program and get rid of the separate silos.

CONGRESSIONAL REQUESTS FOR INFORMATION

Senator SHELBY. On another subject, Madam Secretary. You have evidenced a commitment to work with Congress—you have said this before—to implement the Affordable Care Act. However, some of my colleagues on the HELP authorizing committee, specifically Senator Enzi and Senator Hatch have talked to me, and have many outstanding requests for information from your Department. I know it is a big Department. It is very important that the Committees on Appropriations work with their authorizing committees to conduct oversight and assess the impact that the law is having on patients, employers, States, and taxpayers.

To ensure that the Congress has the necessary information to make informed decisions about the implementation of the new law going forward, Madam Secretary, would you commit—and have you committed before—to have your Department respond to congressional requests, including letters and hearing questions for the record within 30 days of the request? It is my understanding from Senators Enzi and Hatch there have been 52 requests and 67 per-

cent no response or incomplete response. Is that a concern to you? It is to them.

Secretary SEBELIUS. Senator, we are committed to responding thoroughly and as timely as possible. We have delivered hundreds of boxes, thousands of pages of materials. I have had two hearings in the Senate Finance Committee, and I can assure you we are trying to get the information as quickly as possible. The level of requests is significant and takes an enormous amount of time and energy to gather the materials, but we are working as fast as we possibly can to be responsive and as timely as possible.

Senator SHELBY. So you are basically committing to be responsive to their requests.

Secretary SEBELIUS. Yes, sir.

Senator SHELBY. Thank you.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Shelby.

Senator Johnson.

AFFORDABLE CARE ACT

Senator JOHNSON. Thank you, Mr. Chairman.

Madam Secretary, I would like to kind of go back to the earlier questions I was asking about what I consider just really understated cost estimates for the healthcare act. You know, back in the 1960s when they passed Medicare, they projected out 25 years and said that Medicare would cost $12 billion in 1990. In fact, it ended up costing $110 billion, almost 10 times the original estimate. My concern is our Federal Government has not gotten any better at estimating costs.

So you had mentioned, when I started talking, a little bit about the incentives embedded in this bill for not only employers to drop coverage but now it is for employees to want to get into the exchanges because there are such high levels of subsidies. You talked about that being cynical. I am trying to be realistic, and I am not the only one I think that has that same viewpoint.

Douglas Holtz-Eakin, a former CBO director, has issued a pretty good study where he is talking about a very detailed decision matrix that pretty well shows that it is in the employer's best interest and the employee's best interest for about 35 million people to take advantage of those subsidies and the exchanges.

Yesterday I believe The Hill reported that Joel Ario, I believe—I am not sure I am pronouncing that right, but he is the head of the health insurance exchange office within your agency—was quoted by saying that if exchanges worked pretty well, then the employer can say this is a great thing. I can now dump my people into the exchange and it would be good for them and good for me.

And that is just what I want to explain. The decision that an employer is going to be going through is I can pay $15,000 a year to provide healthcare coverage or I can pay a $2,000 penalty, and by doing that, I am making my employee eligible for, in some cases, in excess of $10,000 in subsidies. Right now, in 2018, according to the way the healthcare bill is written, a family that earns $64,000 will be eligible for a $10,000 subsidy. And you know, let us face it. When the Federal Government offers subsidies, they are generally taken advantage of. So I think it is totally unrealistic to expect

only 3 million out of 180 million people to take advantage of those subsidies.

And my question is what happens if I am right. What if Douglas Eakin is right and it will be at least 35 million or even higher? For every 10 million additional people, it is going to cost $50 billion in additional costs, and that is 33 percent higher than the original cost estimate for this healthcare act.

Secretary SEBELIUS. Well, Senator, first of all, the Affordable Care Act has a ban on large employers even considering exchanges for at least their first 3 years. So your scenario in 2018 for large employers is not a possibility because they would not be eligible to enter into an exchange. And I think the ban is written in such a way that Congress will reconsider at the end of 3 years whether that should indeed be extended, and the vast majority right now who have stable coverage at least in the employer market is in the large employer area.

Second, I think that while there are a whole variety of scenarios, what I know about the existing market is that small employers have been abandoning the market altogether. The trend rate for the last 10 years has been sharply downward. So employees who either are self-employed or farm families or who are working for a small employer are less and less and less likely to have any affordable options and therefore are shopping on their own in what is a very fragile individual market. So the trend rate is not good at all.

I think there are, again, some very optimistic opportunities in creating State-based exchanges where small employers for the first time will have the pooling flexibility that their large competitors have. They will have an opportunity to essentially shop without a very sophisticated human resources (HR) department in a predesigned marketplace and will have the benefit right now of tax credits that we are seeing for the first time in a very long time bringing some of those folks back into the market.

So I think the large employee marketplace will stay relatively stable and stay fairly much the same, although hopefully their costs will go down as the CBO predicts, and the small marketplace, which has been disintegrating dramatically over years, will again be stabilized.

Senator JOHNSON. What is the definition of a large employer? What is the definition that will be excluded from these exchanges?

Secretary SEBELIUS. I think the large employer is 100 or more employees.

Senator JOHNSON. Thank you.

Senator HARKIN. Senator Moran.

INDEPENDENT PAYMENT ADVISORY BOARD

Senator MORAN. Mr. Chairman, thank you again.

I want to go back to a couple of topics that we visited about earlier, Secretary, and then add a third one.

Back to the IPAB. I want to make sure I understand that you indicated that there was a justification for not including critical access hospitals in the provisions that eliminate the potential for the independent board's decision. Does something need to be done now or are they safe for a while?

Secretary SEBELIUS. All I was suggesting, Senator, is that I am speculating that the reason that critical access hospitals were treated differently in the original proposal was that critical access hospitals are paid differently in the current system. So their payment protection stays in place. The law requires that they get paid based on cost. And that is not the case of other hospitals.

Senator MORAN. Do you support exempting critical access hospitals from the IPAB through 2019 like the other hospitals?

Secretary SEBELIUS. Well, I would be supportive of taking a look at what the proposal would look like. I share your concern that critical access hospitals are vitally important, and I just need to look at all the framework that protects them right now.

MEDICARE SUSTAINABLE GROWTH RATE

Senator MORAN. I actually think that because they are paid differently, they may be a greater target. But there is a justification that apparently you and I share for why they are paid differently.

On my other question about the so-called "doc fix," is my understanding that the administration has a plan for 2012–2013, but no concrete plan beyond that?

Secretary SEBELIUS. We have not proposed 10 years of offsets. As you know, up until probably 1 year ago, the doc fix was done in a limited fashion a year at a time and never paid for. I think the President has said it is important to pay for it. He has proposed in this budget to have what amounts to about 2½ years of pay-fors going forward and says we look forward to working with Congress on a permanent fix for this situation.

Senator MORAN. Well, I made my position clear on the Affordable Care Act, and that is known. But regardless of your position on that legislation, the system falls apart if we do not make the doc fix substantial and permanent.

Secretary SEBELIUS. There is no question and I have said that since the outset. As you noted, I mean, the Affordable Care Act is not what caused the gap in payment and it is not what will fix it. It really is, I think, something that needs to be discussed in the overall Medicare system.

Senator MORAN. I fear that part of the potential demise of our healthcare delivery system will be related to the Government's reimbursement of healthcare providers, that it is inadequacy, and we will potentially have more providers paid for by the Government under the Affordable Care Act, and if you add more people, more providers who are paid at a rate less than what it costs to provide the service, we lose the physicians who provide those services, we lose the hospitals that deliver those services. And so this seems to me to be an overriding consideration that we just have got to get to.

Finally, your successor's successor has asked for a waiver under the MOE.

Secretary SEBELIUS. My successor's successor.

Senator MORAN. Yes. Is that true?

Secretary SEBELIUS. Who is my successor's—I do not know what we are talking about.

Senator MORAN. It depends on what position you have got. That is true. You have held so many positions. The current Governor of

the State of Kansas has asked for a waiver. I am interested in knowing the status of that request and what criteria that you have in place or will put in place to make those determinations.

Secretary SEBELIUS. Well, it is my understanding, Senator—and I think this is the most updated information—that while there has been some suggestion by Governor Brownback that he would come to our office with some specifics, we do not have anything other than the notion that maybe a waiver would be a good idea. As far as I know, we have no paper. We have no proposal. We have no notion of what it is that he is talking about.

We are working actively around the country with States around not only what they can do to lower their pressing healthcare costs but ways that other States have taken advantage of the current law to deliver more effective services at a lower cost and would look forward to working on Kansas or any other State. But it is my understanding we really do not have anything other than a letter saying we are going to come to you with a proposal.

Senator MORAN. Thank you, Secretary. Appreciate our conversation this morning.

Mr. Chairman, thank you.

Senator HARKIN. Thank you, Senator.

Secretary SEBELIUS. My predecessor's predecessor. Okay. Successor. That is right. I had predecessors too.

Senator HARKIN. Do we need a more Kansas——

Secretary SEBELIUS. No, no, no. I am just sorting that title out.

Senator MORAN. There is very little good news in the Kansas world these days.

Secretary SEBELIUS. We are all bemoaning the Jayhawks.

Senator HARKIN. I watched that game. That was quite a game.

Secretary SEBELIUS. Painful for some of us.

Senator HARKIN. That is true.

Well, Madam Secretary, thank you again for your appearance here. Thank you for your stewardship of this vast and complex Department. Thank you so much for the clarity and the forthrightness of your responses here today.

ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for 10 days for other statements or inclusions of questions by other Senators.

[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

Question. Madame Secretary, your budget includes $765 million to fund the advanced development of the drugs and vaccines that we need to defend against bioterrorism or a public health emergency. The Department would like to fund this advanced development by means of transfers from the Project BioShield Special Reserve Fund (SRF). As you know, the purpose of BioShield is to provide a financial incentive to pharmaceutical companies by guaranteeing that the Federal Government will buy these drugs for the national stockpile. Unless adequate resources remain in BioShield, we may be calling into question the Federal Government's commitment to buy these products and therefore making it more risky for the private sector to remain in the countermeasure business.

Is there a risk of undermining the entire process of developing drugs and countermeasures for the stockpile if significantly more Project BioShield balances are used

for other purposes? What is the Department's plan to reauthorize BioShield and replenish the SRF when it expires at the end of fiscal year 2013?

Answer. Project BioShield and the Special Reserve Fund have provided a market guarantee to attract the interest of industry to medical countermeasures development, and in this they have succeeded. This market guarantee, however, does little to make drug development easier or faster. We are just beginning to see the fruits of our decade-long investment in medical countermeasure development. Initiatives—such as the Strategic Investor, the Centers of Innovation in Advanced Development and Manufacturing and additional support for regulatory science at the Food and Drug Administration—planned to be undertaken following the Medical Countermeasures Enterprise Review of last year are designed specifically to remove obstacles to success and to increase the flow of products through the pipeline, so that Project BioShield can realize its full potential.

The authorities added to the Public Health Service Act by the Pandemic All Hazards Preparedness Act have supported advancements in preparedness and response investments and capabilities. They have proven beneficial to the Project BioShield program by providing increased flexibility to support a more robust medical countermeasure pipeline to respond to chemical, biological, radiological, nuclear (CBRN) and other emerging threats. There are a number of expiring authorizations and authorities that should be reauthorized to ensure we can continue to adequately prepare for public health incidents.

In 2004, in the DHS Appropriations Act (Public Law 108–90), Congress provided advance appropriations of $5.593 billion for CBRN countermeasures acquisition from fiscal year 2004 to fiscal year 2013. Congress subsequently passed the Project BioShield Act (Public Law 108–276) to authorize the use of these funds for this purpose. The Special Reserve Fund (SRF), as the Project BioShield appropriation is called, was intended to serve as a statement of the U.S. Government's commitment to medical countermeasures development and a market guarantee to industry as it undertook the arduous process of developing novel medical countermeasures.

Since its inception, eight products have been acquired using Project BioShield funds and deliveries have been initiated or completed to the Strategic National Stockpile, at an aggregate expenditure of $2.192 billion. Additionally, since the creation of the SRF, $25 million has been rescinded, $995 million had been made available for the support of BARDA medical countermeasure advanced development, and $441 million has been transferred for NIH basic research and for BARDA and NIH pandemic influenza preparedness. Of the funds obligated to date for purposes other than medical countermeasure acquisition, the vast majority have contributed directly to maintenance and development of the medical countermeasure pipeline.

In May 2011, HHS anticipates an award of $433 million for the late-stage development of an antiviral drug to treat individuals infected with smallpox. The fiscal year 2012 President's budget requests $1.5 billion, including a request that another $665 million be made available for advanced research and development and that $100 million be made available to establish the proposed Medical Countermeasure Strategic Investor Initiative, which if enacted would leave $742 million for acquisitions between now and the end of fiscal year 2013.

Investments at BARDA have focused heavily on supporting advanced research and development in recent years, and Project BioShield acquisitions will also continue through the rest of fiscal year 2011 and into fiscal year 2012.

Question. Madame Secretary, there is a critical need to focus on drug abuse prevention. Specifically, we should provide sufficient funding for evidence-based programs that address the use and abuse of alcohol, marijuana and other illegal drugs. Our country is facing what the Office of National Drug Control Policy has called an "epidemic" of prescription drug abuse. Prescription drugs account for the second most commonly abused category of drugs, behind marijuana. For this reason I included language in last year's Senate Report 111–243 indicating my concern about efforts by the Substance Abuse and Mental Health Services Administration (SAMHSA) to blend mental health and substance abuse prevention funding:

"Given the paucity of resources for bona fide substance use and underage drinking prevention programs and strategies, the Committee instructs that money specifically appropriated to CSAP for substance use prevention purposes shall not be used or reallocated for other programs or initiatives within SAMHSA. In addition the Committee is instructing SAMHSA to maintain a specific focus on environmental and population based strategies to reduce drug use and underage drinking due to the cost effectiveness of these approaches."

Your Department recently issued a Request for Applications for the Strategic Prevention Framework State Prevention Enhancement Grants, funded through the Centers for Substance Abuse Prevention (CSAP). The first goal listed for potential

grantees is to: "With primary prevention as the focus, build emotional health, prevent or delay onset of, and mitigate symptoms and complications from substance abuse and mental illness." The third goal listed relates to suicide prevention.

Question. While I recognize that there are common risk and protective factors for substance abuse disorders and mental illness, substance abuse prevention programs are unique in focusing on the environmental strategies for preventing drug and alcohol abuse. Will the grants issued under this RFA be consistent with the intent of the language included in last year's Senate Committee report?

Answer. There is a critical need to focus on substance abuse prevention. As you point out, substance abuse prevention requires unique environmental and population-based approaches, but it also requires a focus on common risk and protective factors that put all the Nation's children at risk. SAMHSA has taken a leadership role, along with colleagues at NIH, CDC, and ACF, to consider the best way to encourage States and communities to work collaboratively on the prevention of substance abuse and on ways to build resilience that will help our young people, their families, and the systems that serve them.

As you note, a common set of risk and protective factors affects the development of certain mental and substance use disorders in youth. The scientific evidence supports an approach that addresses both substance abuse and mental health prevention in tandem. The 2009 Institute of Medicine Report Preventing Mental, Emotional, and Behavioral Disorders Among Young People provides evidence for these common factors. In addition, we know that youth with mental illnesses, such as depression, are much more likely to use/abuse alcohol or use substances. A high proportion of youth are under the influence of alcohol, illegal substances, or nonmedical use of prescription drugs when they attempt or die by suicide. These issues are not disconnected. For too long, we have focused on the unique aspects of prevention of mental illness and substance use/abuse when the evidence shows that both the substance abuse and the mental health fields can benefit from employing environmental strategies and supporting the emotional health of youth.

All SAMHSA grants and contracts are aligned with SAMHSA's Strategic Initiatives. The grants to be issued under the Strategic Prevention Framework State Prevention Enhancement Grants (SPE) request for applications (RFA) support SAMHSA's Strategic Initiative #1—Prevention of Substance Abuse and Mental Illness. These grants are intended to focus solely on substance abuse prevention and are strictly consistent with the intent of the language included in the fiscal year 2011 Senate Committee report. The language you reference in the RFA is a description of SAMHSA's Strategic Initiative, which addresses both substance abuse and the development of emotional health.

We have issued this RFA to assist States, Tribes, and U.S. Territories in conducting one intensive year of capacity building and strategic planning to strengthen and enhance their substance abuse prevention infrastructures to better support communities of high need throughout the Nation. Through stronger, more strategically aligned substance abuse prevention infrastructures, SPE grantees will be better positioned to apply the Strategic Prevention Framework (SPF) process to achieve more collaborative, cost-effective coordination of services and to implement data-driven, environmental, and population-based strategies to reduce substance abuse, including underage drinking.

The fiscal year 2012 President's budget for SAMHSA includes two separate State Prevention Grants, one for substance abuse and one for mental health, reflecting the highest priority of HHS on prevention generally and of SAMHSA on the prevention of both substance abuse and mental illness—with separate approaches for each. These programs will continue HHS/SAMHSA's priority to promote emotional health as well as supporting Congress' direction to focus on environmental and population-based strategies to reduce illicit drug use and underage drinking. Likewise, the fiscal year 2012 Budget continues separate funding to implement underage drinking prevention strategies under the Sober Truth on Preventing (STOP) Underage Drinking Act.

Question. Madame Secretary, since fiscal year 2002 this Committee has included funding for the embryo adoption public awareness campaign. The purpose of this program is to educate Americans about the existence of frozen embryos resulting from in-vitro fertilization and which may be available for adoption. In total, we've provided over $23 million for this program throughout its history.

Please provide an indication of how successful this program has been. For example, how many adoptions have been made since the start of the program?

