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REVIEWING THE PRESIDENT'S FISCAL YEAR 2013 BUDGET PROPOSAL FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEARING

BEFORE THE

COMMITTEE ON EDUCATION
AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

SECOND SESSION

HEARING HELD IN WASHINGTON, DC, APRIL 26, 2012

Serial No. 112–60

Printed for the use of the Committee on Education and the Workforce

Available via the World Wide Web:
www.gpo.gov/fdsys/browse/committee.action?chamber=house&committee=education
or
Committee address: *http://edworkforce.house.gov*

U.S. GOVERNMENT PRINTING OFFICE

73–850 PDF WASHINGTON : 2012

For sale by the Superintendent of Documents, U.S. Government Printing Office
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REVIEWING THE PRESIDENT'S FISCAL YEAR 2013 BUDGET PROPOSAL FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Thursday, April 26, 2012
U.S. House of Representatives
Committee on Education and the Workforce
Washington, DC

The committee met, pursuant to call, at 10:03 a.m., in room 2175, Rayburn House Office Building, Hon. John Kline [chairman of the committee] presiding.

Present: Representatives Kline, Petri, McKeon, Biggert, Wilson, Foxx, Roe, Walberg, DesJarlais, Hanna, Bucshon, Gowdy, Barletta, Roby, Heck, Ross, Kelly, Miller, Kildee, Andrews, Scott, Woolsey, Hinojosa, McCarthy, Tierney, Holt, Davis, Altmire, and Fudge.

Staff present: Andrew Banducci, Professional Staff Member; Katherine Bathgate, Deputy Press Secretary; James Bergeron, Director of Education and Human Services Policy; Casey Buboltz, Coalitions and Member Services Coordinator; Molly Conway, Professional Staff Member; Cristin Datch, Professional Staff Member; Lindsay Fryer, Professional Staff Member; Ed Gilroy, Director of Workforce Policy; Benjamin Hoog, Legislative Assistant; Ryan Kearney, Legislative Assistant; Brian Newell, Deputy Communications Director; Krisann Pearce, General Counsel; Molly McLaughlin Salmi, Deputy Director of Workforce Policy; Mandy Schaumburg, Education and Human Services Oversight Counsel; Dan Shorts, Legislative Assistant; Todd Spangler, Senior Health Policy Advisor; Linda Stevens, Chief Clerk/Assistant to the General Counsel; Alissa Strawcutter, Deputy Clerk; Loren Sweatt, Senior Policy Advisor; Kate Ahlgren, Minority Investigative Counsel; Aaron Albright, Minority Communications Director for Labor; Tylease Alli, Minority Clerk; Ruth Friedman, Minority Director of Education Policy; Waverly Gordon, Minority Fellow, Labor; Brian Levin, Minority New Media Press Assistant; Richard Miller, Minority Senior Labor Policy Advisor; Megan O'Reilly, Minority General Counsel; Julie Peller, Minority Deputy Staff Director; Michele Varnhagen, Minority Chief Policy Advisor/Labor Policy Director; and Daniel Weiss, Minority Special Assistant to the Ranking Member.

Chairman KLINE. A quorum being present, the committee will come to order.

Good morning, Madam Secretary, thank you for being with us today to discuss the policies and priorities of the Department of Health and Human Services.

In his fiscal year 2013 budget, President Obama requests $932 billion for the Department of Health and Human Services, one of the largest allocations for any Federal agency. Nearly $70 billion of this request is dedicated to various social services programs, including Head Start and Community Services block grants.

While they support families nationwide, such programs are also vulnerable to waste and abuse of taxpayer resources. For example, a 2010 report by the Government Accountability Office revealed fraud in the Head Start program, including misleading taxpayers about the number of children enrolled to inflate the amount of Federal funds received.

Despite a lengthy delay, I am pleased the Administration finally took steps to implement a 2007 law to strengthen Head Start and protect taxpayer dollars by requiring the lowest performing programs to re-compete for funding. I hope the department will continue to improve the accountability of this and other Social Services' programs within its jurisdiction.

While these programs and policies will be part of the discussion today, health care is undoubtedly at the forefront of the minds of many here. It is an issue continually raised by our constituents and inextricably linked to the strength of our economy. Congress continues to closely examine the 2010 health care law and its unprecedented regulatory process. What we have learned is deeply troubling. First, we have learned the law will fall far short of the President's promise to lower health care costs. By any basic standard, whether the premiums families and employers pay, or the cost leveraged on taxpayers to finance government programs, health care costs are going up.

The average cost of a family health insurance plan increased 9 percent just last year. Charles Blahous, a public trustee of Medicare and Social Security, recently stripped away the budget gimmicks to reveal the law will add as much as $527 billion to the Federal deficit over the next decade.

Patti-Ann Kanterman, Chief Financial Officer of her family owned business in Pennsylvania, recently told this committee exactly what the law did not do, quote—"It did not reduce the costs of insurance. It did not reduce uncertainty of offering insurance." It is worthwhile to note the President's budget requests $111 billion increase for health insurance subsidies, perhaps an implicit recognition costs are accelerating faster than even he imagined.

We have also learned the laws made it more difficult to hire new workers. According to the Congressional Budget Office, the law will cut 800,000 jobs from the nation's workforce. This reflects the concerns raised by employers like Gail Johnson, president of a small business that offers early childhood education to families in Virginia. Ms. Johnson told the committee the 2010 law will, quote—"slow or stall the growth of small and mid-size businesses as they struggle to absorb its new costs."

Finally, we learned the President's pledge to the American people that they could keep their current health care plan was nothing more than empty rhetoric. The Administration has made it vir-

tually impossible for employers to maintain their grandfathered exemption, which means employers must choose between losing the ability to manage coverage on behalf of their workers or complying with the law's myriad requirements as costs skyrocket.

The consequences of this health care law extend beyond an employer's bottom line. They have consequences for workers as well. Brett Parker, with Bowlmor Lanes in New York City, has testified his kitchen staff will have to accept part-time hours due to the law's employer mandate. Other workers confront similar changes, including lower wages and loss of coverage as employers grapple with the law's regulations and mandates.

Pennsylvania employer Will Knetch echoed the concerns of many when he said the law provides so many unknowns for the business community, it is scary. With 13 million searching for work, our nation simply cannot afford policies that create uncertainty and fear. Folks like Gail Johnson, Brett Parker, Patt-Ann Kanterman, these are America's job creators and their personal experiences reveal the difficult reality now facing countless employers and workers.

Madam Secretary, we realize your job is to administer Federal law to the best of your ability; however, Congress also has a responsibility to protect the best interests of the American people. Toward that end, we will continue to conduct aggressive oversight of the law and the related regulatory actions taken by the Administration. As such, effective oversight requires the timely cooperation of the Administration.

It was disappointing to receive, just last week, answers to questions this committee asked 10 months ago. Adding insult to injury, the responses you provided are out of date and largely irrelevant to the current debate. If it takes this long for the Federal bureaucracy to answer basic questions, it is hard to believe it can effectively run our nation's health care system. I hope you can provide an explanation for the delay and commit to doing better in the future.

With that, I will now recognize my distinguished colleague, George Miller, the senior democratic member of the committee, for his opening remarks.

[The statement of Chairman Kline follows:]

Prepared Statement of Hon. John Kline, Chairman, Committee on Education and the Workforce

In his Fiscal Year 2013 budget, President Obama requests $932 billion for the Department of Health and Human Services, one of the largest allocations for any federal agency. Nearly $70 billion of this request is dedicated to various social services programs, including Head Start and Community Services Block Grants.

While they support families nationwide, such programs are also vulnerable to waste and abuse of taxpayer resources. For example, a 2010 report by the Government Accountability Office revealed fraud in the Head Start program, including misleading taxpayers about the number of children enrolled to inflate the amount of federal funds received. Despite a lengthy delay, I am pleased the administration finally took steps to implement a 2007 law to strengthen Head Start and protect taxpayer dollars by requiring the lowest performing programs to re-compete for funding. I hope the department will continue to improve the accountability of this and other social services programs within its jurisdiction.

While these programs and policies will be a part of the discussion, health care is undoubtedly at the forefront of the minds of many here today. It is an issue continually raised by our constituents and inextricably linked to the strength of our economy. Congress continues to closely examine the 2010 health care law and its unprecedented regulatory process. What we have learned is deeply troubling.

First, we have learned the law will fall far short of the president's promise to lower health care costs. By any basic standard—whether the premiums families and employers pay or the costs leveraged on taxpayers to finance government programs—health care costs are going up. The average cost of a family health insurance plan increased 9 percent just last year. Charles Blahous, a public trustee of Medicare and Social Security, recently stripped away the budget gimmicks to reveal the law will add as much as $527 billion to the federal deficit over the next decade.

Patti-Ann Kanterman, chief financial officer of a family-owned business in Pennsylvania recently told this committee exactly what the law did not do: "It did not reduce the cost of insurance; it did not reduce uncertainty of offering insurance." It is worthwhile to note the president's budget requests a $111 billion increase for health insurance subsidies, perhaps an implicit recognition costs are accelerating faster than even he imagined.

We have also learned the law has made it more difficult to hire new workers. According to the Congressional Budget Office, the law will cut 800,000 jobs from the nation's workforce. This reflects the concerns raised by employers like Gail Johnson, president of a small business that offers early childhood education to families in Virginia. Ms. Johnson told the committee the 2010 law will "slow or stall the growth of small and midsized businesses as [they] struggle to absorb its new costs."

Finally, we learned the president's pledge to the American people that they could keep their current health care plan was nothing more than empty rhetoric. The administration has made it virtually impossible for employers to maintain their grandfathered exemption, which means employers must choose between losing the ability to manage coverage on behalf of their workers or complying with the law's myriad requirements as costs skyrocket.

The consequences of this health care law extend beyond an employer's bottom line; they have consequences for workers as well. Brett Parker with Bowlmor Lanes in New York City has testified his kitchen staff will have to accept part-time hours due to the law's employer mandate. Other workers confront similar changes including lower wages and loss of coverage as employers grapple with the law's regulations and mandates. Pennsylvania employer Will Knetch echoed the concerns of many when he said the law "provides so many unknowns for the business community; it is scary."

With 13 million searching for work, our nation simply cannot afford policies that create uncertainty and fear. Folks like Gail Johnson, Brett Parker, Patti-Ann Kanterman—these are America's job creators, and their personal experiences reveal the difficult reality now facing countless employers and workers.

Madam Secretary, we realize your job is to administer federal law to the best of your ability. However, Congress also has a responsibility to protect the best interests of the American people. Toward that end, we will continue to conduct aggressive oversight of the law and the related regulatory actions taken by the administration.

As such, effective oversight requires the timely cooperation of the administration. It was disappointing to receive just last week answers to questions this committee asked 10 months ago. Adding insult to injury, the responses you provided are out of date and largely irrelevant to the current debate. If it takes this long for the federal bureaucracy to answer basic questions, it's hard to believe it can effectively run our nation's health care system.

I hope you can provide an explanation for the delay and commit to doing better in the future.

Mr. MILLER. Thank you, Mr. Chairman, and I join you in welcoming Secretary Sebelius back before the committee.

From educating our youngest children at Head Start, to ensuring seniors access to health care through Medicare, the Department of Health and Human Services administers programs that make our nation stronger and healthier. HHS is also playing an essential role in implementing the Affordable Care Act. Proper implementation of this historic reform is vitally important. It has been 2 years since the Affordable Care Act was signed into law and 2 more years before it will be fully implemented.

We never said the change would be everything—that it would change everything that is wrong with our health care system or fix things that people—everything that people would like, or as fast as

they would like. But we know the Affordable Care Act is already moving in the right direction. For decades, we debated about what to do about rising health costs faced by families, businesses and governments.

I would remind Members and my colleagues that they have all been visited over the last decade of businesses, small and large, international and American-based, of which, complained about their dramatic rise in health care over that last decade. We think the Affordable Care Act will, in the long-term, lower those health care costs to businesses, families and to our economy and it will put American families back in charge of health care. But, for decades, we kicked the can down the road, costs continued to rise for millions of Americans lost access to the affordable coverage.

The billion dollar insurance industry held American families hostage for too long. They denied coverage due to pre-existing conditions and they rescinded coverage in the middle of treatment. They forced families with stricken loved ones into bankruptcy because those patients had reached their previously unknown, lifetime coverage limit.

But that finally changed with reform. And now the early successes of the law cannot be denied. The national trends are positive. I am also encouraged that I have been hearing from providers, insurers, patients and health systems in my state and district. California is one of the most proactive states in implementing the reform. The state has already activated its exchanges, the Accountable Care Organizations are being embraced by physician groups and insurers as a way to better coordinate care, leading to healthier outcomes and lower overall costs.

For example, Blue Shield of California announced in October they would give out $20 million in grants to 18 California hospital heath systems, clinics and physician groups to form accountable care organizations, the incentives to reduce unnecessary hospital readmissions and save California public employees retirement system $15 million in reduced insurance premiums. Across the country we have seen similar successes.

The Affordable Care Act is already working to put Medicare on stronger financial footing. The law provides new tools to combat fraud and abuse in the Medicare and Medicaid systems. They have helped the government recover a record amount of money, over $4 billion since last year, in fraudulent payments.

Additionally, the growth of Medicare costs have begun to slow. The average Medicare advantage premium is lower this year and the solvency of the Medicare Hospital Trust Fund has been extended until 2024. This is exactly the opposite of what opponents have predicted would happen. While there is more to be done to secure Medicare in the long-term, the Affordable Care Act has begun to show results—reforms should be allowed to work.

Rather than ending Medicare guarantees, as my Republican colleagues have voted to do repeatedly, we must work to strengthen the program. Nor should we turn our backs on the reforms that are already directing the benefits of millions of Americans right now. Seniors are saving billions on medications, working families are no longer just one illness away from bankruptcy, because an insurance company drops coverage due to an arbitrary limit.

Children with pre-existing conditions are no longer denied coverage and more than two and one-half million young adults who aren't offered coverage at work are now allowed to stay on their parent's health plan. All of these reforms would disappear if the law were repealed. Repeal means working families going bankrupt because insurance companies end coverage when they get cancer.

Repeal means sick children being denied coverage. Repeal means young adults in jobs that don't offer health insurance, losing access to their parent's coverage. The repeal means that all other patient's rights set to go into law over the next 2 years would never happen, like completely ending the use of pre-existing conditions to deny care or pricing Americans out of coverage; like ensuring all Americans have access to quality and affordable health insurance that is not dependent upon whether your employer offers it or not.

Mr. Chairman, the Affordable Care Act is making a difference. America has tried to pass meaningful health reform for nearly a century but we couldn't make it happen until President Obama and the previous Congress made it a priority and got it done. Now is not the time to reverse course and go back to the days when the insurance companies were in charge. Our nation's businesses can't afford it, families can't afford it and our government can't afford it.

Once again, Secretary Sebelius, thank you very much for making yourself available to the committee this morning and I look forward to your testimony.

[The statement of Mr. Miller follows:]

Prepared Statement of Hon. George Miller, Senior Democratic Member, Committee on Education and the Workforce

Good morning Mr. Chairman. I join you in welcoming Secretary Sebelius back to the committee.

From educating our youngest children in Head Start to ensuring seniors' access to health care through Medicare, the Department of Health and Human Services administers programs that make our nation stronger and healthier.

HHS is also playing a central role in implementing the Affordable Care Act. Proper implementation of this historic reform is vitally important. It has been two years since the Affordable Care Act was signed into law. And there are two more years to go before it is fully implemented.

We never said we could change everything that's wrong with our health care system, or fix things as fast as people would like. But we know the Affordable Care Act is already moving us in the right direction.

For decades, we debated what to do about rising health costs faced by families, businesses and government. We debated how best to put American families, instead of insurance companies, back in charge of their health care.

But, for decades, we kicked the can down the road. Costs continued to rise and millions of Americans lost access to affordable coverage.

The billion-dollar insurance industry held American families hostage for too long. They denied coverage due to pre-existing condition. They rescinded coverage in the middle of treatment. They forced families with stricken loved ones into bankruptcy because those patients had reached a previously unknown lifetime coverage limit.

But that finally changed with reform. And the early success of this law cannot be denied.

The national trends are positive.

I am also encouraged with what I am hearing from providers, insurers, patients and health systems in my state and district.

California is one of the most pro-active states in the country implementing reform.

The state has already activated its exchange.

Accountable Care Organizations are being embraced by physician groups and insurers as a way to better coordinate care, leading to healthier outcomes at lower overall costs.

For example, Blue Shield of California announced in October that it will give out $20 million in grants to 18 California hospitals, health systems, clinics and physicians groups to form an Accountable Care Organization.

And incentives to reduce unnecessary hospital readmissions saved the California Public Employees Retirement System $15 million in reduced insurance premiums.

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The law provides new tools to combat fraud and abuse in the Medicare and Medicaid systems.

These have helped the government recover a record $4 billion last year in fraudulent payments.

Additionally, the growth of Medicare costs has begun to slow. The average Medicare Advantage premium is lower this year. And the solvency of the Medicare hospital trust fund has been extended until 2024.

This is exactly the opposite of what opponents predicted would happen.

While there is more to be done to secure Medicare for the long-term, the Affordable Care Act has begun to show results. These reforms should be allowed to work.

Rather than ending the Medicare guarantee as my Republican colleagues have voted to do repeatedly, we must work to strengthen the program.

Nor should we turn our backs on the reforms that are also directly benefiting millions of Americans right now.

Seniors are saving billions on their medications.

Working families are no longer just one illness away from bankruptcy because of an insurance company that drops coverage due to an arbitrary limit.

Children with pre-existing conditions are no longer denied coverage.

And more than 2.5 million young adults who aren't offered coverage at work are now allowed to stay on their parents' health plan.

All of these reforms would disappear if the law were to be repealed.

Repeal means working families going bankrupt because of cancer and an insurance company that ends coverage.

Repeal means sick children being denied coverage.

Repeal means young adults, in jobs that don't offer health insurance, losing access to their parents' coverage.

And repeal means that all the other patient rights set to go into law over the next two years would never happen.

Like completely ending the use of preexisting conditions to deny care or pricing Americans out of coverage. Like ensuring all Americans have access to quality and affordable health insurance that is not dependent on whether your employer offers it or not.

Mr. Chairman, the Affordable Care Act is already making a difference.

America tried to pass meaningful health care reform for nearly a century but we couldn't make it happen until President Obama and the previous Congress made it a priority and got it done.

Now is not the time to reverse course and go back to the days where insurance companies were in charge.

Our nation's businesses can't afford it. Families can't afford it. And our government can't afford it.

Once again, thank you, Secretary Sebelius, for making yourself available to the committee.

I look forward to your testimony.

Chairman KLINE. I thank the gentleman.

Pursuant to Committee Rule 7(c), all committee members will be permitted to submit written statements to be included in the permanent hearing record and, without objection, the hearing record will remain open for 14 days to allow statements, questions for the record and other extraneous material referenced during the hearing, to be submitted in the official hearing record.

According to my script, it is now my time to introduce our witness. I think this is, indeed, one of those cases where our witness needs no introduction; everyone knows the Honorable Kathleen Sebelius, the Secretary of Health and Human Services. She has been before this committee before. We welcome her back again.

I am also supposed to remind everybody of the lighting system, which is there in front of you, Madam Secretary. It is the old green, yellow and red light system. Please give your testimony, in its entirety, of course. Everything will be submitted to the record—your entire written testimony.

For my colleagues up here, however, once again, I will be making every effort to hold us to the 5-minute rule so that all members have a chance to engage in the discussion.

And, with that, Madam Secretary, you are recognized.

STATEMENT OF HON. KATHLEEN G. SEBELIUS, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary SEBELIUS. Well, good morning, Chairman Kline and Ranking Member Miller and members of the committee. And I want to start by thanking you for the invitation to discuss the President's 2013 Budget for the Department of Health and Human Services.

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

I look forward to answering your questions about the budget but, first, I want to share a few highlights. Over the last 2 years, as Congressman Miller said, we have been working to deliver the benefits of the Affordable Care Act to the American people. Thanks to the law, more than 2.5 million additional young Americans are already getting coverage through their parent's health plans.

An estimated 32.5 million beneficiaries with Medicare have taken advantage of the recommended preventive services without co-pays or co-insurance. Small business owners are taking advantage of tax breaks on their health care premiums that allow them to expand the care and hire more employees. This year we will build on that progress, continuing to support states as they work to establish affordable insurance exchanges by 2014.

Once these competitive marketplaces are in place, they will ensure that all Americans have access to quality, affordable health coverage. But we know that the lack of insurance is not the only obstacle to care, so our budget also invests in our health care workforce. The budget supports training more than 7,100 primary care providers and placing them where they are needed most.

It also invests in America's network of community health centers. The budget will help health centers provide access to quality care for 21 million people, 300,000 patients more than what could be served last year. The budget ensures that 21st Century America will continue to lead the world in biomedical research by maintaining funding for the National Institutes of Health.

This budget also continues our Administration's commitment to high-quality early education programs that put all of our children on a path to school success and opportunity. Increased funding for the 962,000 children in Head Start and the 1.5 million children in

federally funded childcare assistance program is not only an investment in higher test scores and graduation rates, we know it leads to more productive adults, stronger families and more secure communities.

And our investments also support critical reforms in both Head Start and childcare programs to raise the bar on quality. For example, this year, for the first time, we will require Head Start programs that don't meet important quality benchmarks to compete for funding. In order to make these vital investments, the budget recognizes the need to set priorities, make difficult trade-offs and ensure we use every dollar wisely; that starts with continuing support for President Obama's historic push to stamp out waste, fraud and abuse in the health care system.

Over the last 3 years, every dollar we have put into health care fraud and abuse control has returned more than $7.00. Last year alone, those efforts recovered more than $4 billion. Our budget builds on those efforts by giving law enforcement the technology and data to spot perpetrators early and prevent payments based on fraud from going out in the first place. The budget makes smart investments where they will have the greatest impact, helping to build a stronger, healthier and more prosperous America for the future.

I want to, again, thank you, Mr. Chairman, for inviting me here this morning and I look forward to our conversation.

[The statement of Secretary Sebelius follows:]

Prepared Statement of Hon. Kathleen G. Sebelius, Secretary, U.S. Department of Health and Human Services

Chairman Kline, Ranking Member Miller, and Members of the Committee, thank you for the invitation to discuss the President's FY 2013 Budget for the Department of Health and Human Services (HHS).

The Budget for the Department of Health and Human Services (HHS) invests in health care, disease prevention, social services, and scientific research. HHS makes investments where they will have the greatest impact, build on the efforts of our partners, and lead to meaningful gains in health and opportunity for the American people.

The President's fiscal year (FY) 2013 Budget for HHS includes a reduction in discretionary funding for ongoing activities, and legislative proposals that would save an estimated $350.2 billion over ten years. The Budget totals $940.9 billion in outlays and proposes $76.7 billion in discretionary budget authority. This funding will enable HHS to: Strengthen Health Care; Support American Families; Advance Scientific Knowledge and Innovation; Strengthen the Nation's Health and Human Service Infrastructure and Workforce; Increase Efficiency, Transparency, and Accountability of HHS Programs; and Complete the Implementation of the Recovery Act.

Strengthen health care

Delivering benefits of the Affordable Care Act to the American People: The Affordable Care Act expands access to affordable health coverage to millions of Americans, increases consumer protections to ensure individuals have coverage when they need it most, and slows increases in health costs. Effective implementation of the Affordable Care Act is central to the improved fiscal outlook and well-being of the Nation. The Centers for Medicare & Medicaid Services (CMS) is requesting an additional $1 billion in discretionary funding to continue implementing the Affordable Care Act, including Affordable Insurance Exchanges, and to help keep up with the growth in the Medicare population.

Expand and Improve Health Insurance Coverage: Beginning in 2014, Affordable Insurance Exchanges will provide improved access to insurance coverage for millions of Americans. Exchanges will make purchasing private health insurance easier by providing eligible individuals and small businesses with one-stop-shopping where they can compare benefit plans. New premium tax credits and reductions in cost-

sharing will help ensure that eligible individuals can afford to pay for the cost of private coverage through Exchanges. FY 2013 will be a critical year for building the infrastructure and initiating the many business operations critical to enabling Exchanges to begin operation on January 1, 2014. The expansion of health insurance coverage for millions of low-income individuals who were previously not eligible for coverage also begins in 2014. CMS has worked closely with states to ensure they are prepared to meet the 2014 deadline and will continue this outreach in FY 2013.

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

Strengthen the Delivery System: The Affordable Care Act established a Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center is tasked with developing, testing, and—for those that prove successful—expanding innovative payment and delivery system models to improve quality of care and reduce costs in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Innovation Center began operations in November 2010 and has undertaken an ambitious agenda encompassing patient safety, coordination of care among multiple providers, and enhanced primary care. These projects can serve as crucial stepping stones towards a higher-quality, more efficient health care system.

HHS is also working to ensure that the most vulnerable in our Nation have full access to seamless, high-quality health care. The Affordable Care Act established a new office to more effectively integrate benefits and improve coordination between states and the Federal Government for those who are eligible for both Medicare and Medicaid. While Medicare-Medicaid beneficiaries make up a relatively small portion of enrollment in the two programs, they represent a significant portion of expenditures. HHS is currently supporting 15 states as they design models of care that better integrate Medicare and Medicaid services and is designing additional demonstrations to continue to improve care.

CMS is currently offering three initiatives that will help spur the development of Accountable Care Organizations (ACOs) for Medicare beneficiaries. ACOs are groups of health providers who join together to give high-quality, coordinated care to the patients they serve. If an ACO meets quality standards, it will be eligible to share in savings it achieves for the Medicare program, and may be subject to losses, offering a powerful incentive to restructure care to better serve patients.

Ensuring Access to Quality Care for Vulnerable Populations: Health Centers are a key component of the Nation's health care safety net. The President's Budget includes a total of $3 billion, including an increase of $300 million from mandatory funds under the Affordable Care Act, to the Health Centers program. This investment will provide Americans in underserved areas, both rural and urban, with access to comprehensive primary and preventive health care services. This funding will create 25 new health center sites in areas of the country where they do not currently exist and provide access to quality care for 21 million people, an increase of 300,000 additional patients over FY 2012. The Budget also promotes a policy of steady and sustainable health center growth by distributing Affordable Care Act resources over the longterm. This policy safeguards resources for new and existing health centers to continue services and ensures a smooth transition as health centers increase their capacity to provide care as access to insurance coverage expands.

Improving Healthcare Quality and Patient Safety: The Affordable Care Act directed HHS to develop a national strategy to improve health care services delivery, patient health outcomes, and population health. In FY 2011, HHS released the National Strategy for Quality Improvement in Health Care, which highlights three broad aims: Better Care, Healthy People and Communities, and Affordable Care.

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

CMS will continue funding for the Partnership for Patients, an initiative launched in April 2011 that sets aggressive targets for improving the quality of healthcare: reducing preventable hospital-acquired conditions by 40 percent and preventable readmissions by 20 percent by the end of 2013, as compared to 2010.

Support American families

Healthy Development of Children and Families: HHS oversees many programs that support children and families, including Head Start, Child Care, Child Support, and Temporary Assistance for Needy Families (TANF). The FY 2013 Budget request invests in early education, recognizing the role high-quality early education programs can play in preparing children for school success. The request also supports TANF and proposes to restore funding for the Supplemental Grants without increasing overall TANF funding.

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

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

The Budget provides $6 billion for child care, an increase of $825 million over FY 2012. This funding level will provide child care assistance to 70,000 more children than could otherwise receive services without this increased investment; 1.5 million children in total. In addition to providing funding for direct assistance to more children, the Budget includes $300 million for a new child care quality initiative that states would use to invest directly in programs and teachers so that individual child care programs can do a better job of meeting the early learning and care needs of children and families. The funds would also support efforts to measure the quality of individual child care programs through a rating system or another system of quality indicators, and to clearly communicate program-specific information to parents so they can make informed choices for their families. These investments are consistent with the broader reauthorization principles outlined in the Budget, which encompass a reform agenda that would help transform the Nation's child care system to one that is focused on continuous quality improvement and provides more low-income children access to high-quality early education settings that support children's learning, development, and success in school.

Improve the Foster Care System: The Budget includes an additional $2.8 billion over ten years to support improvements in child welfare. Additional resources will support incentives to states to improve outcomes for children in foster care and those who are receiving in-home services from the child welfare system, and also to require that child support payments made on behalf of children in foster care be used in the best interest of those children. The Budget also creates a new teen pregnancy prevention program specifically targeted to youth in foster care.

Strengthen TANF and Create Jobs: The Budget would provide continued funding for the TANF program and would fund the Supplemental Grants for Population Increases. When Congress takes up reauthorization, we want to work with lawmakers to strengthen the program's effectiveness in accomplishing its goals. This should include using performance indicators to drive program improvement and ensuring that states have the flexibility to engage recipients—including families with serious barriers to employment—in the most effective activities to promote success in the workforce. We also want to work with Congress to revise the Contingency Fund to make it more effective during economic downturns.

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

Preventing Teen Pregnancy: The Budget includes $105 million in the Prevention and Public Health Fund for the Office of the Assistant Secretary for Health for teen pregnancy prevention programs. These programs will support community-based efforts to reduce teen pregnancy using evidence-based models as well as promising programs and innovative strategies. The Budget also includes $15 million in funding for CDC teen pregnancy prevention activities to reduce the number of unintended pregnancies through science-based prevention approaches.

Protect Vulnerable Populations: HHS is committed to ensuring that vulnerable populations continue to receive critical services during this period of economic uncertainty.

Strengthen the nation's health and human service infrastructure and work force

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

Increase efficiency, transparency, and accountabiliy of HHS programs

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

The Administration remains supportive of CSBG's important goals and the services it provides to low-income Americans. We have had to make tough choices to meet current fiscal targets. The 2013 Budget provides $350 million for CSBG, and proposes to strengthen the program to make sure that we are getting the most out of every dollar we spend. The Budget proposes that entities receiving funding from CSBG meet certain performance standards, and compete for funding if they fall below those standards.

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

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

Program Integrity and Oversight: The FY 2013 Budget continues to make program integrity a top priority. The Budget includes $610 million in discretionary

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

From 1997 to 2011, HCFAC programs have returned over $20.6 billion to the Medicare Trust Funds. Approximately $4.1 billion was recovered last year in FY 2011, including $2.5 billion returned to the Trust Funds, and the current three-year return-on-investment of 7.2 to 1 is the highest in the history of the HCFAC program. The Budget proposes a 10-year discretionary investment yielding a conservative estimate of $11.3 billion in Medicare and Medicaid savings and 16 program integrity proposals to build on the Affordable Care Act's comprehensive fraud fighting authorities for savings of an additional $3.6 billion over 10 years.

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

Additionally, Durable Medical Equipment (DME) Competitive Bidding is providing competitive pricing, while continuing to ensure access to quality medical equipment from accredited suppliers, which will save Medicare $25.7 billion over 10 years and help millions of Medicare beneficiaries save $17.1 billion in out-of-pocket costs over 10 years. The Budget proposes to extend some of the efficiencies of DME Competitive Bidding to Medicaid by limiting Federal reimbursement on certain DME services to what Medicare would have paid in the same state for the same services. This proposal is expected to save Medicaid $3.0 billion over 10 years.

Completing implementation of the Recovery Act

The American Recovery and Reinvestment Act provided $140 billion to HHS programs, of which $110 billion had been spent by grant and contract recipients by the end of FY 2011. The vast majority of these funds helped state and local communities cope with the effects of the economic recession.

Thousands of jobs were also created or saved, including subsidized employment and training for over 260,000 people through the Temporary Assistance for Needy Families (TANF) program Emergency Contingency Fund.

The Recovery Act provided states fiscal relief through a temporary increase in Federal matching payments of $84 billion for Medicaid and foster care and adoption assistance.

HHS Recovery Act funds are also making long-term investments in the health of the American people and the health care system itself. Beginning in FY 2011 and continuing for the next few years, HHS will be investing more than $20 billion to support implementation of health information technology in the health care industry on a mass scale. This effort is expected to significantly improve the quality and efficiency of the U.S. health care system. In addition, $10 billion in Recovery Act funds were invested in biomedical research programs around the country, including a major effort to document genomic changes in 20 of the most common cancers and to build research laboratory capacity. Of more immediate impact, $1 billion has been supporting prevention and wellness programs, including projects in 44 communities with a total combined population of over 50 million aimed at reducing tobacco use and the chronic diseases associated with obesity.

HHS has also met the challenges of transparency and accountability in the management of its Recovery Act funds. More than 23,000 grantees and contractors with Recovery Act funding from HHS discretionary programs have submitted reports on the status of their projects over the last 10 quarters. More than 99 percent of the required recipient reports have been submitted on time and are available to the public on Recovery.gov; non-filers have been sanctioned. Finally, HHS Recovery Act program managers are working hand-in-hand with the Secretary's Council on Program Integrity to ensure that risks for fraud, abuse, and waste are identified and steps are taken to mitigate those risks.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

Chairman KLINE. Thank you, Madam Secretary. The health reform law, which we have just been discussing here, cuts $200 billion out of the Medicare Advantage program. As a result of these cuts, the Congressional Budget Office has estimated that 5 million fewer seniors will be enrolled in Medicare Advantage plans during the next decade. And that was a matter of some concern during the debate leading up to the passage of this bill.

And, now, just this week, we have seen an alarming report from the Government Accountability Office, suggesting the Administration viewed these cuts to the health care of millions of seniors as a vulnerability and created a so-called "demonstration project," to temporarily avert the damage. The GAO criticized the $8 billion program that will delay the impact of these cuts until next year. The GAO also reports that such a national program in size and cost is unprecedented and its design, quote—"precludes a credible evaluation of its effectiveness."

The Wall Street Journal picked up on this and ventured that the purpose of the project is to, quote—"give a program that is popular with seniors a temporary reprieve past election day." It is in the interest of every single member of Congress to make sure that taxpayer dollars aren't being spent to protect certain political interests.

Madam Secretary, the GAO called on you to cancel this demonstration project. Is that your intent or are you going to continue forward with this project?

Secretary SEBELIUS. Mr. Chairman, we have no intention of cancelling the project. And I think the good news is that Medicare Advantage programs are stronger than ever and, actually, cheaper than ever. We have more seniors enrolling in Medicare Advantage this year than ever before. We have more programs in the marketplace than ever before. Medicare Advantage programs, when the Affordable Care Act was passed, were paid at about 114 percent of fee-for-service Medicare.

So the Affordable Care Act, over time, reduces that overpayment. We are now down to 107 percent, so rates, indeed, have come down in Medicare Advantage program. That not only benefits the seniors who choose those options, because they pay lower co-pays, but they have more options. And, for the first time ever since Medicare Advantage programs were created, we have instituted a demonstration to inform seniors about quality.

Some of these plans are very high quality, others are not. And we have a 2-year demonstration plan running and I think the good news is we are seeing seniors migrate away from the lower quality plan to the higher quality plan. We are on track to totally eliminate the overpayment to Medicare Advantage Plan, as promised with the Affordable Care Act. Again, a benefit to seniors while keeping the choice that seniors have throughout this country.

Chairman KLINE. The GAO pointed out that the demonstration project, rather than emphasizing those highly successful programs and rewarding them, basically was making the money available to

everybody, which would help provide those costs and encourage people to stay in. What is your response to that?

Secretary SEBELIUS. Well, it is just not accurate. The plans are rated one through five stars. The three, four and five-star programs have gotten some additional incentives to offer quality outcomes. I think the bad news for America's seniors is that for years not only did Medicare Advantage programs charge 14 percent more than fee-for-service, which added costs to every Medicare beneficiary, but there was no quality difference in health care outcomes.

What we are determined to do is not only lower the costs but, actually, to make it very clear to the plans operating in the private marketplace that quality is important and that seniors should know which plans actually offer better outcomes than others.

Chairman KLINE. Clearly, sharp differences between the Government Accountability Office and the Department, which we will continue to explore. I am about to run out of time and I just want to move quickly to another subject. The 2010 Head Start Impact Study found the advantages children gain from Head Start yielded only a few, significant, outcomes that lasted through the end of the first grade.

Now, the third grade follow-up study was set to be completed last September. It has been delayed until later this year. Considering the data for this third grade study was completed in the spring of 2008, what is the cause for the delay and what are your expectations?

Secretary SEBELIUS. Well, Mr. Chairman, I know that the study is underway and that we anticipate completion on the timetable that you have just suggested. We think it is important to continue to monitor what is happening with outcomes. What we know is Head Start does make a difference and it does make a difference not only in the families, but in the children able to start school ready to learn.

And we were really pleased to have an opportunity to work on additional curriculum issues with the Department of Education. I think, also, Mr. Chairman, for the first time ever in the history of the program, we felt it was important to recognize that Head Start programs operate in a variety of ways and some are lower performing and that is not good for our kids.

So, for the first time ever, we have instituted a program where Head Start programs in the bottom quarter of the programs in the country are re-competing for funding, recognizing that we want all of our children in the highest quality programs possible.

Chairman KLINE. Thank you, my time has expired.

Mr. Miller?

Mr. MILLER. Thank you very much.

Madam Secretary, just to follow up on the Head Start question—one, thank you for pushing forward on the re-competing. I know it has been controversial and, in my case, it turns out it cuts very close to home. It is still the right thing to do. I think we will end up with better quality care. I think we will end up with more diligence by the Head Start providers knowing that this process is in place.

And I think both the development of the children and the safety of the children will be dramatically improved because of that. I ap-

preciate that some providers don't like—they think they have the premier program. They don't like the idea that they, somehow, are missing the mark and have to re-compete but I think that is important.

I would also say that for years, you know, we have gone back and forth about what the improvement is in children's ability to learn and the development of children in Head Start, but we also know that, very often, we take those children and we put them into an elementary system in first grade and we measure them at the end of first grade and we measure them at the end of fourth grade.

And much of what we thought was the advantage is lost. And there is a pretty significant body of evidence suggesting that it was lost in first, second and third grade. They came there reasonably well prepared to learn but not much happened when they got to the public school system. And there is some concerns about that so I would just put that into the mix.

I want to go back. I mentioned the development of the Accountable Care organizations. First, what I am quite surprised at, the extent to which in our area of California, Northern California, that these programs have been embraced by the insurers, by the big medical centers, the hospitals, both private and public, and large medical groups of doctors, specialists and across groups with a broad practice in this effort.

The one that was run by CalPERS that we have pointed out—it reduced the number of patients hospitalized for 20 days or more by 50 percent and it reduced hospital admissions by 17 percent. It reduced the total number of inpatients' days by 14 percent and produced a savings of, as we said, over $15 million. I think some $60 million was returned to ratepayers in that instance.

And, now, Blue Cross, Blue Shield and others are trying to set these up in other parts of the state. And both hospitals and physicians are coming to those, understanding that this provides for an improved coordination of care, better care, and drop in readmissions.

Also, in the area, you have put forth this program to deal with the medical errors and falls and accidents, again, sponsored by a—participated in by a small group of hospitals. Now, almost all of the hospitals in the area have joined because of the dramatic savings.

Just in respiratory complications, in terms of keeping the bed properly elevated, dramatically dropping. Pneumonias and complications and deaths from pneumonias, the trips and falls—dramatically reducing the number of falls, which end up in broken hips and bones and, in some case, death.

So we see this joining and this rush into this process in terms of trying to develop better practices for patient care and cost in terms of taxpayers or families who are paying these premiums. So I, really, welcome what is taking place here.

I put an amendment in the bill before Medicare had to pay certain providers within 30 days. I think that probably came to us by all the people that sell things to Medicare; they insisted they be paid in 30 days. And what we saw in some regions of the country, you had people who were billing Medicare off of fraudulently obtained lists and we were paying them within 30 days. And we didn't even know who the hell they were.

I put in that you had to time to do due diligence—who is this person and are they really selling wheelchairs to people who need them or walkers to people who need them or what have you—and, of course, it turns out—and you have recovered, not just because of my amendment, but you have forestalled the payment of people and recovered almost $4 billion, which, I think, is a record in the Medicare program.

I think we got a long ways to go but I am certainly encouraged by the trend line that we have seen over the last couple of years. And I have used up almost all your time but I think he is going to let you have a little bit more.

[Laughter.]

He is nicer to the witnesses than he is to us so——

Chairman KLINE. Did you have a question?

Mr. MILLER. Yes, I would like a response——

Secretary SEBELIUS. Well——

Mr. MILLER [continuing]. On the fact that people are joining these accountable care and trying to initiate Accountable Care Organizations all across the country. But, certainly, dynamically, in California.

Secretary SEBELIUS. Well, I think you raised two aspects of the bill which aren't focused on as much, I think, as some of the insurance issues. One is the whole delivery system changes and the encouragement to use the best practices and, actually, try and take them to scale around the country.

So the Partnership for Patients, which is, kind of, the umbrella title for two efforts that are underway right now: reducing the number of preventable readmissions by about 20 percent and reducing the number of hospital-required infections and errors by 40 percent. Those two efforts over the next 5 years not only save lives but reduce health costs dramatically.

We already have over 3,500 hospitals who are participating in those two efforts around the country, as well as doctor's groups and employer groups and others, who are really excited about this focus. And this affects everybody, regardless of what kind of insurance you have. If you are in the hospital, 100,000 people a year die from what happens to them in the hospital; not what brought them to the hospital but what occurs while they are there.

So lowering hospital-acquired infections and preventing by wrap-around care, bundled care, coordinated care—people from having to cycle back into the hospital is good news, lower rates, lower costs and more patient care.

And, Mr. Chairman, you also—I mean, Congressman Miller, you also mentioned the issue around the improper payments and our tools, now, to really look at what is happening in the fraud scene. We have a whole new predictive modeling technology built—the kind of technology that has been in the private sector for a very long time but missing from the public sector, which allows us not only to calibrate risk, but really watch what is happening.

We have re-credentialed providers in the most likely areas for fraud; durable medical equipment, home health services. We are really watching billings very carefully and that has allowed us to be much more timely not only in stopping payments from going out

the door so we don't do the old pay and chase, but actually discontinuing fraudulent providers from ever billing Medicare again.

So it is a system that should have been in place a long time ago; it is now built and up and running. And I think it is going to yield huge results in the long term.

Chairman KLINE. Thank you, Madam Secretary.

The gentleman's time has expired.

Mrs. Biