DEPARTMENTS OF LABOR, HEALTH, AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES FOR FISCAL YEAR 2011

WEDNESDAY, MARCH 10, 2010

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

The subcommittee met at 3:05 p.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Reed, Pryor, and Cochran.

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

Well, Madam Secretary, welcome back to the subcommittee. I first want to start by commending you for the outstanding work you're doing to help enact healthcare reform. We can see the finish line at last. And your leadership is one of the reasons that we can see that finish line.

I know it will be tempting for Senators on both sides of the dais to want to debate the pros and cons of health reform with you today. But I would urge the subcommittee members to keep their focus on the subject of our hearing. And that is the President's proposed fiscal year 2011 budget for the Department of Health and Human Services (HHS).

On the whole, there's much to like in the HHS budget. As we all know the President's budget holds the line on nonsecurity-related spending overall in fiscal year 2011. But the President promised to use a scalpel, not an ax, to achieve that freeze. And HHS is one of the Federal agencies that would get an increase, 2.5 percent more than in fiscal year 2010.

I was particularly pleased that the President included a major boost for efforts to root out fraud in Medicare and Medicaid. Reducing healthcare fraud and abuse has been a priority of mine for many years. And it will play a key role in bringing our long-term deficits under control. Significant increases were also proposed for the National Institutes of Health (NIH), for Head Start, childcare

and a new caregiver's initiative that will help families take care of their elderly relatives.

Other provisions in the budget raise cause for concern, however. For example, the President's budget would cut funding for the Centers for Disease Control and Prevention (CDC). The budget also includes a $1.8 billion cut to discretionary funding under the LIHEAP program. But overall, I think the President's budget is a good start. I look forward to discussing it in more detail with you during this hearing.

I also want to add, Madam Secretary, how lucky you are to have an Assistant Secretary like Ellen Murray to advise you on all these issues. At last year's budget hearing she was sitting next to me on the dais. Today she is advising you. I can tell you from experience you're in very good hands. And I read it just as she wrote that for me right there.

Senator HARKIN. Now I turn to Senator Cochran.

STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you very much for convening the hearing.

Madam Secretary, we appreciate your being here to talk about the budget request. And we look forward to hearing your testimony.

PREPARED STATEMENT

I ask unanimous consent that the balance of my remarks be placed in the record. I will also include a statement from the Chairman, Senator Inouye. He regrets that he could not be present.

Senator HARKIN. Thank you very much, Senator Cochran.

[The statement follows:]

PREPARED STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, thank you for chairing this hearing to review the budget for fiscal year 2011 for the Department of Health and Human Services. We are pleased to welcome the Secretary of Health and Human Services, Kathleen Sebelius to her second 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 $1 billion 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.

I was also pleased to see your announcement last week regarding the $10 million in funds from the America Recovery and Reinvestment Act to help communities find ways to curb smoking and combat obesity, improve access to healthy foods, and increase physical activity.

This subcommittee will be challenged to balance the competing needs of the programs contained in your $74 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.

PREPARED STATEMENT OF SENATOR DANIEL K. INOUYE

Secretary Sebelius, last October Dr. Mary Wakefield, the Administrator of the Health Resources and Services Administration, visited Hawaii and I would like to thank you for your support of her trip. She visited a number of Community Health Centers and toured several hospitals and educational facilities on the neighboring islands. The people of Hawaii were very grateful to host her visit and thankful for

the opportunity to discuss critical healthcare concerns of the State. In addition she met with representatives from the National Kidney Foundation of Hawaii to talk about the increasing incidence of kidney disease among the Filipino population.

Thank you again, and I will provide questions for the record to the subcommittee later.

Senator HARKIN. Again, Madam Secretary, welcome back to the subcommittee. And again, thank you for your leadership. And just by way of introduction, Kathleen Sebelius became the 21st Secretary of the Department of Health and Human Services on April 29, 2009.

In 2003, she was elected Governor of Kansas and served in that capacity until her appointment as Secretary. Prior to her election as governor she served as a Kansas State Insurance Commissioner. She is a graduate of Trinity Washington University and the University of Kansas.

Madam Secretary, welcome. 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. Well, thank you very much, Chairman Harkin and Senator Cochran and members of the subcommittee. I am glad to be back to discuss the 2011 budget for HHS. I think the budget builds on many of the themes that President Obama laid out in his State of the Union Address this year, strengthening our healthcare system, laying the foundation for future growth, and rooting out waste and fraud to make programs even more effective.

Under this budget we plan to make prudent investments in our Nation's health and long-term prosperity that members of this subcommittee and you, Mr. Chairman, have pushed for years in prevention, in wellness, in attacking healthcare fraud and supporting our children during those formative, early years and in biomedical research that leads to life saving cures to name just a few areas. So today I'd like to briefly highlight a few of these priorities. And then I look forward to our discussion about the issues in this budget.

Mr. Chairman, as you pointed out many times, what we have today in America is a sick/cure system, not a healthcare system. And last February, under your leadership, we took a huge step in the direction to change the focus of that system. With the investments in the Recovery Act we made the single largest investment in prevention and wellness in American history including the almost $373 million in grants for promising local programs that we look forward to releasing in the next couple of weeks. Our budget for 2011 builds on this investment with new efforts to reduce the harmful effects and tremendous costs of chronic disease in the urban populations to create a new health prevention corps and prevent unintended pregnancies, among other programs that we intend to focus on.

Senator Cochran, I know that the First Lady recently traveled to your home State of Mississippi as part of her initiative in the Let's Move campaign to end childhood obesity in a generation and highlighted some of Mississippi's very successful efforts in this area. And these are exactly the kind of promising approaches and strategies that we'd like to make sure and place around the country.

Our budget makes a historic investment in fighting healthcare fraud. Again, Mr. Chairman, your subcommittee started us on this path 2 years ago with the first discretionary funding. We've built on that.

When American families are struggling to make every dollar count we need to be just as vigilant in how we spend their money. The new fraud fighting funds will help us expand proven strategies like putting Medicare fraud strike forces in cities that are hubs for fraudulent activity. And they allow us to invest in promising new approaches like systems that will help us analyze claims data and suspicious activities in real time.

When the budget takes effect it's going to be a lot harder for criminals to get rich stealing from our healthcare system and our seniors. And before you ask, Mr. Chairman, our budget does continue the Senior Medicare Control Program which you helped to start many years ago and is a great reserve of eyes and ears on the ground.

A third area of focus that I want to highlight for the subcommittee is our Early Childhood programs. Again, building on the Recovery Act, our budget includes an increase of $1 billion for Head Start, an extra $1.6 billion for childcare, creating room in childcare programs for 235,000 additional children. And with these increases we're putting a new focus on quality. The years 0 to 5 are at least as important as the years that children spend in kindergarten through the 12th grade, maybe more important according to the scientists. And there's no reason we shouldn't insist on the same high standards and the same rigorous focus on results.

And finally the budget includes a very critical increase of nearly $1 billion for the NIH. And I want to thank Chairman Harkin and Senator Cochran, Senator Specter and others on this subcommittee for their steadfast support for NIH and its critical work discovering the building blocks of disease and developing the cures of the future. The budget is going to help these cures get to American families faster.

So these are just a few areas in which our budget will employ new resources and new approaches to improve the lives of American families. I look forward to discussing some of the other priorities with you in a few minutes. But first I want to just clarify one point.

PREPARED STATEMENT

The budget is intended to be a complement, not a substitute, for health insurance reform. The only way to increase health security and stability, bring down healthcare costs and give Americans better insurance choices is to pass comprehensive health insurance reform. Combined with a reform effort, the budget is a major step toward building a stronger, healthier America. But even then, we'll need your help improving the health, safety, and well being of the American people. It's a goal we can only achieve by working together. And no one has a more important role than Congress.

So I appreciate the opportunity to be with you today and look forward to the discussion.

[The statement follows:]

PREPARED STATEMENT OF HON. KATHLEEN SEBELIUS

Chairman Harkin, Senator Cochran, and members of the subcommittee, thank you for the invitation to discuss the President's fiscal year 2011 budget for the Department of Health and Human Services (HHS).

In his State of the Union Address, President Obama laid out an aggressive agenda to create jobs, strengthen opportunity for working families, and lay a foundation for long-term growth. His fiscal year 2011 budget is the blueprint for putting that vision into action.

At HHS, we are supporting that agenda by working to keep Americans healthy, ensuring they get the healthcare they need, and providing essential human services for children, families, and seniors.

Our budget will make sure that the critical health and human services our Department offers to the American people are of the highest quality and are directly helping families stay healthy, safe, and secure—especially as we continue to climb out of a recession.

It promotes projects that will rebuild our economy by investing in next-generation research and the advanced development of technology that will help us find cures for diseases, innovative new treatments, and new ways to keep Americans safe, whether we are facing a pandemic or a potential terrorist attack.

But this budget isn't just about new programs or new priorities or new research. It is also about a new way of doing business with the taxpayers' money. Where there is waste and fraud, we must root it out. Where there are loopholes, we must close them. And where we have opportunities to increase transparency, accountability, and program integrity, we must take them. These are top priorities of the President. They are top priorities of mine. And our budget reflects that they are top priorities for my Department.

The President's fiscal year 2011 budget for HHS totals $911 billion in outlays. The budget proposes $81 billion in discretionary budget authority for fiscal year 2011, of which $74 billion is within the jurisdiction of the Labor, Health and Human Services, Education, and Related Agencies Subcommittee.

This budget is a major step toward a healthier, stronger America. But it is a complement, not a substitute for health insurance reform.

This administration strongly believes that the only sure way to increase health security and stability, bring down healthcare costs, and give Americans better insurance choices is to pass comprehensive health insurance reform. To that end, the President has put forth a proposal that bridges the House and Senate bills and incorporates the best ideas of Republicans and Democrats.

His proposal—which he has called on Congress to swiftly pass—will give American families and small business owners more control over their healthcare by holding insurance companies accountable. It will give Americans protection from insurance company abuses, create a new consumer-friendly health insurance marketplace, and begin to bring down costs for families, businesses, and Government. Reform is projected to reduce the deficit by about $100 billion in the first decade, and roughly $1 trillion in the second decade, and, by controlling healthcare costs, put the Federal Government on a path to fiscal responsibility.

After meeting last week with the CEOs of America's largest insurance companies, who acknowledged that the current health insurance system fails to provide transparency and affordable coverage to all Americans, I am more convinced than ever that the only way to fix our broken health insurance system is to enact these common-sense reforms. And after more than 1 year of conversation, Americans deserve an up or down vote.

My hope is that Congress will follow through on the hard work they have done over the last 12 months and send a bill to the President soon. But for now, I'd like to begin with a broad overview of my Department's 2011 budget priorities, many of which are aimed toward the same goals. Then I'll look forward to taking some of your questions.

Investing in Prevention

Reducing the burden of chronic disease, collecting and using health data to inform decisionmaking and research, and building an interdisciplinary public health workforce are critical components to successful prevention efforts. The budget includes $20 million for the Centers for Disease Control and Prevention (CDC) Big Cities Initiative to reduce the rates of morbidity and disability due to chronic disease in up to 10 of the largest U.S. cities. These cities will be able to incorporate the lessons learned from implementing evidence-based prevention and wellness strategies of the American Recovery and Reinvestment Act of 2009 (Recovery Act) Communities Putting Prevention to Work Initiative. This Recovery Act initiative is key to promoting

wellness and preventing chronic disease, and we appreciate the support of Congress, and particularly Chairman Harkin, in making these funds available. In March, HHS will award $373 million for the cornerstone of this initiative, funding communities to implement evidence-based strategies to address obesity, increase physical activity, improve nutrition, and decrease smoking. The Big Cities Initiative requested in fiscal year 2011 will allow us to build on the success of the Recovery Act.

The budget also includes $10 million at CDC for a new Health Prevention Corps, which will recruit, train, and assign a cadre of public health professionals in State and local health departments. This program will target disciplines with known shortages, such as epidemiology, environmental health, and laboratory science.

To support teen and unintended pregnancy prevention and care activities in the Office of Public Health and Science and CDC, the budget provides $222 million in funds. Of this, $125 million will be used for replicating programs that have proven effective through rigorous evaluation to reduce teenage pregnancy; research and demonstration grants to develop, replicate, refine, and test additional models and innovative strategies; and training, technical assistance and outreach. Also, provided in the request is $4 million to carry out longitudinal evaluations of teenage pregnancy prevention approaches, and another $4 million in Public Health Service evaluation funds for this activity. This also includes $22 million for CDC to reduce the number of unintended pregnancies through science-based prevention approaches. In addition, the fiscal year 2011 Adolescent Family Life (AFL) budget includes $17 million to provide support for AFL Care demonstration grants and research programs. In an effort to ameliorate the negative effects of childbearing on teen parents, their infants and their families, care grant community-based projects develop, test, and evaluate interventions with pregnant and parenting teens, and focus on ways to build and strengthen families.

Behavioral health is essential to the well-being of all Americans. The budget includes an additional $135 million in the Substance Abuse and Mental Health Services Administration and Health Resources and Services Administration (HRSA) for innovative approaches to prevent and treat substance abuse and mental illness. These efforts include increases of $35 million for community-based prevention, $25 million to expand behavioral health services at health centers, and $17 million associated with homelessness prevention. An increase of $13 million will expand the treatment capacity of drug courts, and $33 million will strengthen our capacity to deter new drug threats and assess our progress in reducing substance abuse.

Reducing Healthcare Fraud

When American families are struggling to make every dollar count, we need to be just as vigilant about how their money is spent. That's why the Obama administration is cracking down on criminals who steal from taxpayers, endanger patients, and jeopardize the future of our health insurance programs.

Last May, President Obama instructed Attorney General Holder and I to create a new Health Care Fraud Prevention and Enforcement Action Team, which we call "HEAT" for short. HEAT is an unprecedented partnership that brings together high-level leaders from both departments so that we can share information, spot trends, coordinate strategy, and develop new fraud prevention tools.

As part of this new partnership, we are developing tools that will allow us to identify criminal activity by analyzing suspicious patterns in claims data. Medicare claims data used to be scattered among several databases. If we wanted to find out how many claims had been made for a certain kind of wheelchair, we had to go look in several different places. This single, searchable database means that for the first time ever, we'll have a complete picture of what kinds of claims are being filed across the country.

Our fiscal year 2011 budget includes $1.7 billion in funding to fight fraud, including $561 million in discretionary funds to strengthen Medicare and Medicaid program integrity activities, with a particular emphasis on fighting healthcare fraud in the field, increasing Medicare and Medicaid audits, and strengthening program oversight while reducing costs. We appreciate the subcommittee's support of past requests for fraud prevention; and building on the successes we have been able to achieve with those funds, we are now seeking an additional $250 million over the fiscal year 2010 level that we hope you can support.

This investment will better equip the Federal Government to minimize inappropriate payments, pinpoint potential weaknesses in program integrity oversight, target emerging fraud schemes by provider and type of service, and establish safeguards to correct programmatic vulnerabilities. This multi-year discretionary investment will save $9.9 billion over 10 years.

The budget also includes a set of new administrative and legislative program integrity proposals that will give HHS the necessary tools to fight fraud by enhancing

provider enrollment scrutiny, increasing claims oversight, and improving Medicare's data analysis capabilities, which will save approximately $14.7 billion over 10 years. Along with the $9.9 billion in savings from the discretionary investments, these new program authorities will save a total of $25 billion in Medicare and Medicaid expenditures over 10 years.

Improving Quality of and Access to Healthcare

At HHS, we continue to find ways to better serve the American public, especially those citizens least able to help themselves. We are working to improve the quality of and access to healthcare for all Americans by supporting programs intended to enhance the healthcare workforce and the quality of healthcare information and treatments through the advancement of health information technology (IT) and the modernization of the healthcare system.

As Congress continues its work to provide security and stability for Americans with health insurance and expand coverage to those Americans who do not have insurance, HHS maintains its efforts toward achieving those goals through activities with the Children's Health Insurance Program (CHIP), health IT, patient-centered health research, prevention and wellness, community health centers, and the health workforce.

The budget includes $3.6 billion for Centers for Medicare & Medicaid Services' (CMS) Program Management. To strengthen the ability of CMS to meet current administrative workload demands resulting from recent legislative requirements and continued growth of the beneficiary population, the funding provides targeted investments to revamp IT systems and optimize staffing levels so that CMS can meet the future challenges of Medicare, Medicaid, and CHIP while being an active purchaser of high-quality and efficient care.

For example, $110 million will support the first year of a comprehensive Health Care Data Improvement Initiative (HCDII) to transform CMS's data environment from one focused primarily on claims processing to one also focused on state-of-the art data analysis and information sharing. Without this funding CMS would not be able to transform Medicare and Medicaid into leaders in value-based purchasing and in data sources for privacy-protected patient-centered health research. This funding is imperative for CMS to meet the needs of future growth, financial accountability, and data content and availability. The HCDII is the cornerstone of a business strategy that will optimize the delivery of efficient, high-quality healthcare services. CMS needs this funding to strengthen disaster recovery and security operations to protect against loss of data or services; to enable timely data sharing and analysis to fight fraud, waste, and abuse; and to transform payment processes to support quality outcomes.