Answer. Because it is a health awareness effort, the impact (and consequently the success) of the Frozen Embryo Donation/Adoption Public Awareness Campaign is difficult to directly link to the number of embryos "adopted" in a given year. The success is better measured by the level of public awareness of the issue among the

target population (in this case infertile couples). The first comprehensive and scientific attempt to assess the overall impact of the Frozen Embryo Donation/Adoption Public Awareness Campaign will be conducted in 2012 through the National Survey of Family Growth, which will survey a nationally representative sample of infertile couples about their level of awareness of the availability of frozen embryos for adoption. Estimates derived from the CDC's surveillance system of Assisted Reproductive Technology indicate that about 2,000 frozen embryos are adopted each year—a number that has been relatively static since 2004.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

NINR'S ROLE IN THE NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

Question. Madam Secretary, scientific inquiry, planned and conducted by nurses, is a vital part of improving the health and healthcare of Americans. Nursing research has been a long time catalyst for many of the positive changes that we have seen in patient care over the years. The National Institute of Nursing Research (NINR) was given an fiscal year 2010 appropriation of $145.575 million and has requested $148.114 million for fiscal year 2012. That would be an increase of $2.539 million (1.7 percent), which is in line with the increases requested for many of the other NIH Institutes. The overall increase requested by NIH for fiscal year 2012 is 2.4 percent. About $1.2 million of the requested increase would support additional funding for NINR's research grants and training awards. About $1 million of the increase would support NINR's share of Institute contributions to several trans-NIH initiatives.

NIH has proposed the creation of a new National Center for Advancing Translational Sciences (NCATS) to provide the infrastructure and technologies to bring important discoveries from basic research to fruition through new diagnostics and therapeutics. What role might NINR have in working with NCATS?

Answer. Nursing science is historically grounded in the translation of research and science, and is an essential scientific nexus for these efforts across the United States and around the globe. NINR and its scientists, intramural and extramural, are leaders in the translation of research into health and healthcare interventions. NINR supports preclinical basic and applied research that integrates biological and behavioral sciences. NINR scientists are employing new scientific technologies from diverse fields including neuroscience, genetics and genomics, molecular biology, biochemistry, and physiology in order to improve quality of life through health promotion, disease prevention, and management of symptoms. NINR and nursing science invests in the infrastructure, resources, and scientific capacity building and training critical for the success of these efforts.

NINR would collaborate with the proposed National Center for Advancing Translational Sciences (NCATS) to maintain and enhance translational and interdisciplinary initiatives across the NIH, as well as with other government and nongovernment organizations. NINR currently leads and participates in several interdisciplinary collaborative programs and partnerships that support translational science including: the NIH Public Trust Initiative; the NIH Pain Consortium; and the Clinical and Translational Science Awards (CTSAs).

In particular, the Clinical and Translational Science Awards (CTSA) program is a major trans-NIH initiative that, since its launch in 2006, has proven to be a critical component in the NIH efforts to accelerate research translation. CTSA funded projects touch on all aspects of translational research including community-based participatory studies, implementation science, and health services research. Central to the CTSA program are multifaceted team science, broadly supported collaborations, and the training and mentoring of the next generation of interdisciplinary translational scientists—all of which are also central foci of nursing science.

NINR encourages its scientists to become leaders in the CTSAs. Working with NIH partners and groups such as the CTSA Nurse Scientists Special Interest Group, NINR co-sponsors CTSA-related workshops and symposia to identify research opportunities, highlight successful exemplars, and develop strategies to maximize the diverse disciplinary strengths of nursing science. While several current CTSA's include scientists from nursing specialties who are at the leading edge of translational and interdisciplinary research, NINR supports the goal of the CTSA Nurse Scientist Special Interest Group to elevate nurse scientists to leadership roles in future CTSAs.

ADOPTION OF BEST PRACTICES BY HEALTHCARE PROFESSIONALS AND THEIR PATIENTS

Question. NINR supports many activities to enhance the evidence base for healthcare decisions, including assessing the effectiveness of new therapies and healthcare interventions for individuals and within diverse populations. What are your successes and frustrations with seeing measurable changes in the adoption of such best practices by healthcare professionals and their patients?

Answer. NINR investigators and research efforts emphasize the development and use of evidence-based interventions with individuals in diverse, real-world settings. Nurses and nurse scientists play primary roles in the translation of research findings into standard practice because of their prominence in front-line health service provision across clinical settings. Currently, over 90 percent of NINR-supported projects are clinically focused.

As a science committed to the translation of evidenced-based research to the clinician, clinic, and community, nursing science shares the frustration of the translation-gap between research and clinical practice. Acknowledging this, nurse scientists are overcoming the barriers to translation and adoption of research findings through highly collaborative, interdisciplinary scientific efforts. NINR supports research efforts from a broad spectrum of disciplines, involving academic and clinical scientists in settings ranging from bench laboratories to hospital bedsides.

NINR has experienced successful translation and adoption of evidence-based programs in key areas such as transitional care, and patient and caregiver interventions. An NINR-supported program partnered an interdisciplinary group of caregivers with older heart failure patients to ease their transition from clinical to home care. In a randomized clinical trial, the program was successful in reducing re-hospitalization rates for this high-risk group of patients, and in addition, it reduced total costs by about 38 percent, or $3,500 per patient. Another NINR-supported program improved the knowledge and coping mechanisms for parents of premature infants by facilitating positive parenting behaviors and lowering parental stress. This intervention also decreased the length of NICU hospitalization by about 4 days and the associated hospital costs by about $4,800 per infant. NINR has also supported the development of a behavioral intervention that significantly reduced the incidence of post-stroke depression in stroke survivors, compared to patients who only received antidepressants. Immediate benefits, as well as sustainable improvements, remained for at least 1 year post-intervention. An intervention such as this one potentially can have a profound impact on the long term health outcomes of individuals who have survived a stroke.

NINR will continue supporting the adoption of evidence-based research into practice through such research programs as the NINR Centers Program. Across the United States, these Centers function as translational research hubs within schools of nursing. Promoting collaboration between disciplines and across institutions through the use of shared resources and expertise, this program is designed to increase research capacity, accelerate translational research, enhance mentorship of doctoral students and early career scientists, and expand the science of investigators working on multiple projects. NINR Centers provide the stable base needed to develop broad, interdisciplinary translational programs of research to speed the application of research into practice.

NINR'S PARTICIPATION IN PROGRAMS TO KEEP UP THE SUPPLY OF NURSE RESEARCHERS

Question. NIH has various grant and training programs that are meant to encourage young investigators to pursue research careers and try out innovative ideas. How does NINR participate in those programs to keep up the supply of nurse researchers?

Answer. NINR is committed to encouraging, supporting, and developing the next generation of nurse scientists. NINR training activities are designed to achieve the vision of creating an innovative, multidisciplinary, and diverse scientific workforce. In addition to supporting pre- and post-doctoral research fellowships and career development awards in the extramural community, NINR also leads and participates in a number of training programs through its Intramural Research Program (IRP).

NINR training activities support individual and institutional graduate and postgraduate research fellowships, as well as career development awards, including awards to trainees from under-represented and disadvantaged backgrounds. These programs provide the next generation of scientists with the necessary, interdisciplinary education and research skills that will enable them to improve clinical practice, enhance quality of life for those with chronic illness, and support preventative health. For example, NINR supports investigators under the NIH K99/R00 Pathway to Independence (PI) program, in which promising postdoctoral scientists receive both mentored and independent research support for up to 5 years.

The NINR IRP also supports several research training opportunities through programs such as the NINR Summer Genetics Institute, a 1-month program designed to increase the research capability in genetics among graduate students and faculty in nursing and to develop and expand the basis for clinical practice in genetics among clinicians. NINR also participates in the NIH Graduate Partnerships Program (GPP), in which doctoral students from schools of nursing with established NINR-supported training programs can complete their dissertation research within the IRP. NINR also sponsors the Pain Methodologies Boot Camp, which is a 1-week intensive research training course in pain methodology at NIH that is aimed at increasing the research capabilities of graduate students and faculty through distinguished guest speakers, classroom discussions, and laboratory training.

An expanded scientific workforce with expertise in these areas of research will significantly contribute to evidence-based improvements and reforms to the healthcare system in the coming years. Collectively, NINR training activities address the national shortage of nurses by contributing to the development of the nursing faculty needed to teach and mentor individuals entering the field.

NINR'S PLANS IN RESEARCH ON AUTISM, CANCER AND ALZEIMER'S DISEASE

Question. Does NINR have any particular plans that respond to the Presidential Initiatives in research on autism, cancer, and Alzheimer's disease?

Answer. NINR is committed to continuing efforts to support research that informs the provision of quality care and improving quality of life for persons with autism, cancer and Alzheimer's disease (AD) and other dementias, as well as supporting their informal caregivers. Recent efforts in autism at NINR include the examination of the effects of an intervention based on self-regulation human-animal interaction theory (e.g. therapeutic horseback riding) on children and adolescents with autism, as well as the development of a peer-mentored disaster-preparedness program for adults living with autism and other developmental disabilities. NINR is also cosponsoring an NIH funding opportunity to support research into the origins, causes, diagnosis, treatment, and optimal service delivery in autism spectrum disorders.

NINR's cancer research focuses on developing the evidence-base for enhancing the individual's role in managing disease, managing debilitating symptoms, and improving health outcomes for individuals and caregivers. Several NINR-supported scientists are examining how clinicians and patients work through the treatment and support decisionmaking process, across the trajectory from diagnosis to end-of-life and palliative care or illness remission. NINR currently supports numerous projects in the area of cancer pain research, including studies to investigate the underlying molecular mechanisms that cause cancer treatment-related pain, as well as a patient-controlled cognitive-behavioral intervention for cancer symptoms. Another study is developing and testing a physician-nurse team intervention to provide clear and timely end-of-life and palliative care communication to parents of children with brain tumors. NINR-supported research also focuses on cancer recurrence prevention and improved quality of life through such scientific efforts as the development of cancer screening programs for diverse populations, a genetic cancer risk assessment tool to improve screening efforts, and a psycho-educational telehealth intervention for rural cancer survivors. NINR also reaches directly to the public through such efforts as the development and dissemination of the NINR publication, "Palliative Care: The Relief You Need when You're Experiencing the Symptoms of Serious Illness" which has been downloaded from the NINR website nearly one million times.

NINR research on interventions for older adults with AD focuses on areas such as: alleviating symptoms such as pain, discomfort, and delirium; improving communication for clinicians; and memory support. For example, NINR is currently supporting a project to test the effectiveness of an activity-based intervention designed to increase quality of life by reducing agitation and passivity and increasing engagement and positive mood in nursing home residents with dementia. Another NINR-funded study involves an evidence-based, nurse practitioner-guided intervention for patients with AD or other dementia, as well as their family caregivers. The intervention is expected to improve overall quality of life by decreasing depressive symptoms, reducing burden, and improving self-efficacy for managing dementia in caregivers. NINR also emphasizes research on interventions aimed at improving quality of life and reducing burden for caregivers. Recognizing the challenges often experienced by caregivers, NINR supports research on strategies to improve the skills caregivers need to provide in-home care, to reduce stress and burden, and to maintain and improve their own health and emotional well-being. Together NINR and the National Institute on Aging are supporting the Resources for Enhancing Alzheimer's Caregiver Health (REACH) II program, a comprehensive, multi-site inter-

vention to assist AD caregivers by providing strategies to manage stress, maintain social support groups, and enhance their own health. Multiple efforts across the Federal Government are currently underway to implement REACH II in the community, such as through the Administration on Aging's Alzheimer's Disease Supportive Services Program.

Question. What is the current nursing shortage and how are current initiatives impacting that shortage?

Answer. Strengthening and growing the primary care workforce—including nurses and nurse practitioners—is critical to reforming the Nation's healthcare system. In fiscal year 2010, the ACA Prevention and Public Health Fund supported $31 million for the training of 600 new nurse practitioners and nurse mid-wives by 2015 and $15 million for Nurse-Managed Clinics, which provide primary care and wellness services to underserved and vulnerable populations. The fiscal year 2012 budget includes $20 million for these Clinics.

The fiscal year 2012 budget includes $333 million, an increase of $43 million over fiscal year 2010, to support the training of nurses and advance practice nurses. The fiscal year 2012 budget initiates a 5-year effort to fund the training of an additional 4,000 new primary care providers—including 1,400 advance practice nurses.

Question. Is the Department investing in any efforts to assure that nurses are available in the regions that need them the most?

Answer. The Administration supports several programs that encourage nurses to practice in underserved areas and facilities throughout our Nation. Applicants with initiatives benefitting rural and underserved areas are given preference for all Public Health Service Act Title VIII nursing workforce funding.

In addition, the Nurse Education Loan Repayment Program and Nursing Scholarship Program offer financial support for nurses who agree to serve in healthcare facilities facing critical shortages of nurses.

The Affordable Care Act provides $1.5 billion for the National Health Service Corps over the next 5 years, which will help bolster the supply of clinicians—including nurse practitioners—serving at rural health clinics, community health centers, and other primary care sites with a shortage of health professionals.

Question. H.R. 1 proposes to reduce funding for the Nurse Education and Loan Repayment program by two-thirds. Is this a good idea to reduce funding when there is such a well documented nursing shortage?

Answer. The Nursing Education Loan Repayment and Scholarship programs provide financial incentives to nurses who agree to work at healthcare facilities with a critical shortage of nurses. The proposed reduction in H.R. 1 would support approximately 850 fewer nurses than would otherwise be supported. The fiscal year 2012 budget includes $94 million, the same level as fiscal year 2010, for this program in recognition of the key role that it plays in supporting the recruitment and retention of nurses in underserved areas.

Question. How is it that HHS says we have a nursing shortage when I hear that graduating nursing can't find jobs?

Answer. While there remains an overall shortage of nurses, nursing shortages vary geographically and by sector (e.g., hospitals, nursing homes). More nurses are delaying retirement and increasing their hours due to the economic downturn, which has allowed for some temporary easing in the nursing shortage in some parts of the country. However, the shortage is still substantial in many parts of the country, and without sustained production of nurses, the situation will worsen.

Question. Will the funds appropriated from the Community Health Center Fund (Sec. 10503 of the Patient Protection and Affordable Care Act) be used to expand this program? If yes, what are the planned program expansions?

Answer. Native Hawaiian Health Care Programs are not eligible for funding under Section 10503 of the Patient Protection and Affordable Care Act.

Question. How would proposals to use some or all of the community health center fund in lieu of the annual health center appropriation affect: the program in general; the ability to sustain program investments made using American Recovery and Reinvestment Act (ARRA Public Law 111–5) funds; the ability to expand the program; and the Native Hawaiian healthcare system that is funded from the annual health center appropriation?

Answer. In fiscal year 2011 the combined resources from the Community Health Center Fund and discretionary appropriations will enable the program to sustain investments made using American Recovery and Reinvestment Act funds as well as create new health center sites. In total, the Health Center Program will receive a nearly $400 million increase in fiscal year 2011 above fiscal year 2010 levels.

Question. Secretary Sebelius, there are many different departments and agencies responsible for our Nation's preparedness and response to a natural or man-made disaster. Can you talk about the unique role EMSC plays in those efforts?

Answer. The Emergency Medical Services for Children (EMSC) Program under section 1910 of the Public Health Service Act (42 U.S.C. 300w–9) is the only Federal program that focuses specifically on improving the pediatric components of emergency medical care. The program was created to address gaps in the provision of quality emergency medical care to children, and to address the specific anatomical, physiological and developmental needs of children. The program focuses on improving the everyday pediatric readiness of the Nation's EMS system to provide the appropriate infrastructure for disaster preparedness. Furthermore, EMSC focuses on emphasizing pediatric specific issues in disaster care of a child in a non-pediatric facility, family reunification, surge capacity due to the increased vulnerability of children in disaster and transfer to other facilities for higher levels of care.

Question. Are our Nation's hospitals, ambulances, and first responders better prepared to treat pediatric patients as a result of the EMSC program?

Answer. During the 2010–11 assessment of performance measures, the 55 funded State Partnership grantees collected data from over 2,600 emergency departments, approximately 6,660 BLS/ALS agencies, and conducted an assessment of more than 22,000 vehicles that transport children in emergency situations.

Findings from select measures demonstrate improvement in the Nation's pre-hospital provider's access to pediatric medical guidance in the field, more Basic Life Support (BLS) and Advanced Life Support (ALS) transport vehicles carrying essential pediatric equipment and States supporting pediatric continuing education for BLS/ALS providers.

Question. How has the EMSC program helped States be better prepared for the disaster response and recovery of children?

Answer. The EMSC program is funding projects that will guide practice in the EMS field for which minimal evidence exist to guide appropriate delivery of care. Findings are translated into tool kits and resources that are readily available to States and local communities. The EMSC National resource center is working with multiple partner-agencies to develop a web-based resource tool with disaster related products, publications and resources. This will be available to States and local communities as they developed their disaster plans.

EMSC is also working with States to develop models of regionalized care where pediatric resources may be limited. State and Territory grantees in the Pacific Basin are working on an inter-island agreement for regionalized care for the pediatric patient. This type of model can be used in disaster planning as well in which specialty care is limited, geographical boundaries may require coordination of many agencies and a prior infrastructure will be essential.

EMSC collaborates with all agencies and systems involved in providing care to the pediatric patient and are active in contributing to the special situation of disaster. EMSC continues to provide important insight to disaster planning since issues of special equipment, surge capacity, regionalized care are integral to everyday readiness of pediatric emergency care.

Question. What would a cut along the lines of that proposed in H.R. 1 mean for the 127 health center sites that have opened within the past year and the almost 3.7 million new patients currently receiving care at a health center because of the investments through the American Recovery and Reinvestment Act?

Answer. Funding levels provided in H.R. 1 would impact the ability of the Health Center Program to fully fund the 127 new access point grants originally supported by the Recovery Act and would also impact the number of patients currently served at health centers, including the 3.7 million patients served through the Recovery Act.

Question. Can you tell us how many applications for new health centers HRSA has received?

Answer. Over 800 applications have been received for the fiscal year 2011 New Access Point funding opportunity.

Question. How many awards does HRSA intend to fund?

Answer. HRSA is in the process of determining how many Health Center New Access Points through Affordable Care Act funding in fiscal year 2011.

Question. How many awards would HRSA make if H.R. 1 is enacted?

Answer. Under H.R. 1, there would have been no new funding available to support Health Center New Access Points in fiscal year 2011.

Question. Can you describe the overarching impact on the healthcare system of the continued health center expansion, as outlined in the President's fiscal year 2012 budget request?

Answer. The President's fiscal year 2012 budget request for health centers, more high quality, cost-effective, preventive and primary healthcare services will be made available nationwide.

Question. Madam Secretary, what additional benefits do health centers bring to their local communities, in addition to the creation of jobs and generation of economic activity?

Answer. Health centers increase access to healthcare through an innovative model of community-based, comprehensive primary healthcare that focus on outreach, disease prevention, and patient education activities. For example, evaluations have found that:

—Uninsured people living within close proximity to a health center are less likely to have an unmet medical need, less likely to have postponed or delayed seeking needed care, and more likely to have had a general medical visit.[1]

—Health center uninsured patients are more likely to have a usual source of care than the uninsured nationally (98 percent versus 75 percent).[2]

Increasing access and reducing disparities in healthcare requires quality providers who can deliver culturally-competent, accessible, and integrated care. Health centers recognize this need and support a multi-disciplinary workforce designed to treat the whole patient. For example, evaluations have found that:

—Health center patient rates of blood pressure control were better than rates in hospital-affiliated clinics or in commercial managed care populations, and racial/ethnic disparities in quality of care were eliminated after adjusting for insurance status.[3]

—A high proportion of health center patients receive appropriate diabetes care.[4]

—Health center low birthweight rates continue to be lower than national averages for all infants. In particular, the health center low birthweight for African-American patients is lower than the rate observed among African-Americans nationally (10.7 percent versus 14.9 percent respectively).[5]

—Health centers play a critical role in providing healthcare services to rural residents who tend to have higher rates of chronic diseases, such as the 27 percent of rural residents suffering from obesity[6] and nearly 10 percent diagnosed with diabetes.[7]

—Over the past 4 years, cost increases at health centers have been at least 20 percent below national increases.[8]

—Rural counties with a community health center site had 33 percent fewer uninsured emergency room/department visits per 10,000 uninsured population than those without a health center.[9]

—The cost of treating patients with diabetes in health center settings was approximately $400 less than that experienced by other primary care settings.[10]

—In 2009, health centers generated over $11 billion in revenues and employed over 123,000 full-time equivalents.

Question. I noticed that the fiscal year 2011 Application and Guidance released in November of 2010 did not include pharmacist as part of the eligible participants in NHSC loan repayment program. Are there any plans in the near future to include pharmacists in the NHSC loan repayment program?

Answer. The National Health Service Corp (NHSC) program is currently conducting an analysis of the Loan Repayment Program (LRP) statute and program policies, which includes a review of the disciplines the NHSC supports.

The inclusion of pharmacists or other disciplines must be consistent with the statute that established the NHSC to recruit and retain primary medical, dental and mental healthcare providers to provide primary health services to underserved populations in health professional shortage areas. The Public Health Service Act, which

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[1] Hadley J and Cunningham P. Availability of Safety Net Providers and Access to Care of Uninsured Persons. Health Services Research 2004;39(5):1527–1546.

[2] Carlson, BL et al, "Primary Care of Patients without Health Insurance by Community Health Centers." April 2001 *Journal of Ambulatory Care Management* 24(2):47–59.

[3] Hicks LS, et al. The Quality of Chronic Disease Care in US Community Health Centers. Health Affairs 2006;25(6):1713–1723.

[4] Maizlish NA, Shaw B, and Hendry K. Glycemic Control in Diabetic Patients Served by Community Health Centers. American Journal of Medical Quality 2004;19(4):172–179.

[5] Shi, L., et al. America's health centers: Reducing racial and ethnic disparities in perinatal care and birth outcomes. Health Services Research, 2004; 39(6):1881–1901.

[6] Bennett, K. J., Olatosi, B., & Probst, J.C. (2008). "Health Disparities: A Rural—Urban Chartbook." South Carolina Rural Health Research Center.

[7] Pleis JR, Lethbridge-Çejku M. Summary health statistics for U.S. adults: National Health Interview Survey, 2006. National Center for Health Statistics. Vital Health Stat 10(235). 2007.

[8] Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group: National Health Expenditures: 2002–2005.

[9] Rust George, et al. "Presence of a Community Health Center and Uninsured Emergency Department Visit Rates in Rural Counties." Journal of Rural Health Winter 2009 25(1):8–16.

[10] Proser M, Deserving the Spotlight: Health Centers Provide High-Quality and Cost Effective Care. J Ambulatory Care Management, 2005; 28(4): 321–330.

authorized the NHSC, defines "primary health services" as "health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals" (42 U.S. Code Sec. 254d(a)(3)(D)). To date, pharmacists have not been considered an eligible discipline for participation in the NHSC program.

As part of the discipline review, the NHSC has also conducted a survey of Community Health Centers and other NSHC-approved sites to determine the demand for additional disciplines in the NHSC. The results of this survey are currently under review. Any updates to the eligible disciplines will be announced through program guidance.

Question. Currently, HRSA collects data on healthcare shortage areas for primary care. Given the poor outcomes in pregnancy in this country and the shortage of physicians and midwives, are there any plans to look at identifying maternity care shortage areas?

Answer. Health Professional Shortage Areas (HPSAs) are designated by the Department as those areas having shortages of primary medical care, dental or mental health providers. HPSAs may be geographic (e.g., a county or service area), demographic (e.g., low-income population) or institutional (e.g., federally qualified health center). Among the factors considered in the designation process are the numbers of healthcare providers in the area. For the primary care HPSA designation, Obstetricians/Gynecologists (OB/GYNs) are included in the provider count when the Department evaluates the number of primary care providers in an area. As you know, the Affordable Care Act required the establishment of a Negotiated Rulemaking Committee (Committee) to make recommendations regarding a revised methodology, criteria and process for making such shortage designations. The Committee is considering the role of OB/GYNs in the development of revised criteria for primary care shortage designation. There are not, however, current plans to separately identify maternity care shortage areas.

Question. In the remote islands of Hawaii women have few options for giving birth. We know that freestanding birth centers have improved access to care and made significant impact on disparities for mothers and babies. What plans, if any, are there to provide funding to develop more of these freestanding birth centers in underserved communities?

Answer. The Health Center Program does not provide funding specifically for the development of birthing centers. However, health centers may choose to address the primary healthcare needs of their target populations through a variety of services including obstetrics care and site locations within their approved Health Center Program grant.

Question. The Maternal and child health services block grant facilitate in planning, promoting, coordinating and evaluating healthcare for pregnant women, mothers, infants, and children, children with special healthcare needs, and families in providing health services for those populations who do not have access to adequate healthcare. I am concerned that decreased funding for this important program may have a negative impact on our Nation. Would you please describe the rationale behind decreasing funding for Maternal Child Block Grants in the fiscal year 2012 budget?

Answer. The fiscal year 2012 budget proposes a decrease to the Maternal and Child Health Block Grant. The proposed budget would reduce funding for categorical research grants and not from the MCH grants to States, in order to respond to the priorities in the fiscal year 2011 final appropriations.

Question. In 2000, Congress launched an important national program, the National Child Traumatic Stress Initiative, which focuses on a child traumatic stress, a critical public health problem. With over 130 funded and affiliate programs, this SAMHSA program addresses the specific needs of children and families who are exposed to a wide range of trauma, including physical and sexual abuse, violence in families and communities, natural disasters and terrorism, accidental or violent death of a loved one, refugee and war experiences, and life-threatening injury and illness. Over the past 10 years, this program has had strong bipartisan and bicameral support. The program has been shown to be extraordinarily effective in expediting science to service through a collaborative and systems change approach that is helping children and families recover by improving the treatment and services they receive. In Hawaii, we have a strong program through our Catholic Charities Center, and have seen firsthand the benefits of this initiative.

Secretary Sebelius, in fiscal year 2010 the funding for this program was $40,798,000. In fiscal year 2012, the funding drops to $11,300,000 a 72 percent cut from fiscal year 2010 funding levels. Would you please describe the rationale behind cutting funding to this valuable program?

Answer. SAMHSA is committed to developing and disseminating trauma-informed services by expanding efforts to infuse trauma-informed related activities and lessons learned from the 10-year history of the National Child Traumatic Stress Network (NCTSN) across its entire grant portfolio. SAMHSA's commitment to bring trauma-informed services to scale will reach beyond individual programs and grantees, build on the success of the NCTSN, and include a focus on a diverse mix of communities (e.g., military families) and trauma-related experiences (e.g., environmental, historic, economic) while allowing States to focus resources in communities with the greatest needs. SAMHSA is also working with the Administration on Children and Families (ACF) and the Department of Justice (DOJ) to provide technical assistance and share evidence-based practices and products garnered generated from the NCTSN. The fiscal year 2012 request for NCTSN does not terminate or reduce any existing grants.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

Question. I am concerned about the timeline of implementing the physician sunshine provisions (section 6002) of the Affordable Care Act. Shining light on industry payments to physicians will help demonstrate the importance of proper research relationships, while exposing and eliminating conflicts of interest and providing important information to patients about their health choices.

As you know, the Department of Health and Human Services (HHS) has a deadline of this October to establish the procedures by which industry must report information. However, it would be helpful to release guidance as soon as possible. Businesses and industry will need time to develop their internal systems to comply with the disclosure deadline of March 31, 2013. As you develop the guidance, I encourage you to work closely with stakeholder groups to ensure that the data collected will be useful and consistent with the legislation's intent.

With these deadlines looming, what is HHS's plan for implementation of the sunshine regulations? Has your staff been meeting regularly with stakeholder groups? What is your timetable for proposing the scope of reportable information? Included in your response, please detail which office will be drafting and finalizing these rules and why that office was chosen.

Answer. HHS is moving forward with the implementation of the Affordable Care Act's requirements related to Section 6002, "Transparency Reports and Reporting of Physician Ownership or Investment Interests." After reviewing the responsibilities this provision delegates to the Department, I decided that the Centers for Medicare & Medicaid Services (CMS) would be the most appropriate agency to implement all of the requirements. CMS is currently in the process of rulemaking to establish procedures for reporting and more information will be forthcoming as the process moves forward. CMS' Center for Strategic Planning and the Center for Program Integrity have dual responsibility for developing these regulations. To prepare for rulemaking, they have individually met with at least seven different industry stakeholders, and consulted with State agencies from Minnesota and Massachusetts, which already have considerable experience with this type of data collection. In addition, on March 24, 2011, CMS held an open door forum to discuss the provision and to solicit feedback from almost 500 industry participants. CMS is working hard to meet the requirements and the deadlines of the physician sunshine provision, including providing industry with the information they will need to comply with it.

Question. An estimated 75 percent of all pregnant women use 4 to 6 prescriptions or over-the-counter drugs at some time during their pregnancy. I am concerned that a proposed rule to improve pregnancy labeling has been pending at the Food and Drug Administration (FDA) for nearly 3 years after comments were received in August, 2008. I have corresponded with HHS and Commissioner Hamburg about this rule and have not received an adequate response regarding a timeline for its finalization. I ask again, what is the status of this rule? Given the importance of this issue to safeguarding the health of pregnant women, I think getting this proposed rule finalized should be a priority. Is it a priority for HHS and the FDA?

Answer. Publication of the rule regarding drug labeling for pregnant and lactating women remains a priority within FDA. Earlier this year, my staff met with your staff to discuss the status of this rule, and as they made clear, FDA staff is actively working on the rule. After a rule is prepared, it undergoes a clearance process prior to publication. Because the timeframes for preparing the regulation and completing each step of the clearance process could be affected by various, unpredictable, factors, FDA cannot say for certain when the final rule will publish. Please be assured that FDA is committed to finalizing this rule as promptly as possible.

NCATS AND THE EFFECT ON CTSAS

Question. I am concerned about the reorganization within the National Institutes of Health (NIH) that will affect the Clinical and Translational Science Awards (CTSA) program, in which Wisconsin has a substantial stake. The NIH invested $42 million into the University of Wisconsin (UW) in a 5-year CTSA commitment. UW has successfully leveraged an additional $40 million in local resources. Together, over the past 4 years these dollars have enabled UW to: (1) train young scientists in clinical and translational research; (2) pursue clinical and translational research endeavors through a streamlined and more efficient research infrastructure; (3) create interdisciplinary research teams that can pursue diversified research more easily; (4) sustain a multi-disciplinary partnership across the State with other major Wisconsin institutions, including the Marshfield Clinic; and (5) partner with more than 100 community organizations to form research partnerships and perform collaborative research aimed at improving health in the community and eliminating health inequities.

The CTSA also promoted intrastate collaboration with UW, whose efforts have been complemented by independent and collaborative activities at the Medical College of Wisconsin, where a similar CTSA grant was awarded. These entities have all made major investments of resources and capital to deliver on their commitments to CTSA—in infrastructure, faculty, and research initiatives, to name a few.

Given the impact of CTSA in Wisconsin, I request clarity regarding the future of this program. The President's budget proposed that the CTSA program become part of the new National Center for Advancing Translational Sciences (NCATS) at NIH. However, the future of CTSA and its scope remains in question. With this in mind, I ask that you provide me with information about plans regarding CTSAs with respect to the following: (1) potential and/or planned changes in the CTSA mission or the scope of the CTSA program in 2011 and beyond, particularly the goal aimed at engaging communities in clinical research efforts; (2) potential and/or planned changes in the CTSA budget and in the number of institutions that may or are likely to receive CTSA funding in 2011 and beyond; (3) potential and/or planned changes in eligibility criteria for participants in the CTSA program; and (4) potential and/or planned changes in the process or rules for applicants to receive CTSA funding.

Answer. The Clinical and Translational Science Awards (CTSA) are slated to be moved into the proposed National Center for Advancing Translational Sciences (NCATS) in fiscal year 2012. We believe that this will be a natural fit; it will serve the CTSAs well to be in an institute that has a complementary mission to their own, which is to advance translational sciences.

The CTSAs conduct and support a wide range of translational research, including therapeutics discovery and development, community engagement, education and training, and regulatory sciences. Their contributions in these areas are critical to the mission of NCATS and the NIH as a whole. However, Director Collins understands the importance of a smooth transition of this program to a new center. His goal is to ensure that the CTSAs can continue their important work as we move to stand up NCATS by October 1. To meet that goal, in April 2011, he convened a trans-NIH working group (the NIH CTSA/NCATS Integration Working Group) to: (a) enumerate the roles and capabilities of the CTSAs that can support and enhance the mission of NCATS; (b) identify CTSA needs and priorities that should be understood and addressed by NIH and NCATS leadership; and (c) propose processes for ensuring a smooth transition from NCRR to NCATS.

This group, which is chaired by Dr. Stephen Katz, Director of the National Institute of Arthritis and Musculoskeletal and Skin Disorders (NIAMS) will consult with a group of CTSA principal investigators, the CTSA Consortium Executive Committee (CCEC), who have been involved in many discussions with the NIH working group as they carry out their charge. The working groups' recommendations will help Dr. Collins and his senior staff make informed decisions about the CTSAs that will ensure a smooth transition into NCATS. No decisions regarding the administration of the currently awarded CTSAs will be made until they have completed their work.

CTSA investigators who are not part of the CECC can engage with the NIH in a number of different ways: utilize the CECC as a conduit of information both from and to NIH; attend CTSA leadership meetings that will be held this summer; and provide input directly to NIH through CTSA staff or the website Feedback NIH.

Question. In 2009, I worked to ensure that long-term care facilities were eligible for health information technology (HIT) funding included in the American Recovery and Reinvestment Act by expanding the general definition of "healthcare provider" to also include nursing and other long-term care facilities. What is the status of pro-

viding HIT funds to long-term care providers? What has been done to help long-term care providers access these funds?

Answer. The Office of the National Coordinator for Health Information Technology (ONC) administers grant programs that support health information exchange within the long-term care community. ONC provided $265 million to Beacon communities across the Nation. For example, Bangor, Maine's Beacon community is bringing long-term care facilities together with hospitals and other physicians to coordinate care by using health IT.

Additionally, through the State HIE Challenge Grant, ONC awarded $6.8 million to four grantees for work in improving long-term and post-acute care transitions through health information exchange. Grant funding supports the following activities:

—Identification of the data elements for health information exchange that are relevant to acute to long-term care transitions.

—Determination of strategies to meet improved acute to long term care transition goals.

—Development of consumer friendly language for personal health records (PHRs), conversion of transfer forms to electronic format, and dissemination of best processes for ensuring safe care transitions—all of which will be integrated into health information exchange for acute to long-term care transitions.

—Implementation of pilot programs at local and/or regional levels to test health information exchange for acute to long-term care transitions, which can then be expanded to the State and national levels.

ONC is also engaging with the long-term care provider community in its efforts to establish a clinical electronic infrastructure and engaging long-term care providers in developing the Electronic Health Record (EHR) Incentive program's "Meaningful Use" definition.

Question. This year offers a prime opportunity to reshape and modernize aging services through the reauthorization of the Older Americans Act (OAA). As Chairman of the Senate Special Committee on Aging, I am looking forward to working with Assistant Secretary Greenlee to reauthorize the OAA. Has the administration set any priorities for OAA reauthorization? Please provide a timeline for when we might expect to receive an OAA proposal from the administration.

Answer. Over the past year, the Administration on Aging conducted the most open system for providing input on recommendations for reauthorizing the Older Americans Act in its history, convening and receiving reports from more than 60 reauthorization listening sessions held throughout the country, and receiving online input from interested individuals and organizations, as well as from seniors and their caregivers. This input represented the interests of thousands of consumers of the OAA's services, and we continue to receive input and work with advocates on a variety of issues.

Based in part upon this extensive public input process, we think that reauthorization can strengthen the Older Americans Act and put it on a solid footing to meet the challenges of a growing population of seniors. We look forward to working with you and the Special Committee on Aging on bipartisan reauthorization legislation.

The following are some examples of areas that we would like to discuss with the Committee as you consider legislation:

—Ensuring that the best evidence-based interventions for helping older individuals manage chronic diseases are utilized. A number of evidence-based programs have proven effective in helping participants adopt healthy behaviors, improve their health status, and reduce their use of hospital services and emergency room visits.

—Improving the Senior Community Service Employment Program (SCSEP) by integrating it with other seniors programs. The President's budget proposes to move this program from the Department of Labor to the Administration on Aging within HHS. The goal of this move is to better integrate this program with other senior services provided by AoA. We would like to discuss with you adopting new models of community service for this program, including programs that engage seniors in providing community service by assisting other seniors so they can remain independent in their homes.

—Combating fraud and abuse in Medicare and Medicaid by embedding the Senior Medicare Patrol Program (SMP) in the OAA as an ongoing consumer-based fraud prevention and detection program. The SMP program serves a unique role in the Department's fight to identify and prevent healthcare fraud by using the skills of senior volunteers to conduct community outreach and education so that seniors and families are better able to recognize and report suspected cases of Medicare and Medicaid fraud and abuse. In fiscal year 2009, the program educated over 215,000 beneficiaries in over 40,000 group education sessions and

one-on-one counseling sessions, resolving or referring for further investigation over 4,000 complaints of potential fraud, error, or abuse.

Question. The Elder Justice Act established the Elder Justice Coordinating Council to meet and make recommendations relating to elder abuse, neglect and exploitation. By law, this council is tasked with meeting twice annually and reporting to Congress by March, 2012. What is the status of and timetable for implementing the Elder Justice Coordinating Council?

Answer. As of March 30, 2011, we have accepted nominations to the Elder Justice Advisory Board, which makes recommendations to the Elder Justice Coordinating Council. The timetable for further action is under development.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

TRAUMA FUNDING

Question. The Administration's fiscal year 2012 budget proposal includes $765 million "to enhance the advanced development of next generation medical countermeasures against chemical, biological, radiological and nuclear threats." The budget proposal also provides $655 million "to ensure the availability of medical countermeasures from the Strategic National Stockpile during a public health emergency."

Given this significant investment in biodefense, I am concerned that the Administration's budget does not similarly support our Nation's fragile trauma centers and systems, which will most certainly be called upon in the event of another terrorist attack or public health emergency. It is very concerning to note that 23 trauma centers have closed over the past decade and 45 million people lack access to a trauma center within 1 hour following injury during which definitive treatment can make the difference between life and death. In addition, $80 billion annually is attributed to trauma medical expenses and $326 billion is estimated for lifetime productivity losses for almost 50 million injuries that required medical treatment.

While the Administration's fiscal year 2011 budget includes funding, albeit decreased, for Public Health and Emergency Preparedness grants and Hospital Preparedness grants, these funds do not fully address the urgent needs of our trauma centers and systems.

Given these facts, what is the Administration doing to make the necessary investments in our Nation's trauma centers and systems?

Is the Administration working to fund the National Trauma Center Stabilization Act and the Trauma Care Systems Planning and Development Act (Public Health Service Act sections 1201–4, 1211–32, 1241–46 and 1281–2) so that all Americans have access to trauma care during every day traumatic events or in the event of another terrorist attack?

Answer. While there is no funding for the National Trauma Center Stabilization Act and the Trauma Care Systems Planning and Development Act in the HHS 2012 budget, the Secretary of Health and Human Services delegated to the Assistant Secretary for Preparedness and Response the authorities vested in the Secretary under sections 1201–1232 of title 12 of the Public Health Service Act, parts A through C of title 12, (42 USC § 300d through 300d-32), as amended, to administer grants and related authorities for trauma care. This also included the transfer of authority from the Health Resources and Services Administration to ASPR the authorities transferred in the affordable care act. These sections include four grant programs relating to trauma and emergency medical care. In addition, section 1201 also provides, among other things, the authority to sponsor workshops and conferences related to trauma and emergency care and to conduct and support research related to trauma and emergency care. This was an important first step in implementing provision of the Affordable Care Act relating to trauma programs. While these activities have not received funding, ASPR has undertaken a cooperative venture with CDC's National Center for Injury Prevention and Control to assist high-profile cities in improving their plans to respond to mass casualty events caused by major traumatic events such as terrorist bombing. Additionally, since the establishment of the Hospital Preparedness Program, over $3.3 billion has been provided to hospitals to improve overall surge capacity and strengthen the capability of hospitals and healthcare systems to plan, respond to, and recover from all hazard events.

TITLE X FUNDING

Question. Title X is the Nation's cornerstone family planning program for low-income women. Each year approximately 5 million low-income individuals receive basic healthcare, including cancer screenings, birth control, and HIV testing, at clinics receiving funds under this program.

As we consider recommendations for the coming year, we're mindful that the House-passed fiscal year 2011 continuing resolution eliminates all $317 million in funding for the Title X program.

Given that 6 in 10 women who receive care at a Title X health center consider it their primary source of medical care, what would be the effects of zeroing out the program?

Answer. The Title X Family Planning program is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. The program establishes the framework for the delivery of publicly funded family planning services in the United States, providing funding to more than 4,500 sites across the United States, including State and local health departments, freestanding clinics, hospitals, family planning councils, and Planned Parenthood agencies. At least 90 percent of Title X program funds are used to provide clinical services. Title X services include preventive health services such as cervical cancer screening, contraceptive counseling and supplies, pelvic exams, breast and cervical cancer screening, basic infertility counseling, clinical breast exams, HIV and STI tests, and other services related to reproductive health and family planning. Title X-funded agencies served an estimated 5 million individuals each year. At least 90 percent of the Title X clients served each year have family incomes at or below 200 percent of the Federal poverty level. For many, a family planning clinic is their entry point into the healthcare system and is considered to be their usual source of care. This is especially true for women with incomes at or below 100 percent of the Federal poverty level, who are uninsured, Hispanic, or black. One-quarter of all poor women who obtain contraceptive services do so at a site that receives Title X funding, as do 17 percent of poor women obtaining a Pap test or pelvic exam and 20 percent obtaining services for a sexually transmitted infection.

In fiscal year 2009, it is estimated that nearly 1 million unplanned pregnancies were averted by services provided at Title X agencies, including more than 233,000 among teens. In 2009, 2,035,017 female clients received screenings for cervical cancer. It is estimated that these screenings contributed to preventing approximately 670 cases of invasive cervical cancer. In 2009, more than 2.5 million clients were tested for Chlamydia and Gonorrhea, and nearly 800,000 were tested for syphilis. In 2009, nearly 1 million HIV tests were conducted. Services provided at Title X-supported clinics were estimated to account for $3.4 billion in savings in 2008 alone. Title X is also cost-effective—Title X-funded centers saved taxpayers an estimated $3.4 billion in 2008—or $3.74 for every $1 spent on contraceptive care. Unintended pregnancy has been linked with numerous negative maternal and child health outcomes. More broadly, contraception can enable women and couples to plan and space births, allowing them to invest in higher education and to participate more broadly in the Nation's workforce. Title X also provides a critical source of funding for our Nation's public healthcare infrastructure, which would look quite different in the absence of Title X funds. In short, in the absence of Title X, rates of unintended pregnancy, infertility and related morbidity, and abortion would be considerably higher. In addition, the public health infrastructure would be negatively impacted, at a considerable cost to the overall healthcare system.

FEDERAL FUNDING FOR PLANNED PARENTHOOD

Question. As you know, the House-passed fiscal year 2011 continuing resolution prohibits Planned Parenthood from receiving any Federal funds. Planned Parenthood operates approximately 575 health centers across the country that receive Title X funds to provide non-abortion-reproductive healthcare like pap smears, birth control, and cancer screenings.

Could you tell me what the impact of disqualifying Planned Parenthood from all Federal funds would be on women and families across the country, were this policy adopted for into next year's budget?

Answer. More than 800 Planned Parenthood clinics receive some portion of their funding through a variety of federally funded public health programs, including Title X and Medicaid. Medicaid is by far the largest source of funding. For some beneficiaries of these public health programs, Planned Parenthood serves as a critical source of services and supplies to prevent unplanned pregnancy, screen for cervical and breast cancer, vaccinate to prevent cervical cancer, and obtain pelvic exams and patient education and counseling. Barring Federal funding to Planned Parenthood agencies could create barriers to these services, many of which are critical to women's health. Planned Parenthood estimates that it serves 1.8 million clients with Federal funds, and provides nearly 4 million STI tests and more than

900,000 cervical cancer screening tests. Without access to these basic services, rates of STIs, unplanned pregnancy, and abortion could increase.

Question. Can you describe the overarching impact the continued health center expansion, as outlined in the President's fiscal year 2012 budget request, will have on the healthcare system, in terms of the cost-effectiveness and quality of services that health centers provide? And what about other benefits—like jobs generated and economic impact?

Answer. Through the President's fiscal year 2012 budget request for health centers, more high quality, cost-effective, preventive and primary healthcare services will be made available. Through the fiscal year 2012 budget request, health centers are projected to employ thousands of additional staff.

Question. As you know, the Balanced Budget Act of 1997 established that teaching hospitals may count, for the purposes of indirect (IME) post-graduate physician education payments, resident time spent in non-hospital settings, so long as certain conditions are met. One of these conditions set out in the legislation is that the "hospital must incur all or substantially all of the costs for the training program in the nonhospital setting . . .".

However, CMS, in its final rules for the Inpatient Prospective Payment System (IPPS) in 2004, interpreted the law to mean that the resident time is allowed only when one hospital sponsors the resident's participation in the non-hospital experience. This interpretation puts many shared residency rotation programs, including family medicine residency programs, in my State at risk, at a time when we should be encouraging more residency programs, not less.

Congress made clear that this was not the intention of the original legislation in Section 5504 of the Patient Protection and Affordable Care Act. This section modifies rules governing when hospitals can receive indirect medical education (IME) and direct graduate medical education (DGME) funding for residents who train in a non-provider setting so that any time spent by the resident in a non-provider setting shall be counted toward direct and indirect medical education if the hospital incurs the costs of the stipends and fringe benefits.

Are there discussions ongoing at HHS to alter the current interpretation of resident shared rotation and IME payments, particularly in light of provisions in the Affordable Care Act?

Answer. As you note in your question, section 5504 of the Affordable Care Act addresses the situation in which more than one hospital incurs the costs of training programs at non-provider settings. The provision allows hospitals to count, on a prospective basis only, a proportional share of the time that a resident spends training in such settings when more than one hospital incurs the costs. The Centers for Medicare & Medicaid Services (CMS) finalized its proposal to implement section 5504 in the CY 2011 Hospital Outpatient Prospective Payment System final rule, which was published in the Federal Register on November 24, 2010. The final rule allows hospitals to share the costs of resident training at non-provider sites, so long as those hospitals divide the resident time proportionally in accordance with a written agreement. In doing so, the final rule requires that hospitals have a reasonable basis for establishing the proportion and that the hospitals document the amount they are paying for the salaries and fringe benefits of the residents for the amount of time the residents are training at that site.

FUNDING FOR THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH'S EDUCATION AND RESEARCH CENTERS

Question. The Administration's fiscal year 2012 budget request zeroed out all funding for the National Institute for Occupational Safety and Health's (NIOSH) Education and Research Centers.

What was the original programmatic intent for the National Institute for Occupational Safety and Health (NIOSH)-funded Education and Research Centers (ERCs)? As part of your reply to this question, please provide a copy of the original program announcement for the record.

Has HHS assessed whether this NIOSH program has fulfilled its statutory mandate under Section 21 of the Occupational Safety and Health Act of 1970 to provide an adequate supply of safety and health professionals?

Has HHS assessed the impact on ERCs from zeroing funding for the program in fiscal year 2012?

Answer. The original programmatic intent of the ERC program, which was established in 1977 in response to Section 21(a) of the Occupational Safety and Health Act, was to create "education programs to provide an adequate supply of qualified personnel to carry out the purposes of the Act". The program was envisioned as a commitment to training future professionals to work in industry, public health, and

academia. NIOSH has established partnerships with 48 academic institutions that comprise the academic network responsible for the Nation's occupational safety and health professional training infrastructure. Through university-based ERCs, NIOSH supports academic degree programs and research training opportunities in the core areas of industrial hygiene, occupational health nursing, occupational medicine, and occupational safety, plus specialized areas relevant to the occupational safety and health field. NIOSH also supports ERC short-term continuing education programs for occupational safety and health professionals and others with worker safety and health responsibilities. Please see attached program announcement from 1976.

[ERC Program Announcement, 1976]

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

PUBLIC HEALTH SERVICE

CENTER FOR DISEASE CONTROL

GRANTS FOR OCCUPATIONAL SAFETY AND HEALTH EDUCATIONAL RESOURCE CENTERS

PROGRAM GUIDELINES

The National Institute for Occupational Safety and Health is implementing a new national competition for training project grants to support a limited number of Occupational Safety and Health Educational Resource Centers. It is proposed to establish by 1980, subject to the availability of funds, at least 10 Center's—at least one in each Department of Health, Education, and Welfare Region.

Authority

Grants for Educational Resource Centers will be awarded under the Institute's basic training grant authority, the Occupational Safety and Health Act of 1970 (29 U.S.C. 670a). Except as otherwise indicated in these guidelines, the basic policies of the Public Health Service Grants Policy Statement (HEW Publication No. (OS) 77–50.000 (Rev.) October 1, 1976) are applicable to this program as are the HEW regulations on Grants for Educational Programs in Occupational Safety and Health (42 CFR Part 86).

Background and Objectives

In 1971, the Institute established training grant programs to assist public or private nonprofit educational institutions in establishing, strengthening or expanding graduate, undergraduate or special training of persons in the field of occupational safety and health in order to provide an adequate supply of qualified personnel to carry out the purposes of the Act. (Catalog of Federal Domestic Assistance 13.263). Past and current training project grants have provided support for primarily, single discipline and single level occupational safety and health training programs, e.g., in occupational medicine, occupational health nursing, industrial hygiene, safety engineering, etc., at either the graduate, undergraduate or technical and paraprofessional level. The multidisciplinary scope of occupational health and safety has been recognized by many to be diverse and complex. It has also been realized that special problems arise at the workplace from which new concepts develop that do not fall within any single, traditional discipline. Yet, within this framework, increased numbers of people must be educated to achieve effective prevention of the many occupational health and safety hazards that occur at the workplace.

The objective of this competition is to provide a mechanism for combining and expanding existing activities and arranging for coordinated multi-discipline and multilevel training and continuing education in occupational safety and health under a single grant servicing a geographic region. The program is intended to afford opportunity for full- and part-time academic career training, for cross training of occupational safety and health practitioners, for mid-career training in the field of Occupational Health and Safety, and access to many different and relevant courses for students pursuing various degrees. Further, the combination of these should result in cross-fertilization among the various disciplines and levels of occupational safety and health practice.

It is anticipated that Centers will form from bases of ongoing educational, research and training activities in occupational safety and health. It is not intended to generate these activities de novo as this would not net the objectives of this program.

Eligibility Requirements

An eligible applicant is any public or private nonprofit educational or training agency or institution located in a State: provided that no agency or institution is eligible for assistance for a separate training project grant in any project period in which it receives an educational resource center grant. However, this will not preclude an existing training grant from being incorporated into an educational resource center grant award.

A Center may be comprised within one educational institution or agency or within an association of two or more institutions or agencies. Educational and administrative justification for any joint arrangement must, however, be fully documented in the application. If such proposals are made, each institution, proposing to participate in a joint arrangement must also participate in the application by delineating the educational and training activities that in totality constitute the Educational Resource Center and which, through interaction and proximity, will improve the probability of the success of the total program, as indicated in the guidelines below. Current Public Health Service policy covering consortia and collaborative arrangements must be complied with. A proposal for a Center which is in effect a collation of unrelated training activities will not be considered responsive.

Characteristics of an Educational Resource Center

An Occupational Safety and Health Educational Resource Center should be an identifiable organizational unit within the sponsoring organization and shall have the following characteristics:

—Cooperative arrangements between a medical school (with anestablished program in preventive or occupational medicine); school of nursing and school of public health or its equivalent, and school of engineering or its equivalent. Other schools or departments with relevant disciplines and resources may be expected to be represented and contribute as appropriate to the conduct of the total program, e.g., toxicology, biostatistics, environmental health, law, business administration, education, etc.

—A Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational health and safety training, He shall oversee the general operation of the Center Program and shall, to the extent possible, directly participate in training activities.

—A full-time professional staff representing various disciplines and qualifications relevant to occupational safety and health to be capable of planning, establishing, and carrying out or administering training projects undertaken by the Center.

—Training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

—A program for conducting education and training of occupational physicians, occupational health nurses, industrial hygienists/engineers and safety personnel. There shall be full-time students in each of these core disciplines, with a goal of a minimum of 30 full-time students. Training may also be conducted in other occupational safety and health career categories, e.g., industrial toxicology, biostatistics and epidemiology, ergonomics, etc. Training programs shall include appropriate field experience including experience with public health and safety agencies and labor-management health and safety activities.

—Impact on the curriculum taught by relevant medical specialties, including radiology, orthopedics, dermatology, internal medicine, neurology, perinatal medicine, pathology, etc.

—A program to assist other institutions or agencies located within their region including schools of medicine, nursing and engineering, among others, by providing curriculum materials and consultation for curriculum/course development in occupational safety and health, and by providing training opportunities for faculty members.

—A specific plan for preparing, distributing and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel of labor-management health and safety committees, in the geographical region in which the Center is located. The goal shall be that the training be made available each year to a minimum of 200–250 trainees representing all of the above categories of personnel, on an approximate proportional basis with emphasis given to providing Occupational Safety and Health training to physicians in family practice, as well as industrial practice, and industrial nurses. Where appropriate, it shall be professionally acceptable in that Continuing Education Units (as approved, for example, by the American Med-

ical Association, American Nursing Association, etc.) may be awarded, These courses should be structured so that either educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational health and safety personnel working in the workplace. Further, the Center shall have a specific plan and demonstrated capability for implementing such training directly and through other institutions or agencies in the region, including cooperative efforts with labor unions and industry trade associations where appropriate, thus serving as a regional resource for addressing the problems of occupational safety and health that are faced by State and local governments, labor and management.

—Specific mechanisms to implement the cooperative arrangements, e.g., between departments, schools/colleges, universities, etc., necessary to insure that the comprehensive, multi- or core-disciplinary training and education that is intended shall be engendered.

—A Board of Advisors or Consultants, with representation of the user and affected population, including representation of employers and employees, of the Center outreach and continuing education and training programs should be established by the grantee institution to assist the Director of the Center in periodic evaluation of the Center activities.

An application for a Center grant must address each of the above points. The nature and organization of the appropriate administrative teaching and support staffs and necessary supplies, equipment, facilities, etc., should be clearly detailed in the proposal and clearly related to the budget requested. This program cannot provide funds for new construction or major alterations or renovations, thus facilities must be available for the primary needs of the proposed Center activities.

Criteria for Review

The applications for Occupational Safety and Health Educational Resource Centers solicited in this announcement will be evaluated in national competition. The review is expected to involve a site visit. The reviewing applications criteria utilized include:

—The overall potential contribution of the project toward meeting the needs for qualified personnel to carry out the purposes of the Occupational Safety and Health Act of 1970, the expressed purpose of which is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources—by providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health."

—The need for training in the areas outlined by the application, including projected enrollment, recruitment, regional needs both in quality and quantity, similar programs, if any, within the geographic area.

—The extent to which arrangements for day-to-day management, allocation of funds and cooperative arrangements are designed to effectively achieve Characteristics of an Educational Resource Center, above.

—The extent to which curriculum content and design includes formalized training objectives, minimal course content to achieve certificate or degree, course descriptions, course sequence, related courses open to students, time devoted to lecture, laboratory and field experience, the nature of the latter (primarily applicable to academic training).

—Previous record of training in this or related areas, including placement of graduates.

—Methods proposed to evaluate effectiveness of training.

—The competence, experience and training of the Center Director and of other professional staff in relation to the type and scope of training and education involved.

—Institutional commitment to Center goals.

— Academic and physical environment in which the training will be conducted, including access to appropriate occupational settings.

— Appropriateness of the budget required to support each component of the program.

Operational Aspects

Although the mechanism for support for the Center will be a training grant, it will differ from other grants in its emphasis on priority of occupational safety and health training in the medical and nursing disciplines and in conducting an outreach program in curriculum development and continuing education projects designed to increase admissions to and enrollment in occupational safety and health

training of persons who, by virtue of their background and interest or position, are likely to engage or participate in the delivery of occupational health and safety services.

While it is expected that each Center will plan, develop, direct and execute its own program, it must also be responsive to the identified needs of the National Institute for Occupational Safety and Health, both in content and direction. The award of a Center grant will establish a special collaborative relationship between the National Institute for Occupational Safety and Health and the grantee institution. NIOSH staff, with consultation and assistance from representatives of the kinds of user groups of the Center program (e.g., academic labor, management and public health and safety agencies) will provide initial and continuing review and evaluation of the Center programs.

From 2005 to 2010, the number of trained occupational safety and health (OSH) professionals has steadily increased. There were 1,191 graduates during the past 5 academic years (from 2005–06 to 2009–10). Of these 1,191 ERC graduates 978 (82 percent) entered careers in OSH or entered more advanced degree programs in OSH. This is due to the increase in awareness of OSH and the comprehensive curriculum which provides a variety of continuing education opportunities for OSH professionals. Of the 287 ERC graduates in 2009–2010, 234 (82 percent) entered careers in OSH or entered more advanced degree programs in OSH.

Within the context of a budget that requires tough choices, we put forth a proposal to discontinue Federal funding for the ERCs. We recognize the vital role of occupational safety and health professional training. This proposal is one of many difficult reductions we proposed as part of the fiscal year 2012 budget.

FUNDING FOR THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH'S AGRICULTURE, FISHING AND FORESTRY PROGRAM

Question. The Administration's fiscal year 2012 budget request also zeroed out all funding for the National Institute for Occupational Safety and Health's (NIOSH) Agriculture, Fishing and Forestry Program.

How does the rate of occupational injury and illness and fatalities in agriculture, fishing and forestry (AgFF) compare with injury rates in general industry.

Did the 2007 National Academy (NA) review of NIOSH's Agriculture, Forestry and Fishing research program recommend elimination of the AgFF program?

Did the NA review recommend relocating AgFF research activities to the Department of Labor or USDA?

Answer. The fatality rate in the Agriculture, Forestry, and Fishing industry is more than seven times higher than that of general industry. Although the data from 2009 are still provisional, based on the Bureau of Labor Statistics (BLS), Census of Fatal Occupational Injuries, workers in the Agriculture, Forestry, and Fishing industry had an average fatality rate of 28.1 per 100,000 full-time equivalent workers from 2006–2009 while general industry had an average rate of 3.8 per 100,000 full-time equivalent workers during the same time period. The rate of nonfatal occupational injuries and illnesses in the Agriculture, Forestry, and Fishing industry is slightly higher at a rate of 5.6 per 100,000 full-time equivalent workers than that of general private industry at a rate of 4.1 per 100,000 full-time equivalent workers from 2005–2009.

While the 2007 National Academy (NA) review of NIOSH's Agricultural, Forestry and Fishing research program raised some questions about the impact of this research on workplace injury and illness, it did not recommend elimination of the AgFF program.

The NA review did not recommend relocating AgFF research activities to the Department of Labor or USDA. Instead, NA recommended that the AgFF program continue to partner with appropriate Federal and State agencies and establish additional interagency partnerships to increase the capacity for carrying out research and transfer activities.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

CHILD WELFARE FINANCE REFORM

Question. Could you explain the Administration's vision for foster care reform, and why the need for reform is so urgent?

Answer. The President's budget proposes $2.5 billion over 10 years to align financial incentives with improved outcomes for children in foster care and those who are receiving in-home services or post-permanency services from the child welfare system, in order to prevent entry or re-entry into foster care. We envision States that

receive performance-based funding to be able to support activities that can improve outcomes for children who have been abused or neglected or at risk of maltreatment. We believe our proposal will keep the focus on moving child welfare in the right direction, particularly during these difficult budget times in States. The proposal incentivizes all States to improve outcomes by allowing them to earn additional funds that can be invested in activities that can drive further progress for the children and families served.

We look forward to working with Congress on developing specific details, guided by the principles outlined in our fiscal year 2012 budget:

—Creating financial incentives to improve child outcomes in key areas, by reducing the length of stay in foster care, increasing permanency through reunification, adoption, and guardianship, decreasing rates of maltreatment recurrence and any maltreatment while in foster care, and reducing rates of re-entry into foster care;

—Improving the well-being of children and youth in the foster care system, transitioning to permanent homes, or transitioning to adulthood;

—Reducing costly and unnecessary administrative requirements, while retaining the focus on children in need;

—Using the best research currently available on child welfare policies and interventions to help the States achieve further declines in the numbers of children who need to enter or remain in foster care, to better reach families with more complex needs, and to improve outcomes for children who are abused, neglected, or at risk of abuse or neglect; and

—Expanding our knowledge base by allowing States to test innovative strategies that improve outcomes for children and reward States for efficient use of Federal and State resources.

CHAFEE FOSTER CARE INDEPENDENCE PROGRAM

Question. Can you explain why, in light of the rising number of foster youth who "age out" of care, the Administration has not proposed to increase funding for Chafee?

Answer. In an environment of limited resources, we have chosen to provide additional funds to align financial incentives with improved outcomes for children in foster care and those who are receiving in-home services or post-permanency services from child welfare system, in order to prevent entry or re-entry into foster care. States may use these funds to provide services to youth who are in foster care before they age out as well as provide post-permanency services to those who age-out of the foster care system. We believe our proposal will keep the focus on moving child welfare in the right direction, particularly during these difficult budget times in States.

Question. If Congress does not meet the President's budget request of $3.3 billion for the Health Centers Program, what will be the impact on rural and urban underserved populations? Can you also describe the economic impacts of not adequately funding the Health Centers Program?

Answer. It will reduce to some extent the expansion of the Health Center Program (and its associated economic impact) into new underserved rural and urban communities.

Question. Recognizing the vital role School Based Health Centers play in serving as a safety net provider for our children and adolescents, why wasn't funding for the operations of School Based Health Centers included in the fiscal year 2012 budget request? For fiscal year 2013, do you see putting School Based Health Centers in the President's budget as an approach that could be utilized to grant greater access to care for our youth?

Answer. School-Based Health Centers may apply for operational support under the Community Health Center program. For example, interested school-based health centers could have applied for the Affordable Care Act New Access Point opportunity announced last August to support new healthcare service delivery sites, if Health Center Program eligibility criteria were met. Previous operational funding for health center sites serving school-aged populations and/or located in schools has been awarded under the Community Health Center Program.

Question. HHS, as well as other Federal agencies, has found great success with telehealth programs in the treatment of high-cost patients. As these programs advance, where do you see the best opportunities not only to maximize cost savings but to provide patients with better care and improve clinical outcomes?

Answer. The Telehealth Network Grant Program (TNGP), grants have offered underserved populations the opportunity to access a diverse variety of clinical services to underserved people in rural areas which include: allergy, asthma control, cardi-

ology, diabetes care and management, pain management, remote patient monitoring, and a variety of other services.

For the relatively more mature Telehealth Networks (TNGP–TH) provisions, one clinical health outcome measure, diabetes case management, is being collected, as well as several outcome measures related to improving access and program efficiency. One of the responsibilities of OAT's Regional Telehealth Resource Centers (TRCs) is to track evidence-based telehealth practices in their regions, and share that information through the technical assistance that they provide to HRSA grantees, rural and other underserved communities. The TRCs share information about cost savings, improved quality and increased access through telehealth applications via their websites, webinars, conference calls, presentations at conferences, and one-on-one consultations.

Question. What are the other areas within the Department of Health and Human Services where Federal support for telehealth technology can be initiated or expanded?

Answer. HRSA's formal telehealth authority is through ORHP's OAT, as mentioned in the previous question. HRSA's ORHP is not aware of other areas within the Department of Health and Human Services where Federal support for telehealth technology can be initiated or expanded.

Question. What areas within HHS, including the Centers for Medicare and Medicaid Services and the Center for Medicaid and Medicare Innovation could be used to increase Federal support for telehealth?

Answer. CMS continually looks for ways to expand the use of telemedicine in our programs to provide high quality healthcare services in the most efficient manner possible. To that end, CMS annually considers requests from the public to add to the list of telehealth services covered by Medicare Part B, and adds new telehealth services as appropriate as part of the Medicare Physician Fee Schedule rulemaking process. CMS also recently finalized new rules for telemedicine services to ensure that patients in rural or remote areas will continue to receive access to high quality, cutting-edge medical care through the use of telemedicine from many of their local hospitals. The new finalized rules streamline the process that hospitals and critical access hospitals (CAH) use for credentialing and granting privileges to physicians and practitioners who deliver care through telemedicine. The new rule will also permit hospitals to more easily partner with non-hospital telemedicine entities, such as teleradiology facilities, to deliver specialty care via telemedicine.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

THE EFFECT OF REDUCING NIH FUNDING TO 5 PERCENT BELOW FISCAL YEAR 2010

Question. In February the House passed an appropriations bill for fiscal year 2011 that proposed cutting the National Institutes of Health's (NIH's) budget by $1.6 billion or 5 percent compared to NIH's fiscal year 2010 budget.

Please provide the NIH's perspective on how such a cut would impact the NIH and our Nation's economic recovery?

Answer. A $1.6 billion decline from NIH's fiscal year 2010 budget levels could have adverse consequences for the research community and could delay current research efforts. It could result in lost opportunities to develop more cost effective diagnostics and treatments in areas such as developmental disorders, addiction, mental illness, infectious disease, cancer, heart disease, and neuro-degeneration.

Specifically, in the area of translational research, more than 100 clinical trials and studies for more precise tests and more effective treatments of common and rare diseases affecting millions of Americans could be halted or curtailed. Medical practices that could have been shown obsolete or needlessly expensive would not be fully evaluated.

In the area of basic research, in just the last 2 years, advances in whole genome sequencing, methods to grow stem cells not derived from human embryos, automated equipment that can perform thousands of experiments at the same time, and previously untried drug design techniques have all become available for the first time, providing unprecedented opportunities for research advances at relatively low cost, many of which could be delayed by these budget cuts. Reductions in funding the pipeline of basic research could slow the discovery of fundamental knowledge about how we grow, age and become ill. Valuable research supporting the prevention of a host of costly, debilitating chronic conditions could suffer setbacks. Some projects could be difficult to pursue at reduced levels and could be cancelled; others could require scope modifications that would dramatically alter the potential research outcomes.

Budget cuts could effect universities and the private-sector. Grantee personnel budgets may be reduced. Training grants could be materially impacted and the population of qualified research trainees and advanced science instructors could diminish. Some universities, especially those with research programs in earlier stages of development, may need to prioritize between training new physicians and scientists and closing laboratories. In the private sector, high-tech and low-tech small-business suppliers could face order cancellations. New equipment prototypes and laboratory methods important to private-sector pharmaceutical and device research could delay development, leaving fewer product options available for U.S. companies to offer as exports in response to the expected rapid rise in health spending in China and the developing world. Supplies of highly-trained technology workers in America could further diminish.

Question. Approximately how many NIH-funded jobs could be lost as a result of a 5 percent cut to the agency's budget?

Answer. NIH estimates that 10,500 full-time-equivalent (FTE) positions could potentially be lost as a result of a $1.6 billion cut to the agency's budget. This estimate is based on the average number of FTE per million dollars of funding reported by recipients of research funds under the Recovery Act.

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 for adults with CHD. The healthcare reform law included a provision, which I authored, that authorizes the CDC to track the epidemiology of congenital heart disease, with an emphasis on adults with CHD and expanding surveillance. If adequately funded, what could be the public health impact of this surveillance system and how could it advance our understanding of the prevalence or CHD across subgroups (including age and race/ethnicity).

Answer. Development of population-based surveillance for congenital heart disease across the lifespan would be a critical first step in generating information on prevalence across different age groups, race/ethnicity and socioeconomic groups in the population, as well as possible determinants of health disparities in neurocognitive outcomes, disabilities, survival, and quality of life. This population-based approach to identifying and following affected persons over time would have a significant public health impact by:

—*Estimating the true prevalence of CHD in the United States*.—It is estimated that about 1 million adults are living with CHD in the United States, and given the improvements in treatment and decreasing mortality, this number continues to grow. However, this estimate is imprecise without population-based surveillance systems to track adolescents and adults with CHD. Accurately determining national prevalence estimates of CHD requires high-quality population-based surveillance of a representative sample of affected individuals using standardized surveillance methods.

—*Estimating the healthcare costs associated with CHD*.—All adults with CHD have significantly higher rates of healthcare utilization than their peers. Furthermore, if adults with CHD develop other chronic conditions, such as diabetes, the interactive effect of the congenital anomaly with the other diseases remains unknown. Currently, estimates of direct costs for adults are often specific to inpatient admissions, and do not include hospitalizations in which CHD was not the primary reason for admission nor costs associated with outpatient visits, prescription medications, or other indirect costs for the affected individuals, their families, and society. Therefore, information from a population-based surveillance system would improve planning for the future utilization of healthcare resources and enhance our understanding of the economic costs of CHD among adults.

—*Identifying factors associated with adverse outcomes across the lifespan*.—Persons with CHD are at risk for adverse health outcomes such as neurodevelopmental and cognitive outcomes and premature death, yet little is known about risk factors for these outcomes and how they differ among subpopulations. Identifying and following affected persons over time to track adverse outcomes could help us understand factors such as health disparities that might predispose to or ameliorate adverse outcomes, and characterize the health services needs of this population.

—*Providing reliable, evidence-based information to guide diagnosis, management, and secondary prevention efforts*.—Currently, many adults with CHD in the United States receive inadequate care because of the lack of information to guide the clinical management of a child with a congenital heart defect as he or she ages into adulthood. Adults and their healthcare providers have become

increasingly aware of the need for reliable, evidence-based information to guide diagnosis, management, and secondary prevention efforts.

Collecting and analyzing data on outcomes over time could improve understanding of the long-term course of CHD, the factors that might influence such course, and the health services needs across the lifespan. These data could also help inform efforts to develop effective primary and secondary prevention strategies directed at reducing the public health impact of CHD. The data could also be used to develop and evaluate the effectiveness of interventions such as guidelines for routine preventable care for children, adolescents, and adults with CHD designed to reduce poor outcomes and high cost of treating individuals who otherwise do not seek or receive adequate care until in a medical crisis.

Question. Currently, when a person enrolls in Medicare, their Social Security Number (SSN) is used the basis of their Medicare identification number. The Social Security Inspector General has indicated that this creates a risk of identity theft and fraud and has suggested that the SSN be removed from the Medicare card. How do you think this risk to Medicare beneficiaries and the Federal program could be reduced?

Answer. CMS is currently investigating the viability and costs of a range of options for removing the SSN from Medicare beneficiary cards. There are considerable costs associated with changing the Medicare beneficiary identifier, not only for CMS but also for our public and private sector partners. The SSN identifier in the health insurance claim number (HICN) is the basis of eligibility for Medicare, and is integrated in more than 50 CMS systems, as well as communications with our partners in the Social Security Administration, State Medicaid departments, private Medicare health and drug plans, and over 2 million healthcare providers and suppliers. The risks of disruptions in beneficiaries' access to care are considerable.

I want to emphasize, however, that CMS shares your concerns about the importance of safeguarding and protecting Medicare beneficiaries from identity theft. We have taken many important steps to minimize the display of SSNs or HICNs on Medicare cards. We removed the SSN from various notices and publications sent to beneficiaries, and from beneficiary reimbursement checks. We prohibited Part C and D Plans from using the SSN or HICN as a beneficiary identifier. We have also taken action to educate beneficiaries about steps they should take to prevent identity theft and fraud, including posting information on the CMS website, and adding information to the "Medicare & You" Handbook.

Question. On December 20, 2010 you sent a response letter entitled "Concern on Hepatitis" to Members of Congress, which directed Assistant Secretary Dr. Howard Koh to convene an interagency working group tasked with developing an HHS Action Plan on Viral Hepatitis. Can a specific date be provided for when the Action Plan will be released? Once the Action Plan is released how will HHS prioritize resources and give direction to the various Departmental operating divisions to ensure steps are taken to curtail the escalating costs associated with viral hepatitis and the costly outcomes such as liver cancer and end-stage liver disease?

Answer. We anticipate that the HHS Action Plan for the Prevention and Treatment of Viral Hepatitis will be released on May 12, 2011. The Action Plan will help HHS improve its current efforts to prevent viral hepatitis by leveraging opportunities to improve coordination of viral hepatitis activities across HHS operating divisions and by providing a framework for HHS to engage other governmental agencies and nongovernmental organizations in viral hepatitis prevention and care. For example, the Action Plan calls for the alignment of HHS guidelines for the diagnosis of Hepatitis B and Hepatitis C infection. Such alignment will improve provider understanding, thus supporting screening efforts and promoting earlier diagnosis of viral hepatitis. Identifying and disseminating best practices regarding prompt linkage of persons testing positive for viral hepatitis into needed care and treatment and developing effective medical management models for use in priority populations, like injection drug users, will improve care outcomes and reduce the negative health outcomes of chronic hepatitis. Finally, on the basis of available funding, the NIH will expand existing clinical trial networks to expand studies of viral hepatitis treatment. Improving treatment for hepatitis C and other causes of viral hepatitis will eventually decrease the number of persons with chronic hepatitis, thus decreasing the costly sequelae of end stage liver disease.

QUESTIONS SUBMITTED BY SENATOR JACK REED

CDC STATE CANCER REGISTRIES (PEDIATRIC CANCER SURVEILLANCE)

Question. The fiscal year 2012 budget for the Centers for Disease Control and Prevention (CDC) proposes to consolidate a variety of programs that address chronic disease into a Coordinated Chronic Disease Prevention and Health Promotion Grant Program. This program will mix core funding with competitive grants to States and other entities. CDC's cancer-related efforts are included in this new program.

As the author of the Conquer Childhood Cancer Act, which authorized investment in childhood cancer surveillance efforts—among other provisions—I am particularly concerned that the consolidation will take attention away from sub-populations. For example, more timely and accurate data collection of pediatric cancer cases and treatments can help researchers determine appropriate treatments and interventions. I helped secure $3 million for this effort last year and it was welcome news to the entire pediatric cancer community.

It appears that with the new approach, States will allocate funds to improving outcomes among large populations where very small changes can make a big difference. While this will help them secure additional, competitive grant funding, there are smaller populations that will likely receive less attention.

How will you ensure that States continue to apply the funds they receive to continue to build their pediatric cancer surveillance efforts?

Answer. The President's fiscal year 2012 budget proposes to consolidate eight separate disease-specific budget lines—Heart Disease and Stroke, Diabetes, Cancer, Arthritis and other Conditions, Nutrition, Health Promotion, Prevention Centers, and non-HIV/AIDS adolescent and school health activities including Coordinated School Health—into a single comprehensive grant program, the Coordinated Chronic Disease Prevention and Health Promotion Grant Program. This consolidation is intended to provide integrated services to State and local health departments by maximizing the reach and impact of every dollar invested by CDC to prevent chronic diseases and promote health in a variety of environments, including schools, and to a variety of sub-populations, including children.

The National Program of Cancer Registries (NPCR) is essential to CDC's efforts to prevent and control cancer. 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. Information about cancer cases and cancer deaths is necessary for health agencies to report on cancer trends, identify populations with the highest cancer burden in order to target interventions, assess the impact of cancer prevention and control efforts, participate in research, especially on small and disparate populations, such as American Indians/Native Alaskans, and respond to reports of suspected increases in cancer occurrence. NPCR is the main source of data on rare cancers—including some pediatric cancers—which can be difficult to study in regional registries. CDC remains committed to conducting public health surveillance, monitoring, and tracking trends in chronic disease risk factors, incidence, and mortality while enhancing access and utilization of population-based surveillance data at the State and local level.

Pediatric cancer is an important public health issue, and has far reaching social, emotional, and physical impacts on children and their families. CDC has implemented a range of key activities related to the Caroline Pryce Walker Conquer Childhood Cancer Act. To date, CDC has:

—Hosted an expert panel to identify gaps in pediatric cancer research and surveillance. This panel helped inform CDC's decision to build cancer registry infrastructure in ways that facilitate pediatric cancer research, enhance registry capacity and reporting speeds, and create new data linkages for research use.

—Secured contractor support to simplify and streamline the process for seeking multiple State institutional review board (IRB) approval for conducting pediatric cancer research. Work is being done to assess State level barriers to research across multiple States requiring linkage to registries or patient contact, and to identify optimal State policies for research.

—Developed a Funding Opportunity Announcement (FOA) to supplement 12 central cancer registries through NPCR to support pediatric cancer surveillance, including early case capture. Funded cancer registries will identify, recruit, and train all potential sources for reporting pediatric and young adult cancer cases, and develop procedures and mechanism to implement early case capture. This FOA will be released in summer 2011.

CDC ENVIRONMENTAL HEALTH (HEALTHY HOMES/LEAD POISONING PREVENTION)

Question. The President's budget proposes to consolidate and reduce by 50 percent the funding for CDC's Healthy Homes/Lead Poisoning Prevention. I am particularly concerned that the budget proposes reducing funding for a program—designed to ensure safe housing—that is extremely cost effective particularly for New England.

In Rhode Island, 70 percent of the State's housing stock was build prior to 1978, when the use of lead paint was prevalent and 10 percent are still in need of desperate repair. Over the past 10 years, Rhode Island has received $40 million for lead poisoning prevention initiatives and, as a result, just 2.3 percent of children are found to have elevated lead blood levels in 2007, which is down from 8.8 percent in 1997.

Cuts to this program will fall squarely on the backs of low-income families and communities of color since they are disproportionately impacted by environmental health hazards. It will result in a decrease in blood lead screening rates and efforts to eliminate lead hazards that still exist today. What are the long-term impacts that reducing this funding will have on States, healthcare costs, lost school days for students, and loss of productivity for parents?

Answer. The goal of the new CDC Healthy Environments consolidated program is to maintain a multi-faceted approach through surveillance, partnerships, implementation and evaluation of science-based interventions to address the health impact of environmental exposures in the home and to reduce the burden of asthma through comprehensive control efforts. As the Healthy Environments program is implemented, the number of funded recipients will decrease from 40 to 34 to implement Healthy Homes programs and only State health departments will be eligible to apply for funding; this will help save significant overhead costs as fewer resources will need to be devoted to grantee management when there are fewer individual grantees. A healthy homes approach works to mitigate health hazards in homes such as lead poisoning hazards, secondhand smoke, asthma triggers, radon, mold, safe drinking water, and the absence of smoke and carbon monoxide detectors. Findings indicate that multi-component, multi-trigger home-based environmental interventions are effective at improving overall quality of life, reducing healthcare costs and improving productivity. By integrating the National Asthma Control Program (NACP) and the Healthy Homes/Childhood Lead Poisoning Prevention Program, CDC's aim is to establish and maintain a more coordinated approach to this multifaceted public health challenge.

Question. Can you please explain the impact on Rhode Island, and the country, if discretionary funding were to be reduced from its current 2010 level, in terms of patients served, patient health status, and the economy as a whole?

Answer. Reductions in the annual health center appropriation level will impact the ability of the Health Center Program to meet projected patient targets nationally and in Rhode Island. Depending on the size of the reduction, it may limit or eliminate the Program's ability to expand the program and/or sustain current program investments and achievements.

QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

Question. I understand that the Health Resources and Services Administration funding is proposed to be reduced in the Administration's fiscal year 2012 budget proposal. Further, the Administration is proposing to eliminate the Public Health Improvements account based on the fact that this account is entirely earmarked.

What Federal funding streams are available for hospitals to apply for facilities and equipment grants?

Answer. The Health Resources and Services Administration's (HRSA) Office of Rural Health Policy (ORHP) published a manual last year, targeted to critical access hospitals, outlining the various steps involved in planning, financing and carrying out construction projects.HRSA also facilitates the funding of equipment for rural hospitals to provide or receive clinical services at a distance through the Telehealth Network Grant Program (TNGP) administered by HRSA/ORHP's Office for the Advancement of Telehealth (OAT). The TNGP supports not-for-profit organizations and offers up to $250,000 per year in funding to demonstrate how telehealth programs and networks can improve access to quality healthcare services in underserved rural and urban communities. By statute, the TNGP limits equipment expenditures to 40 percent of each grant award. We anticipate that a TNGP funding opportunity announcement will be released in fiscal year 2012, subject to appropriations. Although the TNGP funds equipment, its focus is the funding of telehealth networks that provide clinical services to underserved populations and the evaluation of telehealth technology's effectiveness.

Question. Are any of these funding sources targeted at rural hospitals?

Answer. Rural Hospitals are eligible to apply for the USDA funding and TNGP funding. The Telehealth Network Grant Program (TNGP), administered by the Health Resources and Services Administration (HRSA)/Office of Rural Health Policy's (ORHP) Office for the Advancement of Telehealth (OAT) is a primary conduit for demonstrating how telehealth programs and networks can improve access to quality healthcare services in underserved rural and urban communities. TNGP grants demonstrate how telehealth networks improve healthcare services to: (a) expand access to, coordinate, and improve the quality of healthcare services; (b) improve and expand the training of healthcare providers; and/or (c) expand and improve the quality of health information available to healthcare providers, patients, and their families.

Question. The fiscal year 2012 budget request for LIHEAP totals $2.569 billion. This is down from an fiscal year 2011 request of $5.3 billion and an fiscal year 2010 enacted level of $5.1 billion.

While I understand the budget constraints that we are facing right now, I am concerned about families losing this assistance. What resources are out there to assist families with energy costs in lieu of LIHEAP assistance?

I know there are several formulas used to calculate how funding is distributed. In Arkansas, we are put at a disadvantage in the summer months because most of the funding is spent on heating during the winter and little is left over for cooling during the summer. Residents in southern States rely on LIHEAP for cooling as well as heating. How can the LIHEAP funding be adjusted so that southern States can better help their citizens during the hot summer weather?

Answer. Several other ACF programs, including TANF and the Social Services and Community Services Block Grants, provide assistance to low income people which may be used for home energy costs. Outside of HHS, assistance for home weatherization is provided by the Department of Energy. The fiscal year 2012 President's budget requested $320 million for this purpose, an increase of 52 percent above fiscal year 2010. States also provide substantial home energy assistance, $2.6 billion in fiscal year 2009, primarily from rate assistance from publically regulated utilities and State/local home energy assistance funds.

LIHEAP block funds are distributed to States by statutory formula. States determine how to distribute their allocation between heating and cooling assistance. Prior to 1984, funds were allocated to States based largely on their numbers of low income people and the National Weather Service's standard measure for the need for heat. In 1984, Congress enacted the new formula to adjust State allocations to reflect total home energy costs (heating and cooling) by low income households. This formula takes effect when the appropriation for the formula grant exceeds $1.975 billion. Since fiscal year 2009, LIHEAP appropriation language has capped the amount of funding distributed by the new formula at $840 million.

Question. Frequently, I hear concerns about the availability of healthcare providers in rural areas. Many of the rural areas in Arkansas have an aging community of healthcare providers, and the citizens of those communities are worried about preserving access to care. Can you discuss priorities you are working on to ensure we have enough healthcare providers to deliver quality healthcare in rural areas?

Answer. The President's budget included funding to support rural healthcare that focus on improving recruitment and retention of healthcare providers in rural areas. The Health Resources and Services Administration's (HRSA) National Health Service Corps (NHSC) serves as a key resource in this area as 60 percent of the placements for NHSC practice in rural areas. In addition, HRSA's Office of Rural Health Policy is funding the Rural Training Track (RTT) Technical Assistance Center grant to support the existing rural training tracks around the country and to assist communities in developing new RTT programs. HRSA also supports the work of the National Rural Recruitment and Retention Network, a 50 State consortium of clinician recruiters who work to match doctors, nurses and dentists with an interest in rural practice with rural communities in need of a practitioner. Last year, the Rural Recruitment and Retention Network supported the placement of more than 1,030 clinicians in rural areas.

Question. State-based health insurance exchanges will be created to make affordable, quality insurance options available to every American. Debates have been taking place in some States about whether or not States should move forward in setting up exchanges that will be run by State governments before the Supreme Court rules on the constitutionality of the individual mandate. Can you briefly describe the opportunities States have to establish exchanges and what the role could be for either State governments or the Federal Government depending on what decisions States make?

Answer. To receive a multi-year Establishment grant, States must commit to establishing an Exchange. Recognizing that not all States are far enough along to make this determination, grants for up to 1 year of funding will not require a State to commit to operating its own Exchange. By statute, Territories must commit to establishing, and ultimately establish, an Exchange to receive any Exchange grant funding.

Through both the Planning and Establishment grants, States are held to achieving milestones for important Exchange implementation activities such as insurance market research, stakeholder consultation, and assessment of current State eligibility and enrollment systems. If a State ultimately chooses not to implement its own Exchange, or HHS determines a State is not ready to operate an Exchange by 2014, HHS may benefit from this work when it establishes a federally operated Exchange in that State.

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

CLASS ACT

Question. The CLASS Act attempts to address an important public policy concern—the need for non-institutional long-term care—but it is viewed by many experts as financially unsound. The President's fiscal commission recommended reform or repeal of the CLASS Act. You stated to health advocacy groups that, "it would be irresponsible to ignore the concerns about the CLASS program's long-term sustainability in its current form." The President's budget proposal includes a request of $120 million for the CLASS Act, which would be the first discretionary appropriation for the program. If you are unable to certify that it will be sustainable absent a massive taxpayer infusion of funds, why would Congress want to appropriate the requested $120 million in taxpayer funds for a program that experts project will fail?

Answer. We share your view that the CLASS Act addresses an important public policy concern. About 14 million people spend more than $230 billion a year on long-term services and supports to assist them with daily living. Four times that many rely solely on unpaid care provided by family and friends. Despite public misperception that Medicare and Medicaid will cover their long-term care costs, Medicare is only available for time-limited coverage of very specific types of skilled nursing facility services and while Medicaid is the largest public payer of these services, it is only available for people with few financial resources, such as those who were forced to spend their retirement on long-term care and have no place left to turn. The CLASS program represents a significant new opportunity for all Americans who work to prepare themselves financially to remain as independent as possible under a variety of future health circumstances.

The Affordable Care Act requires HHS to develop an actuarially sound benefit plan that is fiscally sustainable. The discretionary request will finance the start up costs associated with establishing the CLASS program. All programs have start up costs, and this one is no different. This funding will be used to establish a solid benefit plan, develop an IT system to help consumers enroll, and implement an information and education plan to ensure participation and fiscal sustainability. This bridge will enable the program to begin enrolling individuals and collecting premiums, which will then be used for benefits once participants are vested and have an eligible claim.

I appreciate your consideration of this request, recognizing that HHS is still in the process of developing the actuarially sound benefit plan. We will not implement a program unless it is solvent and sustainable, as required by the statute. Prior to collecting any premiums, HHS will publish a notice of proposed rulemaking and present three actuarially sound benefit plans, as required by statute, to the CLASS Independence Advisory Council. These transparent processes will help HHS ensure the CLASS program starts with every expectation of sustainability; thus, the $120 million request will help the program with its critical startup activities, such as ensuring a significant education and outreach effort for broad enrollment.

Question. What will prevent from the Department from subsidizing this alleged self-sustaining program with taxpayer funds once it is implemented and then fails?

Answer. The law clearly states that the program must be able to pay for benefits with the premiums it takes in and that no taxpayer dollars may be used to pay for CLASS benefits. Section 3208(b) of the CLASS Act prevents HHS from using taxpayer funds to pay benefits. Specifically, the Act states "No Taxpayer Funds Used To Pay Benefits—No taxpayer funds shall be used for payment of benefits under the CLASS Independent Benefit Plan. For purposes of this subsection, the term 'tax-

payer funds' means any Federal funds from a source other than premiums deposited by CLASS program participants in the CLASS Independence Fund and any associated interest earnings."

Question. The budget proposal for the CLASS Act includes $93.5 million in new Federal spending for "information and education" to ensure that an adequate number of individuals will enroll in the program. While I do not agree with Congress appropriating $120 million for an insolvent program, it makes even less sense to spend $93.5 million of that funding to promote a program that we know as currently structured will fail. How do you justify spending such a large sum of money on promotion efforts given you will be a promoting a program that is not yet defined?

Answer. This $93.5 million will be used to educate Americans about the immense costs of long-term care and their ability to financially prepare for these costs. While a direct objective of this effort will be to expand the risk pool of individuals voluntarily enrolling in the CLASS program, we expect it to also help Americans begin other private preparations for these costs and ultimately reduce demands on State and Federal budgets. By October 1, 2012, HHS is required by statute to designate an actuarially solvent benefit plan that is solvent throughout a 75-year period. These funds will be used to promote this benefit plan, which will have been made available for comment before final designation.

Question. Given the significant actuarial concerns raised about the solvency of the CLASS program, will you agree that all education and outreach materials about the CLASS program will be vetted by independent actuaries who can attest to their completeness and accuracy? I am concerned because it is my understanding that the Medicare actuary did not sign off on the 2010 Medicare mailer that stated, "keep Medicare strong and solvent." Clearly, that statement was not entirely accurate and CMS spent $18 million to distribute these false claims.

Answer. HHS is required to designate an actuarially sound benefit plan that is solvent throughout a 75-year period. By law, the methods and assumptions used to determine the actuarial status of the CLASS Independence Fund will be reviewed and certified by the Chief Actuary of the Centers for Medicare & Medicaid Services and the financial solvency of the program will be documented in an annual report to Congress. The education and outreach materials will be consistent with these reviews.

Question. Modeling suggests that if you have a 2–3 percent participation rate the program is not sustainable. Absent massive media campaigns, how do you know that there will be greater participation? How do you know the market will receive this concept?

Answer. Broad participation is necessary to mitigate adverse selection and ensure the solvency and sustainability of the CLASS program. The proposed $93.5 million information and education effort will help inform eligible Americans about enrolling in the program. In addition, HHS will focus on recruiting employers to participate in the program, further improving enrollment. We also intend to conduct research to determine the best ways to communicate with consumers about the program and their options, and we will discuss the findings from this research with the CLASS Independence Advisory Council to help inform our estimates of participation in the program.

Question. On March 22, the Wall Street Journal highlighted the problems with the Social Security Disability Insurance system, including the inconsistent standards used by State offices that adjudicate claims. As an example, the article pointed to one administrative law judge in Puerto Rico that approved 98 percent of the Social Security disability claims he heard during fiscal year 2010. I am concerned that the inconsistent standards across States in the Social Security Disability Insurance system could apply to the CLASS Act. Secretary Sebelius, will the CLASS Act require a new State-based system to process claims and if so, how will you ensure standards remain consistent across States?

Answer. Section 3205 of the statute precludes use by the CLASS program of the State determination system for Social Security disability claims. At this time, we are considering how to implement the eligibility assessment process through which participants will claim benefits. Considering the voluntary, self-funded nature of this national program, we believe the eligibility assessment system should be consistent across the Nation. Thus, one possible approach that we are considering is contracting with a neutral third-party administrator, like the type servicing private long-term care insurance carriers, to ensure standardization of assessments consistent with the CLASS Act and its regulations.

PREVENTION AND PUBLIC HEALTH FUND

Question. If the Prevention and Public Health Fund is repealed, how will agencies fund the programs you have moved?

Answer. The Administration strongly opposes legislation that attempts to erode the important provisions of the Affordable Health Care that are making healthcare more accessible and affordable for all Americans. The Prevention and Public Health Fund is central to reducing the burden of chronic disease and reducing the healthcare costs associated with treating these diseases. Repeal of the Prevention and Public Health Fund would affect current year plans and have a direct programmatic impact. The Prevention Fund is central to reducing the burden of chronic disease and reducing the healthcare costs associated with treating these diseases. HHS has not replaced the entire base of program funding with Prevention and Public Health resources. Rather, the fiscal year 2011 allocation primarily builds on the prevention activities underway at HHS.

Question. The Affordable Care Act gives the Committee on Appropriations transfer authority for the mandatory funding provided through the Prevention and Public Health Fund. In fiscal year 2010, the Prevention Fund transferred $500 million toward prevention efforts, and in fiscal year 2011 $750 million should be transferred. Each fiscal year 2011 continuing resolution that has passed has included the transfer of these funds. Clearly it is the intent of the Committees on Appropriations to direct the transfer of this funding. Yet, you announced a spending plan for these funds on February 9, 2011, without the enactment of a full year appropriations bill. This means those dollars will be obligated without any congressional input or oversight. Is it the Department's intention to obligate these funds without Congressional transfer authority?

Answer. The Affordable Care Act in section 4002 gives the Committee on Appropriations transfer authority for the mandatory funding provided through the Prevention and Public Health Fund. If Congress had directed the transfer of fiscal year 2011 Prevention and Public Health Fund resources, the Department would have followed the transfer provided in law. The full-year appropriations bill for fiscal year 2011, however, did not direct the transfer of these funds, and section 4002 of the Affordable Care Act gives the Secretary authority to transfer resources from the appropriated amount within HHS.

Question. OMB claims that the "Education Research Centers overlap activities offered by the Department of Labor's Occupational Safety and Health Bureau." However, the mandate of the two agencies is different. The National Institute for Occupational Safety and Health is mandated to conduct research and provide professional training in occupational safety and health, while OSHA is mandated to regulate occupational safety and health conditions in the workplace and provide worker training. Therefore, Madam Secretary, where is the overlap?

Answer. OSHA's Outreach Training Program (OTP), OSHA Training Institute (OTI) Education Center, and Resource Center Loan Program all focus on employee training. OTP provides employee training in basic occupational safety and health courses in construction or general industry safety and health hazard recognition and prevention while the Resource Center Loan Program offers a collection of training videos to help increase employee knowledge of workplace safety. The OSHA Training Institute (OTI) Education Center program was initiated as an extension of the OSHA Training Institute, which is the primary training provider of the Occupational Safety and Health Administration. OTI targets Federal and State compliance officers and State consultants, other Federal agency personnel, and the private sector. While these programs focus on employee training, the ERCs support professional training and provide academic programs and research training in the core areas of industrial hygiene, occupational health nursing, occupational medicine, and occupational safety.

Question. The OMB justification for elimination of Education Research Center's is that the original programmatic plan was to provide funding for institutions to develop and expand existing occupational health and safety training programs and that this goal has been met. However, the statutory goal of the Education Research Centers is "to provide an adequate supply" of qualified occupational safety and health professionals. Has this goal been met? Before you answer, Madam Secretary, I would like to point out that according to the Bureau of Labor Statistics, employment of occupational health and safety specialist and technicians is expected to increase 11 percent during the timeframe of 2008–2018.

Answer. No. The establishment of a set of high quality training programs was the necessary first phase of the original long-range plan. The subsequent and critical steps for providing an adequate supply of qualified safety and health practitioners and researchers require ongoing resources to provide trainee support (for example,

stipends, tuition and fee reimbursement, and research supplies), and to maintain the training program infrastructure, which includes a high-quality faculty and training environment. Within the context of a budget that requires tough choices, we put forth a proposal to discontinue Federal funding for the ERCs. We recognize the vital role of occupational safety and health professional training. This proposal is one of many difficult reductions we proposed as part of the fiscal year 2012 budget.

Question. In the fiscal year 2012 budget request, the President eliminates funding for the Children's Hospitals Graduate Medical Education program. In explaining the elimination, the Administration said it "prefers to focus on targeted investments to increase the primary care workforce." Although they represent 1 percent of all hospitals, children's hospitals train more than 40 percent of general pediatricians. Since the inception of the program, children's hospitals have increased their training by 35 percent, helped address workforce shortages, and improved access to care. When there is a need for an expanded physician workforce nationwide, why are you supporting the elimination of a program that trains the primary care workforce for children?

Answer. Within the context of a budget that requires tough choices, we put forth a proposal to discontinue these general subsidies. This proposal is one of many difficult reductions we would not have put forth under different fiscal circumstances. We recognize the vital role that children's hospitals and pediatric providers play in providing quality healthcare to our Nation's children.

Children's hospitals would continue to be able to compete for funding through the competitive grant programs for which they are eligible. For example, six children's hospitals received over $16 million in fiscal year 2010 from the Primary Care Residency Expansion program funded by the Affordable Care Act. Pediatric residencies can also be supported through the new Teaching Health Center Graduate Medical Education Program created by the Affordable Care Act, which supports primary care medical residents in community-based ambulatory care settings.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

Question. The President's fiscal year 2012 budget for the Department of Health and Human Services proposes the elimination of the Delta Health Alliance at the Health Resources and Services Administration and also proposes the elimination of the Delta Chronic Disease Assessment and the Centers for Disease Control and Prevention. Mississippi has the highest obesity rate in the nation. What are your plans to address the health problems in the Mississippi Delta region?

Answer. The Health Resources and Services Administration (HRSA) currently supports 21 Health Centers in Mississippi and they focus on providing access to quality healthcare for underserved populations. In addition, HRSA's Office of Rural Health Policy (ORHP) has several grant programs which are available to address health disparities in the Mississippi Delta Region.

MISSISSIPPI STATE DEPARTMENT OF HEALTH FUNDING

Question. The President's budget proposes the elimination of the Preventive Health and Health Services Block Grant and proposes a new consolidated chronic disease grant program at the Centers for Disease Control and Prevention. The budget justification says this new grant program will not be a formula grant structure, but rather it will be competitive. Rural areas and States without capacity will be disproportionately affected by competitions. I am concerned that the new chronic disease grant program will create a scenario where the rich get richer and the poor get poorer. What are your plans to ensure that State health departments have the capacity to compete for funds at the Centers for Disease Control?

Answer. Chronic diseases—such as heart disease, stroke, cancer, diabetes, and arthritis—are among the most common, costly, and preventable of all health problems in the United States. Historically, CDC has funded categorical programs in State health departments to address these diseases as well as their common risk factors of obesity, poor nutrition and/or inadequate physical activity. Under the current structure, not all States are funded for these programs.

Because of the inter-relatedness of many common chronic diseases and their risk factors, the Coordinated Chronic Disease Prevention and Health Promotion Grant Program will support essential public health functions at the State level including epidemiology, evaluation, policy, communications and program management. Such an approach will strengthen State based coordination and therefore improve program efficiencies, provide leadership and support for cross-cutting activities and enhance the effectiveness of chronic disease prevention and risk factor reduction efforts across the included categorical programs.

State health departments are eligible to receive funding through the Coordinated Chronic Disease Prevention Program. State health departments are required to deliver programming that reaches across the State and reduces specific disparities within the State, including rural areas. In addition, recognizing the importance of supporting all States, including rural areas, $115 million of the $528 million available is intended to support all State health departments, territories, and some Tribes to establish or strengthen leadership, expertise, coordination of chronic disease prevention programming, surveillance and evaluation. In addition, health departments will be eligible to apply for competitive awards to strengthen coordination of chronic disease prevention programs and implement evidence-based prevention strategies. These competitive grants to State health departments, territories, some tribes and other entities will support activities addressing:

—Policy and environmental approaches to improve nutrition and physical activity in schools, worksites and communities;

—Interventions to improve delivery and use of selected clinical preventive services; and

—Community programs to support chronic disease self management to improve quality of life for people with chronic disease and to prevent diabetes, heart disease and cancer among those at high risk.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

Question. As a former Governor, I am deeply concerned with the Medicaid expansion in the new health law. Tennessee's previous Governor Bredesen, a Democrat, has called it "the mother of all unfunded mandates" and estimated that it will cost Tennessee and additional $1.1 billion for 2014–2019, and that is even with the Federal Government is paying 100 percent of the expansion population from 2014–2016. CBO recently estimated that it will cost States $60 billion through 2021.

The new law also mandates that Medicaid primary care physicians be reimbursed at 100 percent of Medicare rates in 2013–2014, for which the Federal Government will pay for those 2 years. But this creates a funding cliff for 2015. To keep doctors in their programs, States will either be forced to continue to pay Medicaid primary care physicians 100 percent of Medicare rates, or these physicians will effectively see a 40–50 percent cut for in 2015. According to the TennCare Director, the requirement to increase provider reimbursement to 100 percent of Medicare would cost Tennessee roughly an additional $324 million per year.

How are States going to shoulder these additional burdens in the current budget crises most of them are experiencing? Is the administration considering any kind of flexibility options to offer to States in order to avoid being crushed by all the mandates and maintenance of effort requirements?

Answer. We recognize that the economic downturn has forced States to make hard choices to control State spending, and that there are no easy answers. Recognizing the challenges facing States, I sent a letter to Governors in early February outlining existing flexibility and reaffirming the Department of Health and Human Services'—and the Center for Medicare & Medicaid Services'—commitment to working with States to improve care and manage costs in the Medicaid program. As part of that effort, CMS has undertaken an unprecedented level of outreach to States to help them strategize on ways to improve the efficiency of their Medicaid programs in light of current State budget challenges. To accomplish this task, CMS has created Medicaid State Technical Assistance Teams (MSTATs) that are ready to provide intensive and tailored assistance to States on day-to-day operations as well as on new initiatives. As of mid April, CMS has been contacted by 22 States for technical assistance. We are ready to continue working with States to explore new ways to manage their programs that will increase efficiency, reduce spending, and improve health for Medicaid beneficiaries.

Question. One of the problems with the Medicaid expansion is that there is an access problem for patients in the program being unable to see a doctor willing to treat them. There are varying reports on providers not willing to see Medicaid patients, like the 2006 report from the Center for Studying Health System Change Only stating that only about one-half of U.S. physicians accept new Medicaid patients.

Even the CMS chief actuary stated in an analysis done in April, ". . . it is reasonable to expect that a significant portion of the increased demand for Medicaid would be difficult to meet, particularly over the first few years."

By adding 16–18 million more people into the program, what is your administration doing to address access issues for all these new beneficiaries?

Answer. I am committed to ensuring access for Medicaid beneficiaries. The Affordable Care Act provision which helps States boost their payment rates to Medicare levels for 2 years is a good first step, as are all of the provisions that reform our healthcare delivery system to align payments with higher quality care. Federal funding will be available to cover 100 percent of the initial cost of the mandated increases in provider payment for primary care services.

The newly formed Medicaid and CHIP Payment and Access Commission (MACPAC) will play an important role by providing research and analysis on provider payment rates and access in the Medicaid program. In the initial MACPAC report, issued in March 2011, there was extensive discussion about the difficulties in analyzing access issues, and the need to develop additional data sources and new analytic approaches. On May 6, 2011, we published a proposed rule that integrated the MACPAC approach into a strategy to develop a transparent process for States to collect and analyze access issues. We anticipate working closely with MACPAC to learn about best practices and approaches in sustaining access in 2014 and beyond.

Question. Has HHS done an analysis of how many providers are not seeing new or any Medicaid patients? If not, can CMS look into this?

Answer. Access to providers by Medicaid recipients is of paramount importance. As a requirement for States' participation in the Medicaid program, they must ensure that "payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to the general population in the geographic area." As noted above, CMS is currently undertaking rulemaking to provide guidance to States on compliance with this requirement, which includes a framework for State and Federal review. Through the rulemaking process, we are welcoming public notice and comment on our proposed approach, which provides for States to review access through a three-part framework, focusing on beneficiary needs, provider enrollment, and service utilization.

Because States have primary responsibility for managing data on eligible beneficiaries and for enrolling and reimbursing Medicaid providers, States have the most accurate and up to date information on the number of providers participating in each State's Medicaid program, the percent of those accepting new Medicaid patients, and whether those numbers are comparable to the availability of providers for the general population in the area. Our proposed strategy is to require States to perform the initial analysis of available data and issue access reports for both Federal and public scrutiny.

Question. In your January testimony to the HELP Committee, you mentioned tax credits as a way that the law will keep down premiums. I realize that people who receive the tax credits or subsidies will pay less out of their own pocket for premiums, but are you saying that these tax credits/subsidies will bring down the underlying premiums and or the underlying cost of healthcare?

Answer. Many provisions of the Affordable Care Act make healthcare more affordable for American families and businesses, including tax credits and premium assistance, new oversight of private insurance premiums growth, delivery systems reforms that will bend the healthcare cost curve, and larger purchasing pools through Exchanges.

Insurers often raise premiums to protect themselves against unpredictable market conditions. Premium tax-credits offered through Exchanges make health insurance coverage attainable for individuals who have not previously been able to afford the costs of health insurance and will enable wider participation in the health insurance market. Keeping more people in the insurance market at all times, and not just when they get sick, will lead to greater predictability and stability in the individual market.

Question. According to estimates from Senate Finance minority tax staff last year, only 7 percent of Americans would qualify for subsidies and would see these cost savings. What about everyone else? Even CBO has said premiums for families buying coverage on the individual market would see premiums increase by $2,100 a year.

Answer. Even after full implementation of health reform, most Americans will continue to receive insurance through their employers, as has traditionally been the case. CBO estimates that nearly 20 million Americans without access to affordable or adequate coverage through their employers or other sources will receive premium tax credits or cost-sharing subsidies through the Exchanges.

Question. You also stated in your HELP testimony that the new law "is bringing down premiums for consumers by limiting the amount of premiums insurers may spend on administrative costs and by giving States resources to beef up their review process."

How do you square this statement with recent news articles that some insurers are raising premiums as a result of the new law?

Answer. According to our analysis and those of some industry and academic experts, any potential premium impact from the new consumer protections and increased quality provisions under the Affordable Care Act will be minimal. We estimate that the effect will be no more than 1 to 2 percent. This is consistent with estimates from the Urban Institute (1 to 2 percent) and Mercer consultants (2.3 percent). Insurers themselves have also reached a similar conclusion. Pennsylvania's Highmark, for example, estimates the effect of the legislation on premiums from 1.14 to 2 percent.

Any premium increases will be moderated by out-of-pocket savings resulting from the law. These savings include a reduction in the "hidden tax" on insured Americans that subsidizes care for the uninsured. By making sure that high-risk individuals have insurance and emphasizing healthcare that prevents illnesses from becoming serious, long-term health problems, the law will begin to reduce costs resulting from the treatment of patients at the acute stage of illness. The law prioritizes prevention, making many services available without cost-sharing, invests in prevention in communities across the country, and contains a series of provisions designed to improve the way we pay for care.

In addition to the coverage and delivery system changes that will begin to bend the cost curve, the law provides valuable new tools to ensure that consumers are getting value for their premium dollar. Already, we have provided 44 States and the District of Columbia with resources to strengthen the review and transparency of proposed premiums. CMS is making up to $250 million available for States to improve their rate review infrastructure and to fight unreasonable rates. Rate review allows States to examine and in some cases reject or modify the insurance rate before implementation. At the end of the year, the new medical loss ratio standard requires carriers to rebate premiums back to consumers if they fail to meet the standard. Rate review and medical loss ratios work together to help consumers. We will also keep track of insurers with a record of unjustified rate increases; those plans may be excluded from health insurance Exchanges in 2014.

Question. There has been a lot of news coverage lately about the more than 1,100 annual limit waivers granted by your administration. Additionally, several States have applied for waivers from the medical loss ratio (MLR) requirement.

Would it not make more sense for HHS to consider a blanket waiver of annual benefit limits and MLR standards until 2014?

Answer. The Center for Consumer Information and Insurance Oversight (CCIIO)'s waiver policy represents a transition to 2014, when annual limits will be eliminated and limited medical benefit plans will be a thing of the past. Until 2014, the transition ensures that insurance plans that can remove annual limits do so. Those that cannot remove annual limits without significantly raising premiums or reducing access to benefits can receive waivers. This transition assures that Americans can keep this limited coverage until more comprehensive coverage options are available to all in 2014. CCIIO is approving 1 year waivers and collecting data on limited benefits plans that will inform our approach for future years.

The medical loss ratio provision allows CCIIO to adjust the percentage if the potential exists to destabilize the individual market in a State. To date, one State, Maine, has received a reduced loss ratio. Each State market is different and CCIIO has established a process by which a State may apply, if they believe the potential exists for disruption. CCIIO will evaluate each application against the criteria set forth in regulation and guidance.

Question. Does the HHS have contingency plans for larger than expected expenditures for subsidies if more employers drop coverage than expected?

Answer. The reforms in the Affordable Care Act are intended to complement and strengthen the existing employer-based insurance system, not to replace it. We believe that the MLR requirements, review of annual rate increases, and delivery system reforms will help slow the growth of insurance costs to businesses so they can continue to provide the insurance their employees and families need and depend on.

The Congressional Budget Office has found that any decrease in employer-sponsored coverage because of the Affordable Care Act would be minimal. On the contrary, the Affordable Care Act provides tremendous benefits for employers that will encourage them to continue to offer health insurance coverage to their employees. In the coming years, the Congressional Budget Office estimates that health insurance premiums could decrease by up to 3 percent for employers. The new law also provides $40 billion in tax credits to help small businesses purchase coverage for their employees. In 2014, small businesses will be able to purchase private insurance through the Exchanges, which will provide them with the same purchasing power as large businesses.

Question. In the last Congress, HHS received enormous appropriations of tax dollars with very little Congressional direction on the use of those funds going forward. HHS received $1 billion as part of the Federal stimulus program and approximately $2 billion more per year in the future as part of the new healthcare law, all for the Mobilizing for Action through Planning and Partnerships (MAPP) intervention grants. HHS was given these enormous streams of taxpayer dollars without clear direction on the specifics of how those funds should be used.

CDC appears to be using these taxpayer dollars to fund advocacy organizations at the State and local level who engage in legislative advocacy for higher taxes and restrictions focused on consumer goods, which raises a number of serious concerns. Using Federal tax dollars for legislative advocacy is against the law, as the appropriation itself is subject to a restriction clearly prohibiting that the agency from using Federal funds to engage in direct or grassroots lobbying for changes in State or local laws. There also is a Federal criminal statute—the Anti-Lobbying Act—making it a criminal offense to "influence in any manner . . . an official of any government, to favor, adopt, or oppose, by vote or otherwise, any legislation, law, ratification, policy or appropriation."

As a former Governor, I think it is totally inappropriate for the executive branch to unilaterally decide what is or isn't a good State or local law worthy of financial support. If the Administration has a legislative agenda, it should work with the Congress to enact it through the legislative process.

In response to questions about the use of these funds during congressional hearings last year, CDC Associate Director Pechachek, stated that, "The prohibition against lobbying does not mean that communities are prohibited from interacting with policy makers such as legislators in order to promote the goals of the Communities Putting Prevention to Work Program."

How can a program have as a main, underlying objective to seek changes in State and local laws when the Federal Government specifically prohibits the use of Federal grant moneys to engage in direct or grassroots lobbying? Do you agree with this concern?

How much of the billions of dollars in spending under the stimulus and new healthcare law has been used to support efforts to change local and State laws? Would you provide this Committee with the details of that information?

Answer. As part of the American Recovery and Reinvestment Act (ARRA), Congress provided $650 million in funding for CDC to implement the Communities Putting Prevention to Work (CPPW) program. In addition, approximately $44 million from the Prevention and Public Health Fund supported quality but unfunded CPPW grantees, as well as media and evaluation, in fiscal year 2010. CPPW grantees are tackling important health problems, focusing on tobacco, nutrition and physical activity. Addressing these health challenges requires action at the community level, often to make changes that give individuals greater opportunities to make healthy choices.

CDC strictly adheres to all Federal laws prohibiting the use of Federal funds to lobby, and even goes beyond statutory requirements to restrict the activities of grantees at the local level when Federal funds are involved. CDC regularly educates all grantees on Federal laws related to funding awards, including anti-lobbying provisions. CDC references Additional Requirement (AR)-12 "Lobbying Restrictions" in all of its Funding Opportunity Announcements (FOAs), and all prospective recipients must agree to these restrictions prior to receiving funds. The AR states, in part, "Any activity designed to influence action in regard to a particular piece of pending legislation would be considered 'lobbying.' That is, lobbying for or against pending legislation, as well as indirect or 'grass roots' lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies."

CDC is careful to monitor the use of Federal funding, and to ensure that grantees comply with Federal law and the specific guidance of the Funding Opportunity Announcement and conditions outlined in the AR–12. However, anti-lobbying provisions do not prohibit communities from interacting with policymakers through proper official channels, in order to educate them about the burden of chronic diseases and their associated risk factors, as well as evidence-based strategies to promote health. There are many activities that are allowable under Federal law which community leaders may decide to pursue; moreover, policy change does not have to include formal legislative action. For example, health departments may choose to work with local transportation and planning departments to ensure that urban design policies include opportunities for people to be active. Local businesses may voluntarily decide to change their food procurement policies and to provide a greater

selection of healthy food options for employees in vending machines and cafeterias. Transit systems may determine on their own to make their trains and buses smoke-free. Each of these is an example of a type of policy change that impacts people in their daily lives, without requiring legislative action at the local, State, or Federal levels.

CDC supports community efforts to foster these types of linkages between health departments and key stakeholders from multiple sectors across a community, while strictly adhering to all Federal laws prohibiting the use of Federal funds to lobby. CDC carefully monitors the activities of grantees and the use of Federal funds to ensure compliance with Federal law, the specific guidance of the Funding Opportunity Announcement, and conditions outlined in AR–12.

Question. One of the major concerns I have heard from constituents about the new health law is that it will lead to government control and rationing. Treatment choices should be made between doctors and patients, rather than by folks in Washington, DC.

While the FDA has announced its decision to withdraw its approval for Avastin for breast cancer treatment, the European equivalent (the EMEA) has confirmed the use of Avastin for breast cancer. Shouldn't American women on Medicare have access to this drug as well?

Answer. I recognize the critical importance of the physician-patient relationship, especially in deciding an appropriate drug therapy treatment. The Medicare statute authorizes coverage of items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury in the Medicare population.

At this time, CMS is not making any changes to its coverage or reimbursement policies for Avastin and is waiting until the resolution of the FDA process before deciding whether to make any changes. While we do periodically consider new evidence about Medicare-covered drugs or treatments to evaluate whether changes in coverage decisions are warranted, it would be premature to speculate on possible changes in Medicare coverage of Avastin, if any, that may be made in response to future FDA actions.

Question. Avastin is an expensive treatment option. Can you affirm that the FDA was looking purely at science rather than the cost of the drug when making its decision?

Answer. The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring that drugs and biologics are safe and effective. In determining whether a product should be labeled for a particular indication, FDA takes seriously our obligation to carefully weigh the risks and benefits for the patient. Specifically, FDA considers whether the benefits of the drug, including the magnitude of those benefits, outweigh the product's potential toxicities for the indicated use. The Food and Drug Administration does not factor costs into its drug approvals or safety related decisions. FDA's Center for Drug Evaluation and Research has proposed to remove Avastin's indication for metastatic breast cancer based on the Center's evaluation of efficacy and safety data available from clinical trials, without considering the cost of the drug. FDA has not yet reached a final decision on this proposal, and this matter will be the subject of a hearing in June 2011.

Question. More than 40 States have laws in place to ensure those on private insurance have access to cancer drugs even if they are "off-label." Shouldn't women on Medicare have the same guarantee?

Answer. At this time, CMS is not making any changes to its coverage or reimbursement policies for Avastin and is waiting until the resolution of the FDA process before deciding whether to make any changes. While we do periodically consider new evidence about Medicare-covered drugs or treatments to evaluate whether changes in coverage decisions are warranted, it would be premature to speculate on possible changes in Medicare coverage of Avastin, if any, that may be made in response to future FDA actions. I would note, however, that, generally, Medicaid coverage of a drug is contingent upon that drug having FDA approval. I cannot speak to the process behind the coverage decisions of other insurance providers.

Question. If many of the roughly 18,000 women using Avastin for metastatic breast cancer find it effective, and scientific experts at the National Comprehensive Cancer Network, the leading cancer compendia, support its use, can you assure me that Medicare will not restrict coverage of this product?

Answer. I recognize the critical importance of the physician-patient relationship, especially in deciding an appropriate drug therapy treatment. The Medicare statute authorizes coverage of items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury in the Medicare population.

At this time, CMS is not making any changes to its coverage or reimbursement policies for Avastin and is waiting until the resolution of the FDA process before deciding whether to make any changes. While we do periodically consider new evi-

dence about Medicare-covered drugs or treatments to evaluate whether changes in coverage decisions are warranted, it would be premature to speculate on possible changes in Medicare coverage of Avastin, if any, that may be made in response to future FDA actions.

QUESTIONS SUBMITTED BY SENATOR LINDSEY GRAHAM

Question. Can you explain FDA's process for approving drugs for new indications?

Answer. Secretary Sebelius: In order for a new indication for a drug or biologic product to be marketed in the United States, it must be shown to be safe and effective for its intended new use.

In 1998, FDA published guidance for manufacturers planning to file applications for new indications of approved drugs or biologic products. In this guidance, FDA articulated its thinking on the quantity of evidence needed in particular circumstances to establish substantial evidence of effectiveness. The guidance discussed the standards and data requirements for approval of new indications so that duplication of data previously submitted in the original application could be avoided. In particular, FDA addressed situations in which a single adequate and well-controlled trial of a specific new use could be supported by information from other adequate and well-controlled trials, such as trials in other stages of a disease, or in closely related diseases.

The new drug or biologics licensing application that is submitted by the manufacturer in support of a new indication must include the requisite clinical trial information demonstrating safety and effectiveness, and supportive clinical pharmacology, preclinical and product quality information, as needed. FDA scientists review the submitted information and determine whether or not the product may be approved for the new use if the benefits of treatment are found to outweigh the risks for the intended population.

Question. Am I correct in my understanding that FDA does not consider the cost of a drug during its approval process? If cost is considered, how does that cost factor into FDA's decision to approve drugs for certain indications?

Answer. Yes, you are correct. In deciding whether to approve a drug, FDA cannot and does not take price into account.

Question. I am aware that Avastin is a very expensive drug, and I have been made aware of concerns that cost could have been a factor in FDA's decision to remove the breast cancer indication from Avastin's label. Did Avastin's cost play any role in FDA's decision regarding the drug?

Answer. The Food and Drug Administration is responsible for protecting the public health by ensuring that drugs and biologics are safe and effective. In determining whether a product should be labeled for a particular indication, FDA takes seriously its obligation to carefully weigh the risks and benefits for the patient. Specifically, FDA considers whether the benefits of the drug, including the magnitude of those benefits, outweigh the product's potential toxicities for the indicated use. The Food and Drug Administration does not factor costs into its drug approvals or safety related decisions. FDA's Center for Drug Evaluation and Research has proposed to remove Avastin's indication for metastatic breast cancer based on the Center's evaluation of efficacy and safety data available from clinical trials, without considering the cost of the drug. FDA has not yet reached a final decision on this proposal, and this matter will be the subject of a hearing in June, 2011.

Question. What is HHS's policy for awarding grants to organizations that advocate for specific policy positions?

I have heard concerns that Federal stimulus dollars targeted to public health were awarded to advocacy organizations who lobby State and local governments for specific policy changes regarding food and beverages. Can you provide details regarding the grant-making process for public health programs including the information required for proposal when submitted and how often HHS audits grant recipients to be sure they are complying with the aims of the HHS' grant programs?

Answer. Applicants for (and recipients of) Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, extension, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services that are not subject to this prohibition. Appli-

cants for HHS grants with total costs expected to exceed $100,000 are required to certify that they: have not made, and will not make, such a prohibited payment; will be responsible for reporting the use of non-appropriated funds for such purposes; and will include these requirements in consortium agreements, other subawards, and contracts under grants that will exceed $100,000 and will obtain necessary certifications from those consortium participants and contractors.

Disclosure reporting is required after award as indicated and must be certified annually either through providing submitting disclosure statements by doing so on the SF–LLL, Disclosure of Lobbying Activities. Where there are no disclosures to report the grantee certifies this fact by signing the face page of the application without the need to submit the forms. The grantee certifies that there are no lobbying activities to report when they sign the face page of the application.

Consistent with Federal law, in its grant programs, CDC references Additional Requirement (AR)-12 "Lobbying Restrictions" in all of its Funding Opportunity Announcements (FOAs), and all prospective recipients must agree to these restrictions prior to receiving funds. The AR states, in part, "Any activity designed to influence action in regard to a particular piece of pending legislation would be considered 'lobbying.' That is, lobbying for or against pending legislation, as well as indirect or 'grass roots' lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies."

CDC is careful to monitor the use of Federal funding, and to ensure that grantees comply with Federal law, the specific guidance of the FOAs, and conditions outlined in AR–12. Grants or cooperative agreements funded by the American Recovery and Reinvestment Act are also subject to this policy. We note, however, that many organizations engage in advocacy using funding from other sources, and that this does not bar them from applying for and receiving funding from CDC. Recipients are permitted to use their own funds to lobby, so long as it can be demonstrated or shown that the funds that were used for lobbying were entirely separate from any appropriated funds they received from the Federal Government. Recipients are required to disclose all lobbying activities along with their application. CDC only provides funds to undertake activities outlined in the FOA.

CDC's Procurement and Grants Office (PGO) provides specific budgetary oversight to ensure the appropriate use of Federal funds. CDC grants management specialists and program staff are significantly involved in the planning and monitoring of recipient activities, review and approval of spending details, and tracking of grantee drawdown of funds. PGO staff participate in annual site visits to all funded communities. One example is the Communities Putting Prevention to Work (CPPW) program, which has a robust plan for performance monitoring in order to ensure that Federal funds are used effectively and appropriately. The plan positions CDC staff to identify early warning signs that a program is using Federal funds for unauthorized and inappropriate activities. Furthermore, an electronic performance monitoring system provides a central repository for collecting information from a number of program monitoring sources. CDC also complies with other mandatory directives, such as OMB Circular A–133, which requires every organization receiving $500,000 in aggregate Federal grants to submit to annual financial audit. The results of these audits are used in periodic grantee reviews to identify grantees that may present a risk to the control or integrity of fund use.

Question. I have heard concerns that Federal stimulus dollars targeted to public health were awarded to advocacy organizations who lobby State and local governments for specific policy changes regarding food and beverages. Can you provide details regarding the grant-making process for public health programs including the information required for proposal when submitted and how often HHS audits grant recipients to be sure they are complying with the aims of the HHS' grant programs?

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be responsible for reporting the use of non-appropriated funds for such purposes; and will include these requirements in consortium agreements, other subawards, and contracts under grants that will exceed $100,000 and will obtain necessary certifications from those consortium participants and contractors.

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SUBCOMMITTEE RECESS

Senator HARKIN. And with that, again, Madam Secretary, thank you and the subcommittee will stand recessed.

[Whereupon, at 11:37 a.m., Wednesday, March 30, the subcommittee was recessed, to reconvene subject to the call of the Chair.]