To strengthen and support our Nation's healthcare workforce, the budget includes $1.1 billion within the HRSA for a wide range of programs. This funding will enhance the capacity of nursing schools, increase access to oral healthcare through dental workforce development grants, target students from disadvantaged backgrounds, and place an increased emphasis on ensuring that America's senior population gets the care and treatment it needs.

The budget includes an increase of $290 million to ensure better access to health centers through further expansions of health center services and integration of behavioral health into health centers' primary care system. This funding builds on investments made under the Recovery Act and will enable health centers to serve more than 20 million patients in fiscal year 2011, which is 3 million more patients than were served in fiscal year 2008.

The budget advances the President's health IT initiative by accelerating health IT adoption and electronic health records (EHR) utilization—essential tools for modernizing the healthcare system. The budget includes $78 million, an increase of $17 million, for the Office of the National Coordinator for Health Information Technology to continue its current efforts as the Federal health IT leader and coordinator. During fiscal year 2011, HHS will also begin providing an estimated $25 billion over 10 years of Recovery Act Medicare and Medicaid incentive payments primarily to physicians and hospitals who demonstrate meaningful use of certified EHRs, which will improve the reporting of clinical quality measures and promote healthcare quality, efficiency, and patient safety.

The budget supports HHS-wide patient-centered health research, including an additional $261 million within the Agency for Healthcare Research and Quality over fiscal year 2010. HHS also continues to invest the $1.1 billion provided by the Recovery Act to improve healthcare quality by providing patients and physicians with state-of-the-art, evidence-based information to enhance medical decision-making.

Promoting Public Health

Whether responding to pandemic flu or researching major diseases, HHS will continue its unwavering commitment to keeping Americans healthy and safe.

The budget includes more than $3 billion, an increase of $70 million, for CDC and HRSA to enhance HIV/AIDS prevention, care, and treatment. This increase includes $31 million for CDC to integrate surveillance and monitoring systems, address high-risk populations, and support HIV/AIDS coordination and service integration with other infectious diseases. The increase also includes $40 million for HRSA's Ryan White program to expand access to care for underserved populations, provide life-saving drugs, and improve the quality of life for people living with HIV/AIDS.

To improve CDC's ability to collect data on the health of the Nation for use by policy makers and Federal, State, and local leaders, the budget provides $162 million for health statistics, an increase of $23 million above fiscal year 2010. This increase will ensure data availability on key national health indicators by supporting electronic birth and death records in States and enhancing national surveys.

The budget includes $222 million, an increase of $16 million, to address Autism Spectrum Disorders (ASD). Research at the National Institutes of Health (NIH) will pursue comprehensive and innovative approaches to defining the genetic and environmental factors that contribute to ASD, investigate epigenetic changes in the brain, and accelerate clinical trials of novel pharmacological and behavioral interventions, CDC will expand autism monitoring and surveillance and support an autism awareness campaign, and HRSA will increase resources to support children and families affected by ASD through screening programs and evidence-based interventions.

The budget includes $352 million, an increase of $16 million, for CDC Global Health Programs to build global public health capacity by strengthening the global public health workforce; integrating maternal, newborn, and child health programs; and improving global access to clean water, sanitation, and hygiene. Specifically, CDC will expand existing programs and develop programs in new countries to provide workforce training in areas such as epidemiology and outbreak investigation, and to implement programs that distribute water quality interventions to create safe drinking water. In addition, CDC will integrate interventions, such as malaria control measures, expanded immunizations, and safe water treatment, to reduce newborn, infant, and child mortality. Additionally, the budget includes $6 million in the Office of Global Health Affairs to support global health policy leadership and coordination.

Protecting Americans From Public Health Threats and Terrorism

Continued investments in countermeasure development and pandemic preparedness will help ensure that HHS is ready to protect the American people in either natural or manmade public health emergencies. The budget includes $476 million, an increase of $136 million, for the Biomedical Advanced Research and Development Authority to sustain the support of next-generation countermeasure development in high-priority areas by allowing the BioShield Special Reserve Fund to support both procurement activities and advanced research and development.

Reassortment of avian, swine, and human influenza viruses has led to the emergence of a new strain of H1N1 influenza A virus, 2009 H1N1 flu, that is transmissible among humans. On June 24, 2009, Congress appropriated $7.65 billion to HHS for pandemic influenza preparedness and response to 2009 H1N1 flu. HHS has used these resources to support States and hospitals, to invest in the H1N1 vaccine production, and to conduct domestic and international response activities. The budget includes $302 million for ongoing pandemic influenza preparedness activities at CDC, NIH, Food and Drug Administration, and the Office of the Secretary for international activities, virus detection, communications, and research. In addition, the use of balances from the June 2009 funds, will enable HHS to continue advanced development of cell-based and recombinant vaccines, antivirals, respirators, and other activities that will help ensure the Nation's preparedness for future pandemics. Previous appropriations for H5N1 allowed us to be better prepared for H1N1 than we ever would have been otherwise, and only by continued work on better vaccines, antivirals, and preparedness will we be ready for the next virus—which could well be a greater challenge than H1N1 has been.

Improving the Well-being of Children, Seniors, and Households

In addition to supporting efforts to increase our security in case of an emergency, the HHS budget also seeks to increase economic security for families and open up doors of opportunity to those Americans who need it most.

The budget provides critical support of the President's Zero to Five Plan to enhance the quality of early care and education for our Nation's children. The budget

lays the groundwork for a reauthorization of the Child Care and Development Block Grant and entitlement funding for childcare, including a total of $6.6 billion for the Child Care and Development Fund, an increase of $800 million in the Child Care and Development Block Grant and $800 million in the Child Care Entitlement. These resources will enable 1.6 million children to receive child care assistance in fiscal year 2011, approximately 235,000 more than could be served in the absence of these additional funds.

The administration's principles for reform of the Child Care and Development Fund include establishing a high standard of quality across childcare settings, expanding professional development opportunities for the childcare workforce, and promoting coordination across the spectrum of early childhood education programs. The administration looks forward to working with Congress to begin crafting a reauthorization proposal that will make needed reforms to ensure that children receive high-quality care that meets the diverse needs of families and fosters healthy child development.

To enable families to better care for their aging relatives and support seniors trying to remain independent in their communities, the budget provides $102.5 million for a new Caregiver Initiative at the Administration on Aging. This funding includes $50 million for caregiver services, such as counseling, training, and respite care for the families of elderly individuals; $50 million for supportive services, such as transportation, homemaker assistance, adult daycare, and personal care assistance for elderly individuals and their families; and $2.5 million for respite care for family members of people of all ages with special needs. This funding will support 755,000 caregivers with 12 million hours of respite care and more than 186,000 caregivers with counseling, peer support groups, and training.

Funding for the Head Start program, run by the Administration for Children and Families (ACF), will increase by $989 million to sustain and build on the historic expansion made possible by the Recovery Act. In fiscal year 2011, Head Start will serve an estimated 971,000 children, an increase of approximately 66,500 children over fiscal year 2008. Early Head Start will serve approximately 116,000 infants and toddlers, nearly twice as many as were served in fiscal year 2008. The increase also includes $118 million to improve program quality, and the Administration plans to implement key provisions of the 2007 Head Start Act reauthorization related to grantee recompetition, program performance standards, and technical assistance that will improve the quality of services provided to Head Start children and families.

The budget proposes a new way to fund the Low Income Home Energy Assistance Program to help low-income households heat and cool their homes. The request provides $3.3 billion in discretionary funding. The proposed new trigger would provide, under current estimates, $2 billion in mandatory funding. Energy prices are volatile, making it difficult to match funding to the needs of low-income families, so under this proposal, mandatory funds will be automatically released in response to quarterly spikes in energy prices or annual changes in the number of people living in poverty.

Investing in Scientific Research and Development

The investments that HHS is proposing in our human services budget will expand economic opportunity, but another critical way to grow and transform our economy is through a healthy investment in research that will not only save lives but also create jobs.

The budget includes a program level of $32.2 billion for NIH, an increase of nearly $1 billion, to support innovative projects ranging from basic to clinical research, as well as including health services research. This effort will be guided by NIH's five areas of exceptional research opportunities: supporting genomics and other high-throughput technologies; translating basic science into new and better treatments; reinvigorating the biomedical research community; using science to enable healthcare reform; and focusing on global health. The administration's interest in the high-priority areas of cancer and autism fits well into these five NIH theme areas. In fiscal year 2011, NIH estimates it will support a total of 37,001 research project grants, including 9,052 new and competing awards.

Recovery Act

Since the Recovery Act was passed in February 2009, HHS has made great strides in improving access to health and social services, stimulating job creation, and investing in the future of healthcare reform through advances in health IT, prevention, and scientific research. HHS Recovery Act funds have had an immediate impact on the lives of individuals and communities across the country affected by the economic crisis and the loss of jobs.

As of September 30, 2009, the $31.5 billion in Federal payments to States helped maintain State Medicaid services to a growing number of beneficiaries and provided fiscal relief to States. NIH awarded $5 billion for biomedical research in more than 12,000 grants. Area agencies on aging provided more than 350,000 seniors with more than 6 million meals delivered at home and in community settings. Health Centers provided primary healthcare services to more than 1 million new patients.

These programs and activities will continue in fiscal year 2010, as more come on line. For example, 64,000 additional children and their families will participate in a Head Start or Early Head Start experience. HHS will be assisting States and communities to develop capacity, technical assistance and a trained workforce to support the rapid adoption of health IT by hospitals and clinicians. The CDC will support community efforts to reduce the incidence of obesity and tobacco use. New research grants will be awarded to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decisionmakers about what interventions are most effective for patients under specific circumstances.

The Recovery Act provides HHS programs an estimated $141 billion for fiscal years 2009–2019. While most provisions in HHS programs involve rapid investments, the Recovery Act also includes longer-term investments in health IT (primarily through Medicare and Medicaid). As a result, HHS plans to have outlays totaling $86 billion through fiscal year 2010.

Conclusion

This testimony reflects just some of the ways that HHS programs improve the everyday lives of Americans. Under this budget, we will provide greater security for working families as we continue to recover from the worst recession in our generation. We will invest in research on breakthrough solutions for healthcare that will save money, improve the quality of care, and energize our economy. And we will push forward our goal of making Government more open and accountable.

My Department cannot accomplish any of these goals alone. It will require all of us to work together. And I am eager to work 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 answering your questions.

Senator HARKIN. Thank you very much, Madam Secretary. And we'll start 5-minute rounds, whoever is keeping this clock going here. Who keeps the clock going? There we go.

WASTE, FRAUD, AND ABUSE

Madam Secretary again, I applaud you for your continued efforts in the waste, fraud, and abuse areas. We have figures that show how much money we save when we invest in that.

I think for every $1 we spend we save $6 and that's real money. And the largest portion, the Medicare Integrity Program, we get $14 for every $1 we spend. So from the standpoint of just economics it's important, but also to provide more integrity of the programs. So I applaud you for that.

H1N1 EMERGENCY SUPPLEMENTAL

Another thing I wanted to cover with you was the emergency supplemental funding we appropriated last year. We appropriated $7.65 billion to address the critical needs relating to the emerging H1N1 influenza virus. But in the 2011 budget request I've noticed you're using $555 million from this emergency supplemental for things that we usually fund in our annual appropriations bill. These are the annual costs for flu preparedness activities at CDC and in the Office of the Secretary.

I understand it also includes staff salaries. These costs can hardly be called an emergency. Can you just tell me how you justify these emergency supplemental fundings for these types of ongoing costs?

Secretary SEBELIUS. Mr. Chairman, it was our goal in seeking 2011 funding to be mindful of the budget situation and the President's desire not to increase discretionary funding for 3 years starting this year. And recognizing that, first of all the appropriations made by this subcommittee over time and certainly the supplemental funding helped us be very well prepared to face the pandemic that arrived here in April with a new vaccine, with a very robust outreach effort. But as you know when we requested supplemental funding it was still anticipated that we might need two doses per person. We were not at all certain how lethal the disease would be.

We were building a contingency plan based on the best possible preparedness activities. What we found ourselves, as the second wave of the flu has dramatically decreased, that we are still working with State and local efforts to have people vaccinated. But we have additional funding and we thought rather than seeking new funds from the subcommittee process that we'd be more appropriate to use for ongoing flu efforts. The efforts they're being used for are pandemic efforts that, as you know, are underway year in and year out whether we're in the midst of a pandemic or not.

So the CDC activities will continue on. Our work with State and local partners will continue on. The kind of staff support that you mentioned is part of the preparedness efforts that are underway year in and year out. But we just decided not to bank that money and then seek additional funds from the subcommittee, but use the funds that were available in an effort to be as prudent as possible.

EARLY CHILDHOOD PROGRAMS

Senator HARKIN. Very good. I appreciate that.

As a matter of fact, one other area that I've been a long-time supporter of is early childhood programs. On the education side I've talked a great deal with your counterpart, Secretary Duncan. As we both know many States have shown that children who receive high-quality, early childhood services are less likely to commit crimes, more likely to graduate from high school, more likely to hold a job and everything. But the key seems to be whether the services are indeed high quality.

The National Head Start Impact Study released last month shows that most of the gains that children show after participating in these programs tend to wear off after first grade. And this is troubling. So we have to make sure that the quality of early childhood programs is consistently high.

And could you just talk for a minute about how you plan to address the quality issue in the 2011 budget request?

Secretary SEBELIUS. Absolutely. Mr. Chairman, I share your concern that it's always a key issue for parents to have their children in safe childcare situations. But I think more importantly or as important is to make sure that they are actually developing the skills that they're ready to learn once they hit kindergarten. And too often that doesn't happen in many of the childcare settings.

So the study that you mention is a snapshot of some years ago of what the results were of Head Start programs. And I can assure you that there have been a number of investments in quality since

that snapshot was taken. But even more importantly this year we share the notion that we have to greatly enhance quality.

And too often there are somewhat erratic standards at the State level. Some States have set very high-quality standards. Others have not.

So we are actually applying some of the funding this year for the additional Head Start money to quality standards that would be developed and implemented across the country to make sure that whether you're in Arkansas or Rhode Island or Iowa or Mississippi in a Head Start program that you would anticipate the same high-quality standards and that that would be part of the funding going forward.

Senator HARKIN. Is that $118 million?

Secretary SEBELIUS. Yes, sir. I'm sorry. Yes, we didn't apply all of the funding to slots. We think quality enhancements nationwide are a critical part of this effort.

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

LET'S MOVE CAMPAIGN

Senator COCHRAN. Madam Secretary, thank you very much for being here to discuss the budget request before the subcommittee. We appreciate some of the highlights you outlined and of your intentions as Secretary to solve some of the problems that face many of us back in our States. And I noticed right away you're putting an emphasis on obesity and you have called attention to the fact that the First Lady came to Mississippi to talk about the Let's Move campaign, more activity, more healthy eating practices. And we surely need that in our State.

And so I was pleased to see that the emphasis is being placed by your Department and also at the White House on doing something about this really big problem. In Mississippi we win the prize. We're number one in childhood and adult obesity.

So we welcome these efforts. And we hope that we can work with the Department to put the money where the problem is and let you show us what can be done. And we need leadership. And we welcome that.

Do you have any specific things to tell us about what the elements of this program might be?

Secretary SEBELIUS. Well, Senator Cochran, in the Let's Move campaign the First Lady has really outlined four principal goals. And HHS will be involved in a number of them. More tools and information for parents to make good choices and that's everything from our Food and Drug Administration (FDA) looking at new, easier to read, easier to find food labeling to the CDC updating and clarifying nutrition standards.

So parents who want to shop smarter, buy healthier food will be able to find it on a grocery shelf and not have to read some dense barcode on the back of a package. Pediatricians have stepped up saying that they are in agreement that every child who gets a checkup should have a body mass index. But more than just having the body mass index on a regular basis, pediatricians need to have a conversation with the parents about what it means. And literally

write prescriptions for more exercise and/or healthier eating habits. Helping parents, again, to make some choices that matter.

A second pillar is focused on schools where kids spend a lot of their time. The Department of Agriculture is working to upgrade what's fed to children in school breakfast and school lunch programs. And make it healthier and more nutritious working again with the CDC on nutrition guidelines.

The physical education component of schools has kind of fallen off the radar screen in too many cases. And what we know from the Secretary of Education studies is that not only are children healthier, but they actually are better learners if they actually move around some during the course of the school day.

So reinstituting physical education will be part of school. Working with soft drink manufacturers on marketing sugary beverages inside schools and a lot of activity has been done so far in terms of voluntarily removing high-sugar content drinks from schools and substituting water and juices. So that's kind of component number two.

Number three is we've got 23 million Americans who live in so-called food deserts where they don't have access to fresh fruits and vegetables. So they may want to eat in a healthier manner, but they literally don't have any place within 2 miles of their home to go buy a piece of fruit or a fresh vegetable.

So again the Department of Agriculture is not only doing mapping of those so-called food deserts. But looking at initiatives with local farmers, local grocers, to try and establish a different protocol. We have some dollars available in our budget for helping to subsidize some of those healthier choices and figure out if it's a price strategy or an access strategy.

And the fourth component of Let's Move is let's see, I'm blanking on it for a moment. Parents and kids and—I'll get back to you on this and submit the information at a later date.

[The information follows:]

Physical Activity.—The fourth component of the Let's Move campaign is increasing physical activity. The administration will encourage children to be more physically active each day rather than spending more time watching TV and playing video games.

Senator COCHRAN. Health centers. One thing to do is to use the health centers as a place—

Secretary SEBELIUS. That—

Senator COCHRAN. For the children that go to Head Start programs there, the parents can come in and visit with healthcare professionals who are there at those centers.

Secretary SEBELIUS. Ok.

Senator COCHRAN. We found in our State that bringing all these programs together in one location certainly helps a lot, particular to the very young, those who haven't started elementary school. And you can't start too early.

Secretary SEBELIUS. Absolutely.

Senator COCHRAN. I think a lot of these habits are formed very early. And I'm sure you are aware of that. One area of our State, the Mississippi Delta, has had great success in developing a Delta Health Alliance.

And I hope that we can see funding directed to programs like that so that we can continue to see progress that can be made. Local medical centers using Mississippi Valley State University, Delta State University, University of Mississippi, and Mississippi State University, all have roles to play in our State in that effort. So thank you for getting off to such a good start in mapping out a plan of action.

Secretary SEBELIUS. Well and Senator, I look forward to learning the lessons that are already being enacted in Mississippi. I know your governor and the First Lady of Mississippi have taken a real interest and effort in this area. And I absolutely agree that community health centers can play an enormously important role.

Senator COCHRAN. Thank you.

Secretary SEBELIUS. Thank you.

Senator HARKIN. Senator Reed.

LOW INCOME HOME ASSISTANCE PROGRAM (LIHEAP)

Senator REED. Thank you, Mr. Chairman.

Madam Secretary, thank you very much.

The chairman already alluded to the issue of LIHEAP funding which is critical not only to my State but to practically every State in both the cold winter States and the very, very hot summer States. The chairman over the last few years, ensured that we've had very robust funding. This $2 billion reduction to the LIHEAP Block Grant will translate into a $13.6 million cut for Rhode Island, which is a sizable number for us.

And also it undercuts the certainty of planning in terms of what monies they might have. I know you're creating a mandatory stream of funding with a trigger that will kick in when prices rise or when economic conditions worsen, but all of that I think will be discounted because it will be so difficult to anticipate these conditions. And essentially States will be planning for and allocating and getting a waiting list on the basis of a lower block grant.

The other issue too, is that this trigger is going, I think, to be difficult to sort of estimate when it precisely kicks in. And also it's unclear to me what the formula for distribution is if the trigger kicks in. And by way of that, this January there was contingency money released to the States. Rhode Island actually got $4 million less than the previous year at a time when our employment sadly, is second or third in the Nation. So the subjectivity of distribution of this funding is going to, I think, contribute to significant concerns.

My question, I think, is can we do better?

One, in terms of the baseline number?

Two, how do you specifically propose to resolve the trigger and the distribution formula?

Secretary SEBELIUS. Well Senator, let me just start by saying I, first of all, not only appreciate the interest and leadership in the LIHEAP program in the past, but also recognize as a governor who distributed LIHEAP funds how essential it is to people who cannot pay their bills in the winter and some in the summer. So I know what a critical safety net that is.

In terms of the distribution methodology this year which I know again, was a subject of some concern, particularly in the Northeast.

We looked at two factors for the money that was distributed in January.

One was the cost of heating oil, which had come down to some degree over where we had been in the previous year, but in addition to that, the number of States who were actually experiencing unusually cold winters. And there were States that were far more scattered than some patterns we had seen in the past. And added to that the unemployment index as an indicator of States in real economic hardship.

And as you know 14 States were deemed to be, not by our count, but by the weather assessments, 5 percent colder during those winter months than had been experienced in the past. And we then distributed the money, some additional money to those 14 States as well as a formula grant to the others based on what we were seeing. There still is a pot of money for the LIHEAP funding this year that is still being held anticipating either further distributions this winter or in the summer months having some real spikes in temperature that require additional distributions.

In terms of the proposition for 2011 and the trigger proposal, there is a $3.3 billion discretionary fund, but then a $2 billion mandatory fund that would activate with a trigger, which would result actually in an increase in the overall LIHEAP funding for 2011, not a decrease in funding. And the combination trigger would be based on the analysis of the cost of energy plus an assessment of the poverty population in a State based on who is eligible for the Supplemental Nutrition Assistance Program. So it would be again, not our subjective look at it. But it would look at eligibility for the food and nutrition program combined with the heating oil prices for the winter.

We anticipate that if energy prices are high and people are having a struggle paying their bills the trigger would be met. And again, having the poverty sensitivity would help enhance that ability and the formula would be divided according to the population. So I know that there was some discussion last year on our budget about a formula that just looked at the price of winter fuel.

And we thought the addition of a recognition that this is an economic downturn and this is about people paying their bills. So, to look at who is in economic difficulty along with the price made a lot more sense and made the trigger a lot more sensitive.

Senator REED. Just two points because my time expired.

One is let us go over so the numbers because I have an indication that if you look at the formula money plus the trigger money it won't be as much as previous years. But that might be my miscalculation.

Secretary SEBELIUS. We would love to get the—yes. We'd love to get that.

Senator REED. The second point is even in the best of times when the economy is doing very well and the temperature is relatively mild, there are long, long waiting lists in my State and other States. So this notion of needing a trigger because, the demand only comes up during economic crises is not substantiated by the facts. But I thank the chairman for his indulgence.

Thank you, Madam Secretary.

Secretary SEBELIUS. Well then Senator I would volunteer that we would love to work with you on this.

Senator REED. Well, thank you.

Secretary SEBELIUS. First, getting you the numbers and making sure we're on the same page and then talking to you about—because I think we share the same goal that we don't want people struggling to pay their heating bills or having to turn off the heat when they can't pay them. So we want to work with you.

[The information follows:]

LIHEAP FUNDING

[In millions of dollars]

	Fiscal year 2010 appropriation	Fiscal year 2011 President's budget	Increase/ decrease
Discretionary	5,100	3,300	−1,800
Mandatory trigger [1]		2,000	+2,000
Total	5,100	5,300	+200

[1] For scoring purposes, $2 billion is assumed for fiscal year 2011.

Senator REED. Thank you, Madam Secretary. Thank you.

Senator HARKIN. Thank you very much. And I just personally want to thank you, Senator Reed, for your leadership in this area. You've been stalwart on that. And I look forward to making sure you get this all worked out for us.

Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman. Madam Secretary, welcome once again to the subcommittee. It's always good to see you. I believe the administration has made a commendable effort to reduce waste, fraud, and abuse in healthcare programs both in its budget request and in its healthcare reform proposal.

What support do you need from this subcommittee in the appropriations process as it moves forward to ensure that we're taking the necessary steps to end, as much as humanly possibly, waste, fraud, and abuse in our public health programs?

Secretary SEBELIUS. Well, Senator, I'm glad you asked that question.

First of all, let me just reiterate that I think the President takes this effort very, very seriously. It's one of the reasons he asked the Attorney General and me to, as Cabinet officers, convene a joint effort. And we are working very well with the Justice Department, and the strike forces now that are in seven cities are really paying off, big results.

So the budget has a couple of requests.

One is an additional $250 million in discretionary funding, which would allow us to expand the footprint of those strike forces. And as you heard Chairman Harkin say, we know that every dollar invested returns multiple dollars. And that's just dollars we get back in the door for prosecutions and can return to the fund and make the Medicare fund more solvent. I think there's an additional impact that is impossible to measure, which is that we discourage people from committing crimes in the first place by making it very clear that we intend to prosecute vigorously and come after them. So that's one piece of the puzzle.

Another big piece of the puzzle is a data system request that is in for the CMS budget, about $110 million to begin a multiyear process to upgrade our system. What we miss right now is the ability to look at data sets in one system. Medicare is the biggest health insurance program, I think, in the world. We pay out—we pay more than $1 billion in claims to providers over the course of the year; more than $500 billion worth of benefits every year.

We still have those data sets in multiple places. So it's impossible to check errant behavior unless you check six or seven systems. We have a plan that has been developed that by the end of 2011 we would be at a real time, one data set, flexible ability to share that data with law enforcement officers.

To do the same thing that frankly major credit card companies can do, which is watch what's happening.

Senator PRYOR. Right.

Secretary SEBELIUS. And immediately go after folks. And we need more boots on the ground.

Senator PRYOR. Yes. I think it's great that you say that. I'm glad to know that you're on top of that because when I was the State's attorney general we did the Medicaid fraud piece of enforcement.

Secretary SEBELIUS. Yes.

Senator PRYOR. And on all those cases, you know, we would do these extensive investigations and all this but it was always after the fact.

Secretary SEBELIUS. Pay and chase.

Senator PRYOR. Oftentimes it was 1 or 2 years later and some of these people you can never find again.

Secretary SEBELIUS. Right.

Senator PRYOR. Or they've been doing this for so long you're never going to get the money back from them or whatever the case may be. I support the idea of trying to get to a point where we can go to real time. You mentioned credit card companies. But also other health insurance companies do that where they're able to look at claims in real time.

I mean literally when someone is at the register they will get a prompt. I don't know how it works. But under what they're doing, the insurance company will be able to say, "No, we need to check on this right now."

So it's out there. We can do this. We can do this a lot smarter. And I think we can save tens of billions of dollars every year by doing that.

GEOGRAPHIC VARIANCE IN MEDICARE REIMBURSEMENT

We have a concern in Arkansas on what we call geographic variance in Medicare reimbursement. You know that issue very well. And I'm sure in your home State you may have some of this as well.

But if healthcare reform is enacted and I know that's not a certainty as we speak. But if it is, will you work to ensure that any geographic variations in reimbursement are fairly calculated and do not discriminate against rural America?

Secretary SEBELIUS. Well, Senator, as you said, I'm very familiar with the difficulty often of providing quality health services in more rural areas. And the cost estimations have to be calculated

about what it requires to do that. So I would love to work with you and other members. As you know, Senator, I like to refer to your State as "Our Kansas."

So I think we are sister States and we——

Senator PRYOR. We have—and that's exactly right.

Secretary SEBELIUS. But yes, I would very much like to work with you on that issue.

Senator PRYOR. Great.

PANDEMIC PREPAREDNESS

The last question I have for this round is I know we've been through the H1N1 flu pandemic and I'm sure different people would agree or disagree about how well that was managed by the Federal Government. But what does the administration's budget doing to put us in an even better position this coming flu season and the years to come to handle either H1N1 or some other pandemic?

Secretary SEBELIUS. Well, Senator, the ongoing efforts of pandemic planning continue. And the budget, I think, through the CDC, through our hospital preparedness grants, through our partnership efforts with State and local governments continues to ramp that up. I don't think there's any question of that—and this subcommittee was really instrumental in helping those years of preparation so that this year when something hit we were really far more prepared than we would have been if we were facing it for the first time.

We are in the process and I look forward, Mr. Chairman, to coming back to this subcommittee and others in an entire systemwide review. Not just H1N1, but really our whole countermeasures effort. We think it's appropriate to use this most recent situation as a way to say how prepared are we for whatever comes at us next, whether it's a pandemic that we get some warning for and know something about and know what kind of vaccine or a dirty bomb on a subway.

What did we learn?

Where are the gaps in the system?

Where are the efforts that we need to move forward?

We know we need more manufacturing capacity for vaccine. That was very clear.

We know we need different technology for vaccine production. You know, the time table of growing virus in eggs is slow. And that needs to ramp up.

But we need to look at the whole system. And that's underway. And we anticipate when you return from the break in a couple of weeks we will have an ability to report back on a whole range of lessons learned from H1N1.

Senator PRYOR. Great. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Pryor.

VACCINE PRODUCTION AND DISTRIBUTION INFRASTRUCTURE

Just to follow up, if the pandemic did not happen, I am concerned that we then start to think, "Welll, that was just a scare anyway. It really wasn't going to happen."

Now we fall into lethargic mode by thinking that we can delay implementation of preventative measures. You put your finger on it. We have to build the structures.

Secretary SEBELIUS. You bet.

Senator HARKIN. That can respond more rapidly, cell-based systems so we can grow the viruses or RNA-based systems that, can even be more rapidly utilized. But as I understand it we only put one new one online. Is that right?

Secretary SEBELIUS. We cut the ribbon in a plant in North Carolina just this year.

Senator HARKIN. Yes, that's right.

Secretary SEBELIUS. And there is planning underway for the second plant.

Senator HARKIN. And that's going to be on track, on time? We have the funds for that?

Secretary SEBELIUS. I think you have the funds for one additional plant the way the funding looks now instead of I think it was anticipated 5 or 6 years ago that the funds were being set aside for four plants.

Senator HARKIN. Well.

Secretary SEBELIUS. And the cost of the North Carolina plant turns out that it exceeded what was estimated to be a number of years ago.

Senator HARKIN. Well, Madam Secretary, again, one of the problems for having these kinds of plants is the question, what do they do every year? I mean, if you don't have something that's confronting you, how do they keep viable? That's been the big problem with vaccine production.

That's why I suggested, modestly, a year or two ago that perhaps what we ought to do on the Federal level is provide a free flu shot to every person in the country every year. Oh, I forget what the cost came in on that. And there was a cost to it.

But then you balance it against how many people get sick just from annual flu, and are hospitalized, and the people that die from the flu—and you add that cost. Then we could see if you can really do great outreach programs with a free flu shot.

First of all you keep these plants going because they have to meet the demand every year and if we have a pandemic that has a different strain, they can shift to that immediately.

Second, you build up the infrastructure. If you do have a pandemic that is hitting us, one of the big problems is just getting it out through shopping centers and churches and schools and wherever, drug stores and every other place. And if you do that on an annual basis then you build up a really good infrastructure that's ongoing. And I think you also will build up more of a public support for these vaccinations.

A lot of people don't get flu shots because, well, why? I don't know. They don't think they work or they've heard they shouldn't get them. They're afraid of getting them, that type of thing. And there are a lot of people in this country who are allergic to eggs who cannot get these shots because of the egg-based production.

Secretary SEBELIUS. Right.

Senator HARKIN. I haven't revisited that for some time, but again thinking about having a couple of plants that are cell based. How

do we keep them energized? How do we keep—and we can't just leave them set there waiting for the next pandemic to come.

So I would be interested in discussing that with you later on.

Secretary SEBELIUS. Well I think that would be very helpful.

Dr. Nikki Lurie, who is the Assistant Secretary for Preparedness and Response, has been charged with this whole countermeasures review. And certainly one of the issues is how we prepare for things we don't even know are coming. What sort of stockpile do we need against anthrax or unknown viruses that may head our way? What's the market for that? So we would love to continue that conversation with you.

I think one of the lessons learned is the kind of distribution system that you just mentioned. This year, as you know, the H1N1 virus had a much younger target population. So we were trying to encourage vaccination of people who typically do not get a seasonal flu shot. They're too young or they typically don't get the flu.

We've had an estimated 72 to 81 million people vaccinated, using an estimated 81 to 91 million doses, and people are still being vaccinated. And we used a lot of nontraditional sources, school-based clinics which hadn't been used for years and turned out to be very successful with kids. A lot of outreach with faith based groups. We went from a 40,000 site distribution system for the children's vaccines to 150,000 sites for H1N1 vaccine

And so we have a more robust distribution system, a more robust outreach system than has been in place, I would suggest, in a very long time in America. And that's, I think, very good news for whatever comes at us next.

Senator HARKIN. Well, I think we have to keep that——

Secretary SEBELIUS. Right.

Senator HARKIN. Activated, some way.

Secretary SEBELIUS. Yes.

Senator HARKIN. And that is what I'm concerned about. We've done that. But now it's faded out. And we may not do it next year. Then a couple years go by. And we may have to really gen it up again. That's why I focus on the annual flu.

Secretary SEBELIUS. Well with 36,000 people a year dying from flu and 200,000 hospitalized—that's our annual flu data—and that's pretty serious.

COMMUNITIES PUTTING PREVENTION TO WORK

Senator HARKIN. That's pretty serious. And it costs a lot of money.

But I did have one more question. And not to make too far a leap from vaccinations to prevention, but this subcommittee put $1 billion in the stimulus bill for prevention activities at HHS.

As you mentioned in your statement the cornerstone of that is a $373 million grant system to communities which I assume will be awarded sometime soon. I don't know when you might inform me of that. I understand that States and communities that are awarded this ARRA funding will be asked to implement their choice of a list of evidence based programs that your Department determined are the most likely to be effective.

I asked my staff. I have not seen that list. If you have that could you share that with us? And where did you go to come up with this list of evidence-based programs that could be effective?

Secretary SEBELIUS. Ah, Mr. Chairman, first of all, we'd be glad to share those data with you.

[The information follows:]

MAPPS INTERVENTIONS

Attached is the list of evidence-based MAPPS interventions (Media, Access, Point of decision information, Price and, Social support services) from which States and communities awarded ARRA funding for the "Communities Putting Prevention to Work" initiative will choose to implement. This list can be found at http://www.cdc.gov/chronicdisease/recovery/PDF/MAPPS__Intervention__Table.pdf

MAPPS INTERVENTIONS FOR COMMUNITIES PUTTING PREVENTION TO WORK

Five evidence-based MAPPS strategies, when combined, can have a profound influence on improving health behaviors by changing community environments: Media, Access, Point of decision information, Price, and Social support/services. The evidence-based interventions below are drawn from the peer-reviewed literature as well as expert syntheses from the community guide and other peer-reviewed sources, cited below. Communities and states have found these interventions to be successful in practice. Awardees are expected to use this list of evidence-based strategies to design a comprehensive and robust set of strategies to produce the desired outcomes for the initiative.

	Tobacco	Nutrition	Physical activity
Media	Media and advertising restrictions consistent with Federal law [11]. Hard hitting counteradvertising [12 13 14 15]. Ban brand-name sponsorship [15] .. Ban branded promotional items and prizes [16].	Media and advertising restrictions consistent with Federal law [53 54 55 56 57 58 59]. Promote healthy food/drink choices [57 58 60]. Counteradvertising for unhealthy choices [61].	Promote increased physical activity [98 99 103 106 126 127] Promote use of public transit [98 99 103 106 126 127] Promote active transportation (bicycling and walking for commuting and leisure activities) [98 99 103 106 126 127] Counteradvertising for screen time [98 99 103 106 126 127]

	Tobacco	Nutrition	Physical activity
Access	Usage bans (i.e., 100 percent smoke-free policies or 100 percent tobacco-free policies) [6 7 102]. Usage bans (i.e., 100 percent smoke-free policies or 100 percent tobacco-free school campuses [5 6 7 8 9 10]. Zoning restrictions [5 6 7] ..... Restrict sales (e.g., Internet, sales to minors, stores/events without tobacco, etc.) [5 6 7]. Ban self-service displays and vending [5 6 7].	Healthy food/drink availability (e.g., incentives to food retailers to locate/offer healthier choices in underserved areas, healthier choices in child care, schools, worksites) [24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 78 79 80 81 82 83 91 92 93 94 95 96 97]. Limit unhealthy food/drink availability (whole milk, sugar sweetened beverages, high-fat snacks) [34 39 40 41 42 84 85 86 87 88]. Reduce density of fast food establishments [32 43]. Eliminate transfat through purchasing actions, labeling initiatives, restaurant standards [44 45 46]. Reduce sodium through purchasing actions, labeling initiatives, restaurant standards [47 48 49]. Procurement policies and practices [25 26 30 31 50 51]. Farm to institution, including schools, worksites, hospitals, and other community institutions [50 51 52].	Safe, attractive accessible places for activity (i.e., access to outdoor recreation facilities, enhance bicycling and walking infrastructure, place schools within residential areas, increase access to and coverage area of public transportation, mixed-use development, reduce community design that lends to increased injuries) [136 137 138] City planning, zoning, and transportation (e.g., planning to include the provision of sidewalks, parks, mixed-use development, reduce community design that lends to increased injuries) [99 100 101 102 105 106] Require daily quality physical education in schools [113 114 115 116 117 118 119 120] Require daily physical activity in afterschool/child care settings Restrict screen time (afterschool, daycare) [107 108 109 110 111]
Point of purchase/promotion.	Restrict point of purchase advertising as allowable under Federal law [17]. Product placement [17]	Signage for healthy vs. less healthy items [25 26 62 63 89 90]. Product placement and attractiveness [25 26 62 63 89 90]. Menu labeling [65 66 67 68]	Signage for neighborhood destinations in walkable/mixed-use areas (library, park, shops, etc.) [99 100 101 106 140] Signage for public transportation, bike lanes/boulevards [99 100 101 106 140]
Price	Use evidence-based pricing strategies to discourage tobacco use [1 2 3]. Ban free samples and price discounts [4].	Changing relative prices of healthy vs. unhealthy items (e.g., through bulk purchase/procurement/competitive pricing) [22 23 24 25 26 75 76 77].	Reduced price for park/facility use [133 134 135] Incentives for active transit [134 135] Subsidized memberships to recreational facilities [99 100 110 111]
Social support and services.	Quitline and other cessation services [18 19 20].	Support breastfeeding through policy change and maternity care [69 70 71 72 73 74].	Safe routes to school [104 112 128 129 130 131 132] Workplace, faith, park, neighborhood activity groups (e.g., walking, hiking, biking, etc.) [99 100 105 106]

[1] Centers for Disease Control and Prevention. Reducing tobacco use: a report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2000
[2] Institute of Medicine. Ending the tobacco problem: a blueprint for the nation. Washington, DC: The National Academies Press; 2007.
[3] Task Force on Community Preventive Services. Guide to community preventive services: tobacco use prevention and control. *Am J Prev. Med.*, 2001;20(2 Suppl 1):1–87.
[4] Loomis BR, Farrelly MC, Mann NH. The Association of retail promotions for cigarettes with the Master Settlement Agreement, tobacco control programmes and cigarette excise taxes. Tob. Control 2006; 15;458–63.
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Secretary SEBELIUS. And the community grants I think are about to go out the door in the next, I think somewhere in the next 2-week period of time the awards will be made. And the focus looking at not only the—we had a multidiscipline team, scientists from NIH, the surveillance folks from and public health folks from CDC, our Office of Public Health and Science, all looking at not only what the most serious cost drivers were for underlying disease conditions, but also what were effective strategies that had been measured and looked at.

And the two focus areas for the community grants were determined to be smoking cessation efforts and efforts aimed at obesity as the two drivers for a large number of the chronic conditions that

cause healthcare spending to rise and cause quality of life to go down. So the so-called list looked at measures that had existed across States and communities that were effective strategies, had been measured, had been proven effective. And we would be delighted to share those with you.

But the community grants were available to either look at smoking cessation and/or obesity or both, one or the other or both. But those were the two kinds of targets. As opposed to spreading them out across the horizon that the focus on those two areas.

And then the hope is, as you know, with the ARRA funding is to have kind of measurable results. So at the end of 2 years the goal is to have some strategies which really do either encourage young people from not smoking in the first place, decrease smoking dramatically and/or make a real dent in obesity. And then be able to come back and hopefully work with members of Congress to take some of those programs to scale.

If we can find effective ways, effective strategies to deal with those two underlying conditions, we can dramatically change health outcomes and dramatically lower health costs.

Senator HARKIN. Very good. Thank you, Madam Secretary.

Senator COCHRAN. Mr. Chairman.

I think the Secretary has done a great job in presenting the budget request and answering our questions. It's a pleasure working with you in helping make sure that what we decide to appropriate is in the national interest and serves the public interest.

Senator HARKIN. Thank you.

WASTE, FRAUD, AND ABUSE

I just had one other thing that I would bring up and that is this waste, fraud and abuse that, you mentioned. I have a partial list in front of me. I have an entire list that adds up to literally billions of dollars of fines and settlements paid by pharmaceutical companies.

Secretary SEBELIUS. You bet.

Senator HARKIN. That have been ripping off Medicare and Medicaid.

Secretary SEBELIUS. Yes, sir.

Senator HARKIN. So a lot of times we think about Medicare fraud and abuse, waste, you know you think well, there's somebody out there, some person out there that's putting in for something that they shouldn't get. Well, what about Pfizer? Pfizer just paid $2.3 billion, the largest——

Secretary SEBELIUS. The largest——

Senator HARKIN [continuing]. Settlement in United States history.

Secretary SEBELIUS. Yes.

Senator HARKIN. Now attorneys know that when you settle, you settle because you're afraid of what may happen if you actually go to court. That's why you settle. They settled $2.3 billion, $668 million to Medicare, $331 million to Medicaid. That was just this year.

Four other pharmaceutical companies, Mylan Pharmaceuticals, AstraZeneca, UDL and Ortho-McNeil, just paid $124 million to Medicaid this year. And Ethex was fined $23.4 million. Now all of

these were done by the Attorney General's Office. And that's just this year.

I can go back 6, 7, 8 years. Attorneys General in the Bush administration and others that went after these companies and got all these fines and settlements, hundreds of millions of big, big dollars. Well, that's good. I applaud the Attorneys General for doing that, both the present Attorney General and his predecessors.

But what can we put in place so they don't do that in the first place? And I hope that your Department will look at that. How was it that these pharmaceutical companies got by with this? And some of them got by with it—this didn't just happen over a couple of months. I mean they've been doing it for years.

Then all of a sudden someone catches them. The Department of Justice asks for them. That takes a long time, couple years. And then they finally build a case. They get the evidence. And then they either get fined or they get settled.

So I hope and this is just—I don't know if you want to respond to this or not, but I would really be looking forward to working with you on how you can build systems up that just don't allow these kinds of big bucks to be taken out of the system over long periods of time.

Secretary SEBELIUS. Well, I couldn't agree with you more, Mr. Chairman. I think that in the case of the Pfizer settlement, it was a situation where they were improperly marketing and prescribing a drug specifically in violation of the authority that they had been given by the FDA. And it not only was a case of, you know, driving profits for their company, but also putting patients in jeopardy. I don't think there's any question that patients were being inappropriately prescribed a drug that they knew was not going to work for the situation that they had.

So it's kind of a double concern. It not only involved dollars, but it involved patient safety. And I can guarantee that the new FDA leadership takes that very seriously, and has enhanced the efforts to make sure that off market products are not allowed and that we follow up much more vigorously. But also I think, again, having a settlement like this puts a number of manufacturers on notice that we are taking this very seriously. And intend to make sure that they are appropriately using the authority that they've been given.

Senator HARKIN. Is there a good working relationship between you and FDA on issues like this?

Secretary SEBELIUS. Oh, absolutely, absolutely. And the drug safety and the drug protocol is something I think they take very seriously. And we're very involved in this effort as is our Inspector General. I mean, this was again, a collaborative effort.

You're right. It took a number of years. The good news is that money went right back in to both the Medicare Trust Fund and the Medicaid funds for States. States got a share of those returns. And I think it helps make those more solvent for the future.

Senator HARKIN. Madam Secretary, thank you very much. That's very reassuring.

Senator COCHRAN. Thank you, Mr. Chairman. I join you in thanking the Secretary for your cooperation with our subcommittee. We look forward to working with you as we go through this fiscal year. Thank you very much.

Secretary SEBELIUS. Thank you, Senator.

ADDITIONAL COMMITTEE QUESTIONS

Senator HARKIN. Thank you, Senator Cochran.

Thank you, Madam Secretary.

If there is nothing else that you would like us to consider——

Secretary SEBELIUS. Mr. Chairman, we look forward to working with you. Thank you very much.

[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

PROJECT BIOSHIELD

Question. Madam Secretary, I would like to commend your the Department of Health and Human Services (HHS) for including in its most recent broad agency announcement for medical countermeasure development a clear articulation of the Department's scenario-based medical countermeasure requirements for anthrax and smallpox. For several years, industry has been concerned regarding the lack of clearly articulated evidence-based requirements. This public articulation of the requirements is very welcome; however, it raises important concerns about the resources that remain in the Project BioShield Special Reserve Fund (SRF). Are the remaining SRF funds sufficient to procure technologically appropriate countermeasures for the identified requirements?

Answer. The Assistant Secretary for Preparedness and Response (ASPR) has plans for the $2.4 billion remaining in the SRF, including anticipated procurements of countermeasures for the threat areas of anthrax, botulism, smallpox, and acute radiation syndrome illnesses. Under Biomedical Advanced Development Authority (BARDA) advanced research and development program there are numerous medical countermeasures under development. Some of these programs may mature enough before the end of fiscal year 2013 to become eligible for late-stage development and procurement under Project BioShield. These medical countermeasures address threat areas such as anthrax, smallpox, botulism, acute radiation syndrome, and chemical agent nerve analysis.

Question. How does HHS anticipate balancing the needs to continue funding advanced development activities with the need to continue stockpiling products to meet these stated requirements?

Answer. In early December, I directed my Department to conduct a full review of the public health emergency medical countermeasure enterprise, which is the program that ultimately translates the ideas from the research bench into approved products that the United States can depend upon in the event of naturally occurring emerging diseases, pandemic diseases, or threats from chemical, biological, radiological, and nuclear (CBRN) agents. The MCM enterprise review is examining how policies affect every step of the medical countermeasure development, manufacturing, and stockpiling process, finding ways to improve and implement necessary changes. The goals of the review are to enhance the medical countermeasure development and production process, increase the number of promising discoveries going into advanced development, and provide more robust and rapid product manufacturing. HHS senior leadership with those of other Departments like the Department of Defense (DOD) meets regularly to discuss the medical countermeasure portfolios for CBRN and flu programs across the Federal Government and HHS toward understanding and achieving strategic goals and meeting product requirements.

Question. Does HHS have a long-term strategy for how it plans to replenish the SRF or otherwise devote funding to the procurement of countermeasures for these identified requirements?

Answer. HHS has initiated a long-term strategy for development and procurement of CBRN medical countermeasures that coordinates with DOD quadrennial strategy and planning for medical countermeasures. This strategy will be informed by the findings and recommendations of the medical countermeasure review that is nearing completion. Initiatives resulting from the medical countermeasure review will inform the budget process and assist in the balancing of resources for medical countermeasures with those of other high-priority initiatives at HHS.

MEDICAL COUNTERMEASURES

Question. Last summer, in the face of the H1N1 pandemic, HHS moved with remarkable speed to approve new influenza vaccines and approve emergency-use authorization for medical products critical to protecting Americans. The entire Department responded to this threat as if it were a matter of national security. While the process was not without its problems in general it was fast, efficient and remarkably transparent. I am concerned that this same sense of urgency is not being applied to medical countermeasures being developed to prevent or mitigate the threats that have been identified as critical national security priorities but have not yet materialized. The intentional release of CBRN agents or the detonation of a nuclear device will come with little or no warning, we as a Nation must have already developed and stockpiled safe and effective countermeasures if we are to respond to these types of threats. What measures has HHS taken to ensure the efficient and timely review of medical countermeasures for CBRN threats?

Answer. In early December, I directed my Department to conduct a full review of the medical countermeasure process from the research bench into approved products that the United States can depend upon in the event of naturally occurring emerging diseases, pandemic diseases, or threats from CBRN agents. This review was initiated, based in part by observations of our national response capability at that time for the 2009 H1N1 influenza pandemic, and by procurement actions to develop an approved next-generation anthrax vaccine under the BioShield authorities. The executive leaders within HHS, including those from the ASPR, Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the National Institute of Allergy and Infectious Diseases, have worked diligently toward completing a comprehensive review of the medical countermeasure enterprise, which will be provided to me soon.

Question. Does BARDA or the NIH provide funding resources to the FDA to help offset the cost associated with pre-biologics license application (pre-BLA) or pre-new drug application (pre-NDA) regulatory activities? Could additional funds improve the ability of FDA to providing timely review and responses to companies that are under contract with the Federal Government to develop products that the national security apparatus of the U.S. Government has identified as critical unmet needs?

Answer. BARDA and the National Institutes of Health (NIH) do not provide funding to FDA to help offset the cost associated with pre-BLA or pre-NDA regulatory activities. Currently, the administration is conducting a comprehensive review of the Public Health Emergency Medical Countermeasure Enterprise, including medical countermeasure development priorities and resources, which includes FDA's resources to robustly engage with partners throughout a product's developmental lifecycle. FDA places a top priority on regulatory inquiries and submissions from sponsors and U.S. Government partners that are engaged in developing products that have been identified as meeting a critical need.

Question. How extensively has the leadership of the FDA and the staff responsible for reviewing medical countermeasures been briefed on the national security threat assessments for CBRN agents? How many FDA employees that are involved in the review of medical countermeasures being developed under contract with BARDA and NIH have the appropriate security clearances necessary to allow them to receive classified briefings?

Answer. FDA leadership has been briefed and is very aware of the national security threat assessments for CBRN agents. FDA leadership is briefed by the HHS Office of Security and Strategic Information, and FDA has an employee assigned to that Office. In addition, FDA's Office of Criminal Investigations, within the Office of Regulatory Affairs, works with the intelligence community to obtain information and briefs FDA's leadership as needed. Across FDA's three Centers that review medical countermeasure products, 106 employees that have been or in the future may be involved in medical countermeasure-related reviews have received special clearances to review classified documents related to product review submissions.

EARLY CHILDHOOD EDUCATION

Question. Madam Secretary, you and Secretary Duncan have been working very closely in the area of early childhood education. How do you see the collaboration continuing? What lessons has HHS learned about approaches to supporting at-risk children and their families that can be carried over into K–3 education?

Answer. Because quality early childhood education spans the ages of birth to age 8 and involves the transition of children from early childhood programs into our Nation's schools, continued collaboration between the two Departments is essential. Secretary Duncan and I have been working very closely, and we have a number of joint efforts currently underway. We have formed working groups consisting of the

best minds in both Departments to address the most pressing issues in the early childhood field, including creating a more educated, better-trained early childhood workforce; better connecting the early education and health systems; and improving the way data are collected and used to improve early childhood systems at the State level; and coordinating Federal research and evaluation efforts in the area of early childhood. The two Departments are currently co-hosting listening sessions across the country to hear from the foremost experts and early childhood practitioners concerning these issues. The Departments consult regularly on the early childhood initiatives underway in each Department and will continue to collaborate on future initiatives and legislation that are vital to the development and education of our Nation's youngest children.

Historically, HHS's approach to supporting the early education of at-risk children has been to foster growth in all developmental domains. In addition to emphasizing early education domains, such as literacy and early math, a strong focus on health, nutrition, and social-emotional development, for example, is essential in efforts to prepare children for school. This is a vital lesson that can be carried over into K–3 education. Children who miss school for health-related reasons or cannot attend to what is being taught cannot be successful in school. In addition, HHS has been very successful in promoting family involvement and support as two essential elements of high-quality early education for at-risk families. Parents whose children attend the Head Start program, for example, not only receive services and parenting support as part of their child's participation in the program, but also are active partners in the child's education, weighing in on the curriculum selection and staffing decisions. The support that families receive, and the sense of empowerment they feel, play a role in positively affecting children's school readiness outcomes.

Question. How many States have applied for State Advisory Council funding to date and how do you plan to encourage States to implement that requirement of the Head Start Act?

Answer. We have received six applications for State Advisory Council funding. One of these six States has received its funding and a second State is about to receive its funding.

We have been in communication with all 50 States, the 5 territories, and the District of Columbia and all but a few have indicated that they are actively working on completing their application. Several intend to submit their applications in May, but the majority of States have indicated target submission dates in June and July—knowing they have until August 1, 2010 to submit.

We are mailing a communication to the Governors during the week of May 3 asking them to indicate their intent to apply and the target date for submittal of their application. We hope to get all responses by the end of May and have asked Governor's to fax back their responses by May 25 allowing us sufficient time to request States to submit an addendum to their initial application if they are interested in an additional supplemental award subject to the availability of funds.

Question. I understand that HHS is in the process of writing regulations to implement the 2007 amendments to the Head Start Act. Where is HHS in this process? When do you expect the new performance standards to be released for comment?

Answer. HHS is in the process of revising the performance standards to ensure that they reflect the most recent evidence on the components of a high-quality early childhood program. During the revision process, the Office of Head Start conducted listening sessions with each of the 12 regions, including American Indian/Alaska Native and Migrant and Seasonal Head Start, as well as a parent focus group and a national stakeholder group in order to incorporate input from grantees. HHS expects to publish a Notice of Proposed Rulemaking (NPRM) for public comment before the end of the year.

HHS also is drafting a regulation that establishes a designation renewal system to determine if a Head Start agency is delivering a high-quality and comprehensive Head Start program. HHS expects to publish an NPRM by this fall.

BREAST CANCER SCREENING

Question. Secretary Sebelius, the President's budget would cut $4 million from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). If I'm doing the figures correctly, that funding level would result in 7,000 fewer cancer screenings next year. Is that true? How do you expect to transition this program as new legislation is enacted to extend insurance and preventive screenings in particular?

Answer. The fiscal year 2011 President's budget requests $211 million for the NBCCEDP, which is $4 million below fiscal year 2010. This reduction is part of a CDC-wide effort to achieve efficiencies in travel and contracting and to maintain the

program's impact with the goal of funding the same the number of cancer screenings. Thus, the proposed travel and contract reductions will not have any programmatic impact on the NBCCEDP activities. Regarding the provisions in the Affordable Care Act that extends coverage for recommended cancer screening services, CDC is actively exploring innovative ways to increase and improve cancer screenings. These approaches include using policy and systems change strategies; improving case management and care coordination, tailoring outreach to underserved communities; improving quality assurance of screening services; enhancing surveillance to monitor screening use and quality; and increasing education and awareness for the public and providers. CDC is also working to identify what the remaining uninsured population may be beyond 2014 and looking to define potential roles that State and local health departments could play in quality assurance and delivery of preventive services.

BLOOD DISORDERS

Question. The President's budget proposes consolidating a number of programs in the CDC. In particular, I'm concerned about the plan for funding around blood disorders? Can you give me some details on CDC's plans for the blood disorders programs in fiscal year 2011? What activities will be supported and at what funding level?

Answer. The fiscal year 2011 President's budget requests $20 million for a program that realigns CDC's Blood Disorders Program to address the public health challenges associated with blood disorders and related secondary conditions. Rather than fund a disease-specific program for specific categories of blood disorders, the new program uses a comprehensive and coordinated agenda to prioritize population-based programs targeting the most prevalent blood disorders. This public health approach will impact as many as 4 million people suffering with a blood disorder in the United States versus approximately 20,000 under the current programmatic model. This approach builds upon the successful collaboration CDC has with the national network of hemophilia treatment centers as well as the thrombosis and thalassemia centers. In fiscal year 2011, CDC plans to focus on the following three areas of greatest burden and unmet need: deep vein thrombosis and pulmonary embolism, hemoglobinopathies (such as sickle cell disease and thalassemia), and bleeding disorders. By using this broader approach, CDC anticipates increased program efficiencies by merging and re-designing data collection systems from those that focus on single disorders to a single system that collects data needed for monitoring health outcomes for multiple disease and disorders.

TOBACCO LAB

Question. Madam Secretary, as you know, last year the Family Smoking Prevention and Tobacco Control Act became law. That bill gave authority to the HHS to regulate tobacco for the first time, however, that bill would not have been possible without the detailed information gathered by the smoking lab at the CDC. I understand the FDA is working on developing their own laboratory to test tobacco products. What functions do you foresee FDA taking over and what functions will CDC retain? How are the CDC and the FDA coordinating the transition?

Answer. FDA is responsible for the regulation of tobacco products and the administration of the Family Smoking Prevention and Tobacco Control Act, among other statutes. FDA executes its regulatory and public health responsibilities in four areas: protecting the public health, scientific standard-setting and product review, compliance and regulation, and public education and outreach. Comparatively, CDC performs research and surveillance to further the scientific understanding of how chemical composition and product design influence the health consequences of tobacco products, to provide a scientific basis for evaluating risk, and to aid public health officials in evaluating the effectiveness of tobacco control measures. As we move forward, CDC will continue to perform these functions. As FDA implements this historic piece of legislation, CDC and FDA are coordinating efforts, which include developing new methods for evaluating the constituents and ingredients in tobacco products; evaluating the impact of regulatory actions; and testing tobacco products and constituents.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

COMMUNITY HEALTH CENTERS (CHC)

Question. Senator Burdick and I were instrumental in the establishment of the National Institute for Nursing Research (NINR) and for 25 years the Institute has

been dedicated to improving the health and healthcare of Americans through the funding of nursing research and research training. Since it was established, the Institute has focused on promoting and improving the health of individuals, families, communities, and populations. How does the (National Institutes of Health) NIH plan to further expand this critical arm of research?

Answer. The fiscal year 2011 budget request includes $150.2 million, and increase of $4.6 million above the fiscal year 2010 appropriation, for the National Institute of Nursing Research (NINR). NINR continues to support and advance innovative research studies in self-management, symptom management, caregiving; health promotion and disease prevention; research capacity development; technology integration; and end-of-life research. NINR has begun to develop their next strategic plan which is scheduled for release early in fiscal year 2012. Stakeholder input, a priority setting process, and public health concerns will shape the direction of NINR.

Question. At my request, the University of Hawaii at Hilo established the College of Pharmacy. The College of Pharmacy's inaugural class of 90 students began in August 2007, will graduate in 2011, and will hopefully stay in Hawaii to meet the growing demand for pharmacists. Historically, Hawaii's youth interested in becoming pharmacists would travel to the mainland for school, and not return. It is my vision that the people of Hawaii will have educational opportunities in the health professions that will in turn increase access to care to residents in rural and underserved communities. Has there been any discussion on establishing schools of allied health in remote communities to meet the growing needs for healthcare and improve access to care in rural America?

Answer. HRSA programs work to increase access to healthcare in rural America through the training of allied health professionals. For example, the Area Health Education Centers (AHEC) Program encourages the establishment and maintenance of community-based training programs in off-campus rural and underserved areas in an overall effort to attract students into health careers with an emphasis on careers in the delivery of primary care to underserved populations. The program works to train culturally competent health professionals who will return to their home communities and provide healthcare to the underserved. In fiscal year 2008, the AHEC Program provided education and training to approximately 4,000 allied health students in community-based rural training sites.

Question. America faces a shortage of nurse faculty, further complicating the problems of the nursing shortage. According to a study conducted by the American Association of Colleges of Nursing in 2008, schools of nursing turned away 49,948 qualified applicants to baccalaureate and graduate nursing programs. The top reason cited for not accepting these potential students was a lack of qualified nurse faculty. This element of the shortage has created a negative chain reaction—without more nurse faculty, additional nurses cannot be educated; and without more nurses, the shortage will continue. What efforts has the Department of Health and Human Services (HHS) made to address the shortage of qualified nurse faculty?

Answer. HRSA's principal tools for addressing the nurse faculty shortage are the Nurse Faculty Loan Program (NFLP) and the Advanced Education Nursing (AEN) Program. The NFLP makes grants to schools that provide low-interest loans to nurse faculty students and then cancel a portion of the loans when the individual completes a service commitment. The AEN program provides grants to nursing schools to develop and operate advanced practice nursing training programs, as well as to provide traineeship support to students. During the latest reporting period covering academic year 2008–2009, fiscal year 2008, 133 schools participated in the NFLP facilitating the graduation of 223 students qualified to fill nurse faculty positions. During the same period, 194 NFLP graduates reported employment as nurse faculty. In fiscal year 2009, 149 schools participated with an estimated 1,100 students receiving loans to support their education to become faculty. Grantees report that the NFLP has facilitated the graduation of 764 students qualified to fill nurse faculty positions.

The NFLP also received funding under the American Recovery and Reinvestment Act (ARRA). In fiscal year 2009, these funds were used to provide additional support to 65 (included in the 149) schools of nursing to support an estimated 500 additional students for a total of 1,600 students receiving funding from regular appropriations and ARRA. In fiscal year 2010, the remaining ARRA funds will be used to make an estimated 700 additional loans.

In fiscal year 2009, 160 AEN Program grants were awarded to schools of nursing. Twenty-one of the projects focused specifically on innovative teaching and learning content to prepare nurse educators. We estimate that 160 grants will be awarded in fiscal year 2010.

Question. Using Hawaii as an example, what happens when a State is unable to pay health plans contracted to provide access to care for Medicaid beneficiaries? In

this particular case, the Governor has apparently refused to release funds necessary to draw down Federal matching funds designated for the State's Medicaid Program. Does the department have any remedies in place to mandate that the States make funds available to ensure access to care for Medicaid beneficiaries?

Answer. Our goal is to address payment issues before they impact Medicaid beneficiaries' access to care. In any case where Centers for Medicare & Medicaid Services (CMS) hears a State is contemplating a payment delay, our regional office staff work with the States to understand the impact of any delays on plans and beneficiaries and, where appropriate, to identify alternative approaches. We are aware that Hawaii is planning to delay its contractual payments to Medicaid managed care organizations (MCOs) in order to postpone payments to the next State fiscal year. The CMS is working aggressively with the State to share our concerns and ensure that the delayed payments to the MCOs do not result in the MCOs' inability to pay their network providers or otherwise impact beneficiary access.

Question. With your increased focus on prevention, it seems as though a natural partnership would be with the community health centers whose focus is on public health and prevention. Has the department explored any collaborative partnership ideas with the Centers for Disease Control and Prevention (CDC) and the CHCs?

Answer. HRSA convened a 3-day meeting with CDC in November of 2009 to explore opportunities for continued collaboration. HRSA has been working closely with CDC on the HHS Healthy Weight Initiative as well as the Tobacco Prevention and Control Initiative. Additionally, HRSA is partnering with CDC on improving HIV screening and testing within health centers.

Question. In regards to partnerships, rural areas in States like Hawaii and Alaska may have community health centers and/or an Indian Health Service (in Alaska) or Tribal Health facility. What, if any, type of collaboration has taken place in ensuring rural residents receive healthcare closest to home?

Answer. HHS works with each health center organization to identify the need for primary care services for the underserved and vulnerable populations in their respective service areas. HHS encourages health centers to identify additional existing primary care providers in the area, and to collaborate with them so that the target populations receive appropriate levels of care for their needs. Nationally, there are 7 jointly funded CHC and Urban Indian Health Clinics. In addition, 19 tribal entities currently receive section 330 health center funding to provide care within their communities.

Question. On November 21, 1989, section 218 of Public Law 101–166 stated that the NIH building No. 36 is hereby named the Lowell P. Weicker Building and on May 30, 1991, the NIH dedicated building 36 to Governor Weicker. During NIH campus renovations, the Weicker building was destroyed to make room for a Neuroscience Research Center. Has the NIH given any consideration to preserving the honorable recognition of Governor Lowell P. Weicker?

Answer. NIH is currently reviewing the status of existing facilities on our campus, including the naming of buildings. However, naming another building for Senator Weicker, or any individual, requires congressional action.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

WORKFORCE/SUSTAINABLE GROWTH RATE (SGR)

Question. I was glad to hear you talk about the need to support and strengthen our healthcare workforce. I know how important it is to ensure that our workforce needs are met. As we work to ensure quality, affordable healthcare coverage for all Americans, we must make sure there are enough qualified professionals to provide that care. This is why I led the charge to write a strong workforce title in the HELP healthcare reform bill. I was also glad to hear in your testimony particular focus on ensuring that America's senior population gets the care and treatment it needs. And one of the greatest barriers to that is the unfair and inequitable way that Medicare reimburses doctors and providers using the deeply flawed SGR formula. I have heard from so many doctors across my home State of Washington who have had to re-evaluate their ability to treat Medicare patients. Some have decided to turn away new Medicare patients, while others have been forced to drop them all together. We need to do something about this. The President's budget includes $371 billion over 10 years to address physician payments. The budget seems to assume that Congress will pass a serious of short-term patches rather than a single permanent fix, and it reflects zero growth in the fee schedule. But short-term solutions aren't enough. Without a more equitable and accurate system of reimbursement, doctors will continue to worry about being paid for doing their job, and seniors will find it harder

and harder to access the care they need. This is especially true in areas like my home State of Washington where doctors and hospitals are penalized for treating patients efficiently and well. So my questions are: What is the administration's policy on a long-term fix to the SGR?

Answer. The administration supports comprehensive, but fiscally responsible reforms to the physician payment formula. We also believe that Medicare and the country need to move toward a system in which doctors face incentives for providing high-quality care rather than simply "more" care—a principle reflected in the Affordable Care Act's (ACA) payment and delivery reforms.

I look forward to working with you and your colleagues in Congress to reform Medicare's payment methodology for physicians' services to address these concerns in a sustainable and responsible manner.

Question. Why was a long-term solution for this problem not addressed in the President's fiscal year 2011 budget?

Answer. The President's fiscal year 2011 budget request reflected the likely cost of providing zero percent annual payment updates for physicians—an honest budgeting approach to reflect the expected cost of truly addressing this policy. To that end, the fiscal year 2011 budget includes an adjustment totaling $371 billion over 10 years (fiscal year 2011–fiscal year 2020) to reflect the administration's best estimate of future congressional action, based on Congress' repeated interventions on scheduled physician payment reductions in recent years. However, this adjustment does not signal a specific administration policy. Rather, the administration intends to continue to work with Congress to jointly develop a long-term solution to the physician reimbursement formula.

TITLE X

Question. I was pleased to hear you mention in your testimony the investment the President's budget makes in science-based teen-pregnancy prevention initiatives. Another proven program that helps prevent unintended pregnancies is the title X program, which is the only Federal program exclusively dedicated to family planning and reproductive-health services. Publicly funded family-planning services have helped reduce the rates of unintended pregnancy and abortion in the United States, and in fact, the Centers for Disease Control and Prevention (CDC) has included family planning on its list of the top 10 most valuable public-health achievements of the 20th century. I was pleased to see that the President's budget again calls for an increase in title X funding. Do you agree that, in order to reduce the need for abortion, we must invest in valuable family planning services?

Answer. Yes, publicly funded family planning services provided under the title X program play an important role in preventing teen and unintended pregnancy. During 2008, family planning services were provided through title X-funded clinics to more than 5 million individuals, 24 percent of whom were under the age of 20. It is estimated that the contraceptive services provided through the title X family planning program helped to prevent almost 1 million unintended pregnancies during 2008.

TEEN-PREGNANCY PREVENTION INITIATIVES

Question. Last year's fiscal year 2010 omnibus eliminated funding for rigid abstinence-only-until-marriage programs, which by law were required to have nonmarital abstinence promotion as their "exclusive purpose" and were prohibited from discussing the benefits of contraception. In sharp contrast, the new approach—championed by this subcommittee—will focus on programs that have demonstrated their effectiveness, and all funded programs will be required to be age appropriate and medically accurate. The next step is for administration officials to draft the more detailed rules and regulations to determine which specific programs get funded. When is the Office of Adolescent Health (OAH) expected to release its request for proposals and how will it determine which programs are eligible for funding under this new initiative? How do you anticipate distributing the funds?

Answer. OAH has released three Funding Opportunity Announcements (FOA). The "Tier 1" FOA for replicating programs that have proven effective through rigorous evaluation was released on April 2, 2010. Applicants may apply in 1 of 4 funding ranges:

—*Range A.*—$400,000 to $600,000 per year
—*Range B.*—$600,000 to $1,000,000 per year
—*Range C.*—$1,000,000 to $1,500,000 per year
—*Range D.*—$1,500,000 to $4,000,000 per year

The "Tier 2" FOA for innovative approaches to teen pregnancy prevention was released on April 9, 2010, in conjunction with the Administration for Children and

Families (ACF) Personal Responsibility Education Program funds reserved for innovative youth pregnancy prevention strategies. Applicants may apply in 1 of 2 funding ranges:

—*Range A.*—$400,000 to $600,000 per year

—*Range B.*—$600,000 to $1,000,000 per year

A third FOA, which will also use Tier 2 funds in collaboration with CDC, provides funds for demonstrating the effectiveness of multi-component, community-wide approaches to teenage pregnancy prevention; was released on May 4, 2010. Applicants may apply in 1 of 2 funding ranges:

—*Range A.*—$750,000 to $1,500,000 per year

—*Range B.*—$300,000 to $700,000 per year

All three FOA's will be subject to a competitive peer-review process.

Under a contract with the Department of Health and Human Services (HHS), Mathematical Policy Research (MPR) conducted an independent, systematic review of the evidence base. This review defined the criteria for the quality of an evaluation study and the strength of evidence for a particular intervention. Based on these criteria, HHS has defined a set of rigorous standards an evaluation must meet for a program to be considered effective and therefore eligible for funding under this announcement.

Applicants were requested to review the list of evidence-based curriculum and youth development programs which HHS identified as having met these standards. A summary listing of these interventions was published in appendix A of the FOA. Program models listed in appendix A are eligible for replication under this funding announcement. Applicants that wish to replicate a program that is not on the list in Appendix A, may apply to do so, but a set of stringent criteria, described below, must be met.

More detailed information about the review process and the programs eligible for replication is available at: http://www.hhs.gov/ophs/oah.

If an applicant wants to apply to replicate a program model that is not on the list in appendix A, all of the following criteria must be met to qualify for funding under this FOA:

—The research or evaluation of the program model that the applicant seeks to replicate was not previously reviewed.

—There is research on or evaluations of the program model that meet the screening and evidence criteria used for the review of the other program models.

—The application must include all relevant research and evaluation information.

—The application must be submitted by May 17, 2010 to provide for the time that will be needed to review the evidence submitted.

Tier 1 final award decisions will be made by the Director of the OAH. Tier 2 final award decisions will be made collaboratively by the Director of OAH and the Commissioner of ACYF. In making decisions, the Director and the Commissioner will take into account the score and rank order given by the Objective Review Committee, and other considerations as follows:

The availability of funds.

—Representation of evidence-based teenage pregnancy prevention programs across communities, including varied types of interventions and evidence-based strategies.

—Geographic distribution nationwide.

—Inclusion of communities of varying sizes, including rural, suburban, and urban communities.

—Feasibility of evaluation plan (for applications in Tier 1 Ranges C and D and Tier 2).

—Inclusion of a range of populations disproportionately affected by teenage pregnancy.

Question. In determining which programs or group of programs are (or are not) effective, both the quality of a study and the magnitude of a program's impact are crucial. A large body of evidence shows that more comprehensive approaches—those that encourage abstinence, but also contraceptive use for young people who are having sex—can be effective. But rigid, moralistic, abstinence-only-until-marriage programs of the type promoted under previous Federal policy have been found in study after study not to be effective. How will the administration define a program as effective or promising?

Answer. Under a contract with HHS, MPR conducted an independent systematic review of the evidence base for programs to prevent teen pregnancy. This review defined the criteria for the quality of an evaluation study and the strength of evidence for a particular intervention. Based on these criteria, HHS has defined a set of rigorous standards an evaluation must meet in order for a program to be considered effective and therefore eligible for funding as an evidence-based program under Tier

1 of the new teenage pregnancy prevention program. The MPR review had four steps:

—*Find Potentially Relevant Studies*.—Studies were identified by a review of reference lists from earlier research syntheses, a public call for studies to solicit new and unpublished research, a search of relevant research and policy organizations' Web sites, and keyword searches of electronic databases. Nearly 1,000 potentially relevant studies were identified.

—*Screen Studies To Review*.—To be eligible for review, a study had to examine the effects of an intervention using quantitative data and statistical analysis. It had to estimate program impacts on a relevant outcome-sexual activity (for example, delayed sexual initiation), contraceptive use, sexually transmitted infections (STIs), pregnancy, or births. The study had to focus on United States youth ages 19 or younger and have been conducted or published since 1989. A total of 199 studies met these screening criteria.

—*Assess Quality of Studies*.—Impact studies that met the screening criteria were reviewed by trained MPR staff and assigned a rating of high, moderate, or low based on the rigorous and thorough execution of their research designs. The high rating was reserved for random assignment studies with low attrition of sample members and no sample reassignment. The moderate rating was given to quasi-experimental designs with well-matched comparison groups at baseline, and to certain random assignment studies that did not meet all the criteria for the high rating.

—*Assess Evidence of Effectiveness*.—A framework was developed for grouping programs into different evidence categories, based on the impact findings of studies meeting the criteria for a high or moderate rating. HHS then defined which of these categories would be eligible for funding. To qualify for funding, a program had to be supported by at least one high- or moderate-rated impact study showing a positive, statistically significant impact on at least one priority outcome (sexual activity, contraceptive use, STIs, pregnancy, or births), for either the full study sample or key subgroup (defined by gender or baseline sexual experience).

In total, 28 programs met the funding criteria, reflecting a range of program models and target populations. Of those programs, 20 had evidence of impacts on sexual activity (for example, sexual initiation, number of partners, or frequency of sexual activity), 9 on contraceptive use, 4 on STIs, and 5 on pregnancy or births.

Question. As the President's principal advisor on health-related matters, how do you plan to work with the President to promote responsible sex education for young people?

Answer. I have made reducing teen and unintended pregnancies one of my areas for key interagency collaborations at HHS. I have identified the several strategies to reduce teen and unintended pregnancy that are comprehensive in nature, cross organizational boundaries, and focus on the evidence of what works both in the public health and social services arenas.

In addressing these strategies, HHS will draw upon the expertise of the public health and human services parts of HHS, including the ACF, the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the CDC, the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), the newly created OAH and the Office of Population Affairs (OPA) within the Office of Public Health and Science. Key among the strategies are:

—*Invest in Evidence-based Teen Pregnancy Reduction Strategies and Continue To Develop the Evidence-based Practice*.—HHS will employ a comprehensive, evidence-based approach to reducing teen pregnancy. Under the newly funded Teen Pregnancy Prevention Program, HHS will fund the replication of models that have been rigorously evaluated and shown to be effective at reducing teen pregnancy or other behavioral risk factors as well as research and demonstration projects designed to test innovative strategies to prevent teen pregnancy. By conducting high-quality evaluations of both types of approaches—those replicating evidence-based models and innovative strategies—this initiative will expand the evidence base and uncover new ways to address this issue. Additional funding made available under the ACA will provide formula grants to States to fund evidence based models and test new strategies as well. ACF, ASPE, CDC, OAH, and OPA will each play a critical role in these efforts.

—*Target Populations at Highest Risk for Teen Pregnancy*.—HHS efforts will focus on demographic groups that have the highest teen pregnancy rates, including Hispanic, African-American, and American Indian youth, and target services to high-risk, vulnerable and culturally under-represented youth populations, including youth in foster care, runaway and homeless youth, youth with HIV/AIDS, youth living in areas with high teen birth rates, delinquent youth, and youth who are disconnected from usual service delivery systems.

SEXUALLY TRANSMITTED DISEASES (STDS) PREVENTION IN TEENS

Question. Unintended teen pregnancy is not the only negative sexual health outcome facing America's young people. One young person every hour is infected with HIV and young people ages 15–25 contract about one-half of the 19 million STDs annually, even though they make up only one-quarter of the sexually active population. By focusing the funding only on teen pregnancy prevention, and not including the equally important health issues of STDs and HIV, it seems that an opportunity has been missed to provide true, comprehensive sex education that promotes healthy behaviors and relationships for all young people, including lesbian, gay, bisexual, and transgender youth. So many negative health outcomes are inter-related and educators on the ground know that they best serve young people when they address the inter-related health needs of young people. What is the administration's position on making this a comprehensive prevention initiative that addresses the inter-related health needs of adolescents, including unintended pregnancy, STD, and HIV prevention?

Answer. As the review of the evidence revealed, 28 programs met the funding criteria, reflecting a range of program models and target populations. And these results also support the inter-relatedness of health needs of adolescents. Of those 28 programs, 20 had evidence of impacts on sexual activity (for example, sexual initiation, number of partners, or frequency of sexual activity), 9 on contraceptive use, 4 on STIs, and 5 on pregnancy or births.

Addressing the health needs of adolescents is very important to me. Specifically, I have made reducing teen and unintended pregnancy and supporting the National HIV/AIDS strategy two of my key areas for interagency collaborations at HHS. (As well as a strategic initiative to prevent and reduce tobacco use that includes national campaigns to prevent and reduce youth tobacco use.) I have identified the following set of strategies to reduce teen and unintended pregnancy.

In addressing these strategies, HHS will draw upon the expertise of the public health and human services parts of the Department, including the ACF, ASPE, CDC, HRSA, NIH, the newly created OAH, and OPA within the Office of Public Health and Science.

—*Invest in Evidence-based Teen Pregnancy Reduction Strategies and Continue To Develop the Evidence-based Practice*.—HHS will employ a comprehensive, evidence-based approach to reducing teen pregnancy. Under the newly funded Teen Pregnancy Prevention Program, HHS will fund the replication of models that have been rigorously evaluated and shown to be effective at reducing teen pregnancy or other behavioral risk factors as well as research and demonstration projects designed to test innovative strategies to prevent teen pregnancy. By conducting high-quality evaluations of both types of approaches—those replicating evidence-based models and innovative strategies—this initiative will expand the evidence base and uncover new ways to address this issue. Additional funding made available under the ACA will provide formula grants to States to fund evidence based models and test new strategies as well. ACF, ASPE, CDC, OAH, and OPA will each play a critical role in these efforts.

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—*Increase Access to Clinical Services*—HHS will ensure access to a broad range of family planning and related preventive health services, including patient education and counseling; STI and HIV prevention education, testing, and referral. Services can be provided through community health centers, title X family planning clinics, and public programs. HHS-funded health services under the title X family planning program will encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on ways to resist attempts to coerce them into engaging in sexual activity.

ANTIMICROBIAL RESISTANCE

Question. The World Health Organization (WHO) has identified antimicrobial resistance as one of the three greatest threats to human health. Two recent reports demonstrate that there are few candidate drugs in the pipeline to treat infections due to highly drug-resistant bacteria. One of these reports, for example, found only 15 antibacterial drugs in the development pipeline, with only 5 having progressed to clinical trials to confirm clinical efficacy (phase III or later). Are there any plans

to create a seamless approach to the research and development of new antibacterial drugs, particularly those designed to combat gram-negative infections, to ease the transition across the spectrum of enterprise from basic research to product development and procurement? What other actions can NIH/National Institute of Allergy and Infectious Diseases (NIAID) take to ensure that these needed new antibacterial drugs become available as soon as possible?

Answer. The NIAID conducts and supports basic research to identify new antimicrobial targets and translational research to apply this information to the development of therapeutics; to advance the development of new and improved diagnostic tools for infections; and to create safe and effective vaccines to control infectious diseases and thereby limit the need for antimicrobial drugs.

NIAID provides a broad array of pre-clinical and clinical research resources and services to researchers in academia and industry designed to facilitate the movement of a product from bench to bedside. By providing these critical services to the research community, NIAID can help to bridge gaps in the product development pipeline and lower the financial risks incurred by industry to develop novel antimicrobials. NIAID is attuned to the need for antimicrobials for Gram-negative bacteria and is working with several biotechnology companies and pharmaceutical companies to develop novel agents. NIAID also is conducting studies to inform the rational use of existing antimicrobial drugs or alternative therapies to help limit the development of antimicrobial resistance.

In addition, development of broad spectrum antibiotics is a key program in the portfolio of medical countermeasures that HHS' Biomedical Advanced Development Authority (BARDA) uses to address the medical consequences of biothreats like anthrax, plague, tularemia, or enhanced bacterial threats that are antibiotic resistance. BARDA's efforts focus on development of these products toward licensure and stockpiling after NIAID and industry have shown proof of principle for the antibiotic candidates. BARDA supports industry in the advanced development of new antibiotics through cost-reimbursement contracts. BARDA continues to look for new and improved ways to support development of new antibiotics to treat newly emerging bacterial pathogens with antibiotic resistance.

VACCINE-PREVENTABLE DEATHS

Question. We have been extremely successful in reducing the number of vaccine-preventable deaths in children. Unfortunately, we still have around 45,000 such deaths each year in adults. Millions of American adults go without routine and recommended vaccinations because our medical system is not set up to ensure adults receive regular preventive healthcare, which costs us about $10 billion annually in direct healthcare costs. What plans does CDC have for programs to increase the numbers of adults who receive vaccinations each year?

Answer. One area of focus of CDC's adult immunization efforts is to increase influenza vaccination rates among healthcare workers. CDC is collaborating with the Centers for Medicare and Medicaid Services to explore public reporting of influenza vaccination rates among this high risk population as a quality performance measure for healthcare institutions. CDC is also working with State immunization programs to maintain the number of providers and partnerships that were developed out of the H1N1 response, including obstetricians and gynecologists, internists, pharmacists, and school-located vaccination clinics.

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

FOSTERING CONNECTIONS TO SUCCESS AND INCREASING ADOPTIONS ACT

Question. Last year, Congress passed the Fostering Connections to Success and Increasing Adoptions Act with the intention of reforming the foster care and child welfare system. Many States have reported difficulties in implementing the provisions outlined in the bill and are looking for additional guidance from the Department of Health and Human Services (HHS). What is HHS doing to help States implement these reforms? How can we continue to provide reforms to transform the child welfare system so that it is efficient and promotes permanent placement of children in families rather than long-term foster or institutional care?

Answer. HHS is committed to ensuring the safety, permanency, and well-being of children, particularly those who are at risk of entering or are already in the child welfare system. To that end, we are working hard to implement the many reforms made through the Fostering Connections to Success and Increasing Adoptions Act.

We have issued a number of policy guidance documents and program instructions on Fostering Connections and continue to address additional questions from States

and tribes. For example, we have issued detailed guidance on how a State or tribe can take up the option of the new Title IV–E Guardianship Assistance Program and submit claims for Federal reimbursement.

HHS is also focused specifically on implementing a number of initiatives to achieve permanency in a timely manner for children so that they do not end up in long-term foster or institutional care. For example, the President's new fiscal year 2010 long-term foster care initiative is a $20 million, 5-year demonstration grant program engaging States, localities, tribes, and private organizations in implementing innovative intervention strategies aimed at reducing the number of children who stay in foster care for extended periods of time. In addition to funding services, the initiative awards grantees bonus funding for demonstrating improvement in the outcomes for children who have been in foster care for an extended period of time or who are at risk of remaining in foster care for long periods. We will conduct a rigorous national cross-site evaluation of the demonstration to determine whether this approach is successful and can be replicated. HHS also continues to work in collaboration with States to engage in program improvement efforts that reduce barriers to permanency as identified through the Child and Family Service Reviews. Further, HHS is actively engaged in raising the profile of the needs of children in need of permanency through our support for the AdoptUsKids initiative. This initiative focuses on the adoption of older youth and other children who remain in foster care for the longest periods. As of March 2010, more than 12,000 foster children previously featured on the initiative's Web site found permanent, adoptive homes.

Finally, we are providing assistance to States and tribes on Fostering Connections and permanency initiatives through a comprehensive network of training and technical assistance partners. This network includes National Resource Centers and regional Implementation Centers that focus on in-depth and long-term consultation and support to States and tribes to execute strategies to achieve sustainable, systemic change for greater safety, permanency, and well-being for families.

We look forward to working with the subcommittee on additional reforms that may achieve permanency for our Nation's most vulnerable children.

MENTAL HEALTH SERVICES

Question. Providing mental health services in the wake of a disaster and during the recovery is critical to the community, however, the system seems to be fragmented. How can we coordinate the work so that children especially can get the support that they need?

Answer. Emergency Support Function (ESF) #8 of the National Response Framework, the Federal Government's guiding principles for a unified national response to disasters and emergencies, lays out the principles for providing public health and medical services during disasters and emergencies. These services explicitly include mental and behavioral health. The Office of the Assistant Secretary for Preparedness and Response (ASPR) in its coordination role for ESF #8 actively works with ESF #8 partners to identify and address mental health needs, including those of children that are appropriate for Federal assistance. During a response, the Emergency Management Group (EMG) utilizes behavioral health subject matter experts within the ASPR Division of At-risk, Behavioral Health, and Community Resilience to provide guidance, assist with triage of State requests for assistance, and support coordination efforts as needed between the EMG, HHS Operating Divisions like the Substance Abuse and Mental Health Services Administration (SAMHSA), ESF #8 partners like the American Red Cross, and affected States' Disaster Behavioral Health Coordinators.

Additionally, in order to provide the needed mental health services and supports following a disaster and into the recovery period, the Federal Emergency Management Administration (FEMA) and SAMHSA coordinate to support State and local mental health networks through financial support, training, and technical assistance.

FEMA funds several grants targeted to areas with Presidentially declared disasters for which SAMHSA—through its Emergency Mental Health Management and Traumatic Stress Services Branch at the Center for Mental Health Services—provides technical assistance, program guidance, and oversight. Among these funding opportunities are Crisis Counseling Assistance and Training Program (CCP) grants to increase local mental health staff and provide outreach and education for States which have identified a gap in mental health resources following a disaster. CCP Immediate Services Program grants to State mental health authorities to provide up to 60 days of funding for services immediately following the declaration of a disaster, and CCP Regular Services Program grants can provide an additional 9

months of support following a disaster. Supplementary funding is also available for special circumstances.

In ongoing efforts, SAMHSA collaborates with FEMA to provide training—including annual trainings—to State mental health staff to develop crisis counseling training and preparedness plans and to encourage State-to-State information exchange. SAMHSA also maintains the Disaster Technical Assistance Center and the Disaster Behavioral Health Information Series to provide toolkits and a readily available source of information—including information specifically focused on children and adolescent mental health—to assist States, territories, and local entities in delivering effective mental healthcare during disasters.

Additionally, the National Commission on Children and Disasters (NCDD) was established to carryout a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from disasters. Through its interim report released last October, NCDD identified gaps and shortcomings in the provision of mental health services to children in disasters and made recommendations that will be used to inform legislative and executive branch policies and programs.

In order to address the concerns of NCDD, HHS' ASPR has established a monthly meeting with the Commissioners to discuss HHS's progress. Additionally, this month, the ASPR and the Assistant Secretary for Children and Families will begin convening an HHS Working Group on Children and Disasters to facilitate communication and collaboration across the Department to improve the coordination of services for children—including mental and behavior health services—before, during, and after disasters and emergencies.

COMMUNITY HEALTH CENTERS

Question. The primary care community health centers created to fill the need after Hurricane Katrina have proved to be an extremely successful model to keep the uninsured and under-insured out of the emergency room. How can we provide ongoing support for successful programs like this?

Answer. The fiscal year 2011 President's budget request includes an increase of $290 million for the Health Center program to continue the American Recovery and Reinvestment Act investment in 127 Health Center New Access Points as well as the services initiated under the Increased Demand for Services grants to health centers nationwide. This funding level will also support the development of approximately 25 new access points, increasing access to comprehensive primary healthcare services to an estimated 150,000 additional health center patients. Additionally, this level will support an estimated 125 service expansion grants to expand the integration of behavioral health into existing primary healthcare systems, enhancing the availability and quality of addiction care at existing health centers.

HEALTHCARE REFORM

Question. What is your perspective on healthcare reform, its impact on State budgets, and the cost of healthcare for those who currently have insurance?

Answer. Health insurance reform ensures a strong Federal-State partnership and does not strain State budgets. Specifically, health insurance reform: provides new, additional funding to States to support coverage expansions; strengthens States' roles in insurance oversight, delivery system reform, and prevention; reduces Medicaid and Medicare costs; reduces State uncompensated care; ends the "hidden tax" to finance care for the uninsured; eliminates the need for most State-funded coverage programs; creates jobs, spurs the local economy and generates tax revenues; and invests in community health centers.

In terms of healthcare costs for families: In its analysis, the nonpartisan Congressional Budget Office confirmed that lower administrative costs, increased competition, and better pooling for risk will mean lower average premiums for American families:

—Americans buying comparable health plans to what they have today in the individual market would see premiums fall by 14 to 20 percent.

—Most Americans buying coverage on their own would qualify for tax credits that would reduce their premiums by an average of nearly 60 percent—even as they get better coverage than what they have today.

—Those who get coverage through their employer today will likely see a decrease in premiums as well.

—And Americans who currently struggle to find coverage today would see lower premiums because more people will be covered.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

MEDICAID COVERAGE

Question. An article in the New York Times on March 15, 2010, entitled, "As Medicaid Payments Shrink, Patients Are Abandoned," highlighted what I have been hearing from Illinois providers for some time now. In this difficult economy, States are squeezing payments to providers in Medicaid at the same time the economy is fueling continuous growth in enrollment. As a result, patients are finding it increasingly difficult to locate doctors and dentists who will accept their Medicaid coverage. Many of the providers in Illinois tell us they cannot afford to take Medicaid patients. As a result, many delay care or forego it altogether, or end up going to hospital emergency rooms. Can you speak to the importance of provider payments in Medicaid, the impact on patient care, and any consideration the Department of Health and Human Services (HHS) has given to providing additional incentives to States to increase their payment rates?

Answer. The administration recognizes the importance of adequate Medicaid provider payment rates and is pleased that the Health Care and Education Reconciliation Act of 2010 increases Medicaid payments to primary care physicians for calendars years 2013 and 2014. As a former Governor, I understand the tough choices States have to make when facing a difficult economy. However, I also recognize that Medicaid provider payment rates can affect access to care, and therefore is an area ripe for examination. I expect the newly formed Medicaid and CHIP Payment Advisory Commission will provide helpful guidance to enable us to undertake more robust consideration of Medicaid rates so that we can ensure all Medicaid beneficiaries have access to the healthcare providers they need.

CRITICAL ACCESS HOSPITALS (CAH)

Question. CAHs are, by definition, critically important to rural communities throughout Illinois. Within CAHs, there is a heavy reliance on anesthesia services provided by certified registered nurse anesthetists (CRNA). CRNAs are the sole anesthesia providers in the vast majority of rural hospitals. Without CRNA services, many U.S. rural and CAHs would not be able to offer care. Recent rulings by the Centers for Medicare and Medicaid Services (CMS) have denied rural hospitals' claims for tens of thousands of dollars each in annual Medicare funding that they had come to rely upon to serve their communities. In addition, due to recent reclassifications of certain CAHs from rural to urban and as being located in a "Lugar" county, CMS has denied "pass-through" payment to these facilities for CRNA services. Can you advise the subcommittee on the potential for revisiting the CMS policy of denying reimbursement for on-call costs of CRNA services in the Rural Pass-through Program and the policy of denying payments to CAHs that have recently been reclassified as urban and in Lugar counties?

Answer. With respect to on-call costs of CRNA services in CAHs, section 1834(g)(5) of the Social Security Act (SSA) states that in determining the reasonable costs of outpatient CAH services, the Secretary recognizes as allowable costs amounts for "physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved." The statute is explicit in allowing Medicare payment for on-call costs only of these designated practitioners and only for emergency services in CAHs. Accordingly, CMS does not have the authority to pay for on-call costs of CRNA services.

With respect to pass-through payments for CRNAs, in the fiscal year 2011 hospital inpatient prospective payment system (IPPS) proposed rule published on May 4, we are proposing to permit urban hospitals that have been classified as rural under section 1886(d)(8)(E) of the SSA to be paid on the basis of reasonable costs for anesthesia services and related care furnished by a qualified nonphysician anesthetist. We are not proposing to change our policy that would permit Lugar hospitals to be paid reasonable costs for such services. As stated in the proposed rule, Lugar facilities are considered urban under section 1886(d) of the SSA, and therefore, we do not believe it would be consistent with the statute to permit these facilities, which are not considered rural, to be paid on the basis of reasonable costs for CRNA services.

HEALTH PROFESSIONS PROGRAMS

Question. The University of Illinois at Chicago (UIC) is the largest medical school in the United States, and it houses the largest component of minority students in the country, including the largest single training center for Latino medical students and third largest for African-American students. In fact, 70 percent of the minority

physicians in Chicago and 60 percent of those in the State were trained at UIC. I commend the administration's investment in the Minority Centers of Excellence program and the Health Career Opportunity Program, increasing funding for these two programs for the first time in years. What other plans does HHS have to ensure a diverse healthcare workforce and for a robust health professions pipeline programs at Health Resources and Services Administration (HRSA) in fiscal year 2011?

Answer. The administration prioritizes increasing the diversity of the health professions workforce and views it as a key strategy for increasing access to healthcare and reducing health disparities. In fact, HHS invested $50 million of the $200 million in American Recovery and Reinvestment Act (ARRA) funds designated for workforce programs in programs that specifically focus on increasing the diversity of the workforce. More than 50 percent of students in HRSA's Bureau of Health Professions-funded training programs are from minority and/or disadvantaged backgrounds. This year HRSA engaged its stakeholders to discuss strategies for increasing the diversity of the health professions workforce and for measuring the effectiveness of these strategies. In fiscal year 2011, HRSA will continue to implement program improvements that can result in a more diverse workforce.

Question. I have noted that health professionals graduating from the minority health professions schools have a propensity to practice in medically underserved areas, many times community health centers. However, the existing Graduate Medical Education Program does little, if anything, to promote the practice of residents in underserved areas or in settings outside of the traditional hospital. What can we do to highlight this relationship and strengthen the pipeline from the minority health institutions to the community health centers with financial resources already allocated?

Answer. With a looming shortage of primary care professionals and increased attention on preventive medicine, we acknowledge the value of training more residents in nonhospital sites and it is our intent to make sure Medicare medical education rules encourage and facilitate this kind of activity.

Medicare permits hospitals to receive indirect medical education and other medical education payments for those residents training in nonhospital sites if the hospital incurs "all or substantially all the costs" of the training at those sites. The Affordable Care Act (ACA) clarifies this standard by requiring hospitals to pay stipends and benefits for trainees in nontraditional settings. The ACA also provides other avenues to encourage training in nonhospital settings, including financial support for teaching health centers, increased funding for primary care, and a 5-year, $230 million program to support the expansion of primary care residency programs in community-based teaching health centers.

Question. The workforce shortages in State and local health departments have been well-documented. The President's budget for fiscal year 2011 includes a new proposal for a Health Prevention Corps (HPC). Can you elaborate about how this proposal will help address workforce shortages in State and local health departments, and how the Centers for Disease Control and Prevention (CDC) plans to recruit a diverse work force into this field?

Answer. The fiscal year 2011 President's budget requests $10 million for the HPC, which will recruit, train, and place participants in State and local health departments to fill positions in disciplines with documented workforce shortages. While HPC participants are learning on the job, they will also provide direct service to their health department and the State or local jurisdiction, such as by participating in public health surveillance activities, supporting outbreak investigations or environmental health assessments, or identifying important biologic specimens. CDC plans to ensure diversity among the HPC participants by recruiting strategically through social networking, student associations (including minority student associations), college career counselors, student and school listservs, alumni associations, and university/college organizations.

CHILDHOOD OBESITY PREVENTION

Question. I'm very pleased to see that childhood obesity prevention has been an important priority for this administration and particularly the First Lady. CDC has invested in research and strategic partnerships to develop best practices in nutrition and physical activity. How has the CDC partnered with school systems to put this information into practice, and what additional steps could be taken in the future to ensure that this information is disseminated effectively?

Answer. CDC supports a variety of programs and activities that address childhood overweightness and obesity in school and community settings. For instance, CDC's Division of Adolescent and School Health provides funding and technical support to 22 State departments of education and one tribe to address critical health issues,

including obesity. CDC also supports school-based activities that contribute to obesity prevention and control efforts, such as promoting a systematic, data-driven approach to implementing evidence-based school health policies and programs, and developing and disseminating tools to help schools implement these practices.

In addition, communities funded through the Healthy Communities Program and the Recovery Act Communities Putting Prevention to Work Program are partnering with school district leaders and staff to address childhood obesity through nutrition and physical activity strategies. These programs aim to promote wellness and to provide positive, sustainable health change by advancing policy, systems, and environmental change approaches, with a strategic focus on obesity prevention.

COMMUNITY HEALTH CENTERS

Question. As you know, through the ARRA, we made a historic investment in our Nation's community health centers. While this investment is reaping benefits in communities across the Nation—including more than 35 health centers in Illinois, we know that there is still tremendous unmet need in health centers across the country. One demonstration of this need was in the competition for Facility Investment Program (FIP) funding available to health centers for large-scale construction projects through ARRA. Although more than 600 applications were submitted, only 85 could be approved. Those applications are still valid, and I am interested in the potential for funding these high-scoring, but unfunded applications. In addition, can you project how many jobs could be created if Congress were to provide additional funds for health center FIP funding in the range of $2 billion.

Answer. As you note, significant interest has been expressed in the Health Center Facility Investment Program that was funded through the ARRA. The ACA includes an additional $1.5 billion (for fiscal year 2011 through fiscal year 2015) for investments in health center facilities. We envision health centers that applied for ARRA funding being eligible for receipt of this funding. At this point, it is difficult to project how many jobs will be created through the expenditure of this funding.

MEDICARE SECONDARY PAYER (MSP)

Question. Recently, I have heard concerns regarding the MSP system and a beneficiary's privacy. It seems that the current system is making it very difficult for many beneficiaries to settle cases and receive their settlement funds in the same timeframe as non-Medicare beneficiaries. The MSP reporting requirements in section 111 of the Medicare and Medicaid Extension Act of 2007 gave the Secretary discretion to establish the rules governing this new reporting process. I understand that those rules require beneficiaries to provide their social security number (SSN) or Medicare health information claim numbers (HICN) number to third parties as part of this reporting process. In light of our concerns of identity theft and the fact that HHS advises beneficiaries to keep these numbers private, what can be done so that beneficiaries do not have to disclose this information?

Answer. HHS and CMS are committed to protecting the identity of Medicare beneficiaries and ensuring that they are able to access their healthcare benefits in a secure way. The HICN, also known as the Medicare number, serves as a beneficiary's identification number for Medicare entitlement. An individual may become entitled to Medicare through Social Security based on his or her own earnings or that of a spouse, parent, or child. HICNs reflect the social security number (SSN) of the individual who is entitled to Medicare, preceded or followed by a suffix that pertains to the specific beneficiary. Therefore, while in many cases a beneficiary's HICN includes their personal SSN, it is not always the case.

Since the MSP process requires CMS to re-examine all billing and payments made by Medicare on behalf of a beneficiary, it would be impossible to perform this search without using a beneficiary's Medicare number, or the HICN. However, I want to assure you that we have strong guidelines and procedures in place to ensure that beneficiaries are protected from unauthorized disclosure of their personal information.

QUESTIONS SUBMITTED BY SENATOR JACK REED

LOW INCOME HOME ASSISTANCE PROGRAM (LIHEAP)

Question. I am deeply concerned about the proposed $2 billion cut in the LIHEAP block grant, which represents a $13.6 million reduction in funding for the State of Rhode Island. While the budget proposal calls for the creation of a so-called mandatory "trigger" fund to make up the difference, there is no certainty that the gap in

the block grant will be filled for each State. Is it a certainty that the mandatory fund will be triggered in fiscal year 2011?

Answer. Under current economic estimates, substantial mandatory funding will be triggered in fiscal year 2011 under the administration's legislative proposal. We estimate that $2 billion will be released, bringing total LIHEAP funding to $5.3 billion, an increase of $200 million above fiscal year 2010.

Question. If the mandatory fund is triggered, how can States be assured that they will not see a cut from the level of funding they received in fiscal year 2010 in the absence of any kind of funding formula?

Answer. Under our legislative proposal, the administration would determine a State allocation of triggered mandatory funds. A funding formula was not proposed because we believe having discretion over State allocations provides flexibility necessary to respond to the unique aspects of each heating or cooling season. Since we expect substantial funds to be triggered by an overall increase in the percentage of households receiving Supplemental Nutrition Assistance (SNAP) we would expect that States where SNAP usage has increased the most would see increased funding compared to fiscal year 2010. The discretion provided by the proposal would allow us to address unique circumstances. For example, if two States had the same increase in SNAP usage, the one experiencing severe weather could receive additional funds.

Question. How are States supposed to plan their programs without a clear sense of how much funding they will receive? Why is it not simpler and more predictable to fully fund the block grant?

Answer. Since LIHEAP funding is currently subject to an annual appropriation, States must currently plan their programs without knowing how much discretionary funding they will receive. LIHEAP appropriations are frequently not enacted until mid-winter, several months after States begin their heating programs. Under our legislative proposal, however, most mandatory funding would be allocated to the States at the beginning of the Federal fiscal year, as they start their heating programs.

Question. In the out-years, the budget shows a significant decline in funding that will be released under the trigger. Given the administration's commitment to capping nonsecurity discretionary spending and the reduced baseline established for the block grant in this budget (again, $2 billion less than fiscal year 2009 and 2010), it will be difficult to make up for the shortfall that will occur on the mandatory side. Indeed, it appears that this proposal would lock-in a cut to overall LIHEAP funding in future years. How does the administration plan to ensure that the program does not experience such a cut? Will you propose increased funding for the block grant in future years?

Answer. The administration believes that the $5.3 billion requested for LIHEAP is appropriate given the circumstances predicted for fiscal year 2011. These circumstances include a significant increase in energy prices and a 48 percent increase in the proportion of U.S. households receiving SNAP. After fiscal year 2011, current predictions show more stable energy prices and significant decreases in the proportion of households receiving SNAP. Based on these predictions, the amount of mandatory funding that we would project to be released by the trigger proposal also declines significantly. Should energy prices increase rapidly, and/or SNAP participation remain high, the trigger would automatically provide a higher level of mandatory funds. While current economic estimates show declining mandatory funding after fiscal year 2011, the trigger proposal ensures that the amount of mandatory LIHEAP funding will be higher automatically if there is an increase in need

VACCINATIONS—SECTION 317 IMMUNIZATION PROGRAM.

Question. In 2009, the Centers for Disease Control and Prevention (CDC) submitted a report to Congress which illustrated that the section 317 immunization program requires additional funding to carry out its essential public health mission of protecting Americans from preventable diseases. I am pleased that the American recovery and Reinvestment Act (ARRA) began to address this funding need. For the first time, entire families in some States received the Tetanus-Diphtheria-Pertussis vaccine. In other States, children were able to receive their annual influenza vaccine in their school, which helped keep children in the classroom, not sick at home. With the success that we have seen over the past year, how did you reach the decision to not maintain this enhanced funding level in the proposed fiscal year 2011 budget?

Answer. The support that the ARRA provided to CDC's section 317 Immunization Program was one-time funding. The fiscal year 2011 President's budget requests $579 million, which is +$17 million above fiscal year 2010. CDC will continue support for the purchase of vaccine and for State immunization infrastructure and oper-

ations so that public health departments can provide vaccine underinsured and uninsured children and adults. With these efforts, CDC plans to keep childhood immunization rates at record high levels in the United States.

HEALTHCARE WORKER VACCINATION

Question. Healthcare workers are in direct contact with individuals who are often highly susceptible to contracting other diseases and conditions. As such, ensuring that health workers, not just patients, receive vaccinations are not just a matter of wellness, but also patient safety. Unfortunately, we know from a recent reports that only 40 percent of health workers nationwide, for example, receive annual flu vaccinations. Recognizing that this was a problem, hospitals in my State of Rhode Island are required to report flu vaccination rates of health workers to the Department of Health. Individual health workers actually accept or decline (for a specified reason) their vaccine at their place of employment, which has increased the rate of vaccination in just the past few years. What could be done at the national level to increase vaccination rates among healthcare workers?

Answer. Mandatory healthcare personnel influenza vaccination requirements and public reporting of healthcare personnel influenza vaccination status has been used to increase coverage rates at the healthcare institution and State-levels. CDC is currently working with Centers for Medicare and Medicaid Services (CMS) to assess the effectiveness and feasibility of establishing a mechanism for public reporting of influenza vaccination coverage among healthcare personnel by making this a national quality performance measure for healthcare institutions.

TITLE VII HEALTH PROFESSIONS FUNDING

Question. We know that a strong healthcare workforce will help to meet the healthcare needs of patients around the country. And, as we work to pass health reform legislation, we know that the number of new individuals who will, for the first time, have access to primary care doctors will create even greater strain on the system. For this reason, I was pleased that the ARRA provided an additional $200 million to train a new generation of healthcare workers. This investment will also make a significant economic impact. In 2008, medical schools and teaching hospitals had a combined $512 billion impact on the national economy. And each trained and practicing primary care doctor, for example, has a $1.5 million impact on the economy. How will you work to prioritize funding increases that directly impact job creation and economic recovery?

Answer. Health Resources and Services Administration (HRSA) is coordinating with the Department of Labor (DOL) to ensure investments in health workforce are complimentary, reduce shortages in health professions, and provide economic opportunities. HRSA and DOL will soon submit to the Congress a joint strategic plan for how they will invest their resources in fiscal year 2010 and beyond. One key area of emphasis is building career ladders in the healthcare sector. Career ladder programs allow individuals to expand their skills and increase their income. In fiscal year 2010, Congress appropriated funds for HRSA to implement an initiative to improve training for nursing aides and home health aides. This initiative will generate more economic opportunities for individuals who pursue these careers. According to Bureau of Labor statistics, these two occupations are among the fastest growing.

THE HEMOPHILIA PROGRAM (CDC)

Question. The President's budget for fiscal year 2011 proposes to eliminate CDC's Blood Disorders Division and establishes a new program described as "a public health approach to blood disorders." The explanation provides few details on what existing activities will be maintained or changed and what new activities will be initiated. Can you provide a detailed explanation of CDC's new approach, with a particular emphasis on how it will impact the cost-effective research, treatment, and surveillance conducted under the Hemophilia Program, as well as a description of how the $20.4 million will be spent?

Answer. The fiscal year 2011 President's budget requests $20 million for a program that realigns CDC's Blood Disorders Division to address the public health challenges associated with blood disorders and related secondary conditions. Rather than fund a disease-specific program for specific categories of blood disorders, the new program uses a comprehensive and coordinated agenda to prioritize population-based programs targeting the most prevalent blood disorders. This public health approach will impact as many as 4 million people suffering with a blood disorder in the United States versus approximately 20,000 under the current programmatic model. In fiscal year 2011, CDC plans to focus on the following three areas of greatest burden and unmet need: deep vein thrombosis and pulmonary embolism,

hemoglobinopathies (such as sickle cell disease and thalassemia), and bleeding disorders. CDC has a long and robust history of partnership with a national network of 135 hemophilia treatment centers that has a documented history of improved health outcomes for hemophilia patients. CDC plans to continue this national network for the hemophilia population as well as those suffering from the most prevalent blood disorders.

OCEAN STATE CROHN'S AND COLITIS AREA REGISTRY

Question. The President's budget eliminates a very successful program at the CDC focused on Crohn's disease and ulcerative colitis—painful and debilitating diseases. The CDC program supports much-needed epidemiology research on these disorders which has been conducted exclusively in Rhode Island through the Crohn's and Colitis Foundation of America (CCFA). A substantial Federal investment has already been made in connecting more than 22 physicians groups and hospitals in Rhode Island that are engaged in the research. And CDC Director and Administrator Dr. Frieden wrote in a recent letter that, "[w]e have been pleased with the success of our collaboration with CCFA" and "the registry is meeting its aim to gain insight into the etiology of IBD, to learn why the course of illness varies among individuals, and determine what factors may improve outcomes." If these statements are accurate, what is the rationale for eliminating this successful program and how can we work together to ensure that existing efforts are maintained with adequate Federal funding?

Answer. For fiscal year 2011, the President's budget does not continue the specific $686,000 provided in fiscal year 2010 for Inflammatory Bowel Disease (IBD) as the request seeks to eliminate duplicative programs that take narrow, disease-specific approaches rather than a broader public health approach. CDC will continue to provide technical assistance to partners who are researching the natural history of IBD and factors that predict the course of the disease. This research includes studies examining provider variation in the treatment of Crohn's disease, disparities in mortality for IBD patients, disparities in surveillance for colorectal cancer associated with this disease, and variation in outcomes in relation to race.

QUESTION SUBMITTED BY SENATOR MARK PRYOR

ABSTINENCE

Question. The Consolidated Appropriations Act, 2010, established a funding stream for a new Teen Pregnancy Prevention Program. The Conference Report included language providing $110,000,000 for a new teenage pregnancy prevention initiative. The Conference Report underscored the value of abstinence: "The conferees intend that programs funded under this initiative will stress the value of abstinence and provide age-appropriate information to youth that is scientifically and medically accurate." It is my understanding that Arkansas and other States' programs dedicated to abstinence education would likely be able to apply for funds from a $25 million pool of research and development grant program funding, but no guarantee exists that these programs would receive continued funding and they could be eliminated.

Answer. Twenty-eight different programs met the funding criteria, reflecting a range of program models and target populations, some included abstinence components. States such as Arkansas may select one of these models and apply under tier 1 or may apply under the tier 2 innovative approaches pool from either the Teen Pregnancy Prevention funds in OS or the Personal Responsibility Education Program (PREP) innovative strategies funds in ACF. Additionally, the department of Health and Human Services is still determining the funding process for the PREP evidence-based replication programs which totals approximately $55 million and is designed to educate adolescents on a number of personal responsibility areas including abstinence. In addition, the Patient Protection and Affordable Care Act includes $50 million in annual mandatory funding for States to provide abstinence education, which may be a source of support for these programs.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

AMERICAN RECOVERY AND REINVESTMENT ACT (ARRA)

Question. Madam Secretary, the Department Health and Human Services (HHS) fiscal year 2011 budget presented provides an increase of $1 billion. While this would appear to be a satisfactory amount, when taking into account the stimulus

funding provided for the National Institutes of Health (NIH) which will be coming to an end this year, the reduction is catastrophic. The stimulus funds have brought a resurgence of scientists to labs to find cures to the greatest maladies of our times. Given the need to continue this funding please explain HHS's thinking behind this $1 billion increase.

Answer. The fiscal year 2011 budget request does not fully continue the one-time ARRA funding expected to be obligated in fiscal year 2010. NIH planned for most of the research supported by the ARRA to be completed in 1 or 2 years, or to supplement and accelerate ongoing research. However, NIH does plan to use part of its $1 billion budgeted increase in fiscal year 2011 to continue specific initiatives begun or expanded with ARRA funds. Examples of such projects being continued with fiscal year 2011 funds include using The Cancer Genome Atlas to catalog all of the reasons why normal cells become malignant; shortening the time it takes to develop and test new cancer treatments through the Accelerating Clinical Trials of Novel Oncologic Pathways Program; sequencing candidate genes to identify genetic contributors to autism spectrum disorder; and strengthening the NIH Basic Behavioral and Social Sciences Opportunity Network initiative.

Question. Last year, President Obama signed an executive order to expand the number of embryonic stem cell lines that are eligible for Federal funding. Last year $143 million (including ARRA funds) was spent on human embryonic research by the NIH. Do you believe that funding level was sufficient and what we can expect for fiscal year 2011?

Answer. Funding levels have not been the limiting factor in the support of human embryonic research. The major limitations have been the restrictions on the number of stem cell lines available for research and the quantity of applications submitted. President Obama's Executive Order 13505 of March 9, 2009, removing previous Federal restrictions, and NIH's new stem cell research guidelines of July 7, 2009, implementing the Executive Order has gone a long way in addressing these past limitations. Currently, NIH has formally approved 64 human embryonic stem cell lines to be eligible for Federal research support. NIH estimates it will spend at least $126 million in fiscal year 2011 on human embryonic stem cell research, an increase of $38 million, or 43 percent, more than fiscal year 2008 levels.

I would also mention that on February 26, 2010, NIH announced a new initiative to use its Common Fund resources beginning in fiscal year 2010 to establish an intramural Induced Pluripotent Stem Cell Center to drive the translation of scientific knowledge about stem cell biology into new cell-based treatments. The capability of transforming human skin fibroblasts and other cells into induced pluripotent stem cells could lead to major advances in therapeutic replacement of damaged or abnormal tissue without risk of transplant rejection.

With this opening up of Federal support for human embryonic stem cells, and with the development of induced pluripotent stem cells, researchers will have an unprecedented opportunity in fiscal years 2010 and 2011 to understand the earliest stages of human development, and to explore powerful new therapeutic approaches to Parkinson's disease, type 1 diabetes, spinal cord injury, and a long list of rare genetic diseases.

MEDICARE PART D

Question. Prior to Medicare Part D, when Medicaid was the primary payer of medications in long-term care, pharmacies were required to provide a credit for unused medication in most States. As a result, pharmacies looked for ways to reduce or reuse the medications, which helped curb the amount of waste. However, since the inception of Medicare Part D, which has no mechanism to provide a credit for unused medication, waste has grown significantly, costing taxpayers billions and contaminating our water supplies. Because of the current reimbursement system in Part D, long-term care pharmacies have no incentive to reduce medication waste. Is medication waste in long-term care something the agency is paying attention to and what steps can the agency take to eliminate this waste? Are you considering any incentives, such as higher dispensing fees for long-term care pharmacies and/or technology and research grants?

Answer. Thank you for the question Senator Specter. Centers for Medicare and Medicaid Services (CMS) shares your concern regarding the wasteful dispensing of prescription drugs in long-term care settings. We have been addressing medication waste concerns as we work toward implementing the provision in the Affordable Care Act (ACA) which we worked on with Congress to ensure that prescription drugs are dispensed with a higher degree of efficiency. The ACA requires part D plans to implement waste reduction techniques beginning with the 2012 plan year. We are in the process of consulting with key stakeholders such as pharmacists,

nursing homes, and plans as we develop utilization management techniques that will reduce the waste associated with the dispensing of 30-day refills in long-term care settings.

BIOPRODUCTION FACILITY

Question. On May 20, 2009, we met to discuss the establishment of a facility to develop and manufacture biologics. Since that time we have seen the production of H1N1 vaccine fall woefully short, missing the delivery date for vaccines by months. A public/private manufacturing and development facility would help ensure access to vaccines and other medical countermeasures for Americans. I have worked with Biomedical Advanced Research and Development Authority (BARDA) to move this project forward and they have indicated their support. Could you explain why funding for this important project was not included in your budget?

Answer. HHS is currently conducting a review of medical countermeasure (MCM) development, which will examine domestic manufacturing capacity for pandemic influenza vaccines and other MCMs. HHS is also working with the Department of Defense in order to coordinate countermeasure facility needs.

The fiscal year 2010 budget for BARDA includes $5 million to support the initial planning phase of core services (formerly called bioproduction facilities). HHS plans to solicit proposals and award contracts to support architectural and mechanical engineering concept design for potential facilities. The goal will be to evaluate the potential of strategic partnerships between the Federal Government, major biopharmaceutical companies, and smaller biotech companies to create domestic-based, flexible, multi-product manufacturing facilities focused on providing countermeasure services. Priority services would include the advanced development and manufacturing of biological medical countermeasures with limited or no commercial markets.

ANTHRAX VACCINE

Question. It is my understanding that the Department has a requirement and need to contract for additional doses of the Food and Drug Administration (FDA) licensed anthrax vaccine because the number of the doses in the Strategic National Stockpile currently are well below the total needed to meet HHS's 75 million anthrax vaccine dose requirement and the shelf-life dates for using the earlier stockpiled anthrax vaccine doses have expired and others will continue to expire. It is also my understanding that with the termination of an earlier contract and delays in the development of new experimental anthrax vaccines, HHS now estimates that it will take at least 8 years before potential development and FDA licensure of new anthrax vaccines. Given that many Government and other experts are saying that the number one WMD threat is anthrax and there is a continuing need for protecting first responders and citizens from another potential anthrax attack with both vaccines and drugs, what are your plans and timing for contracting for additional doses of the current FDA licensed vaccine to replenish the stockpile and move toward meeting the 75 million dose stockpile requirement?

Answer. The medical countermeasure review will propose enhancements to the countermeasure production process, addressing promising discoveries, advanced development, robust manufacturing, including for MCMs for anthrax threats.

The Centers for Disease Control and Prevention (CDC) currently has a contract in place with Emergent for procurement of additional 14.5 million doses of FDA-licensed anthrax vaccine in order to move toward meeting the 75 million dose stockpile requirement, and is receiving the full production capacity of this vaccine.

BARDA terminated on December 7, 2009 a solicitation under Project BioShield RFP for rPA anthrax vaccine after multiple technical evaluation panels determined that none of the proposal from Offerors were able to meet the maximum statutory requirement of reaching FDA licensure within 8 years. On the same day, BARDA issued special instructions under their broad agency announcement to support advanced development of next generation anthrax vaccines including rPA vaccine candidates. Proposals were received, reviewed, and are currently under contract negotiations with an expectation to issue contract awards in fiscal year 2010.

Question. Given the delays and uncertainties with the development, procurement, manufacture, and availability associated with vaccines in general and most recently for the pandemic vaccine, would it not be prudent now for HHS to enter into negotiations as early as possible for procurement of a multi-year supply of the anthrax vaccine for the stockpile to assure that we are better prepared to respond to an anthrax attack or multiple attacks?

Answer. CDC currently has a contract, with a multi-year contracting mechanism to ensure preparedness, in place with Emergent for procurement of additional 14.5

million doses of FDA-licensed anthrax vaccine in order to move toward meeting the 75 million dose stockpile requirement, and is receiving the full production capacity of this vaccine.

SUBCOMMITTEE RECESS

Senator HARKIN. Same here. The subcommittee will stand recessed. Thank you, Madam.

[Whereupon, at 3:58 p.m., Wednesday, March 10, the subcommittee was recessed, to reconvene subject to the call of the Chair.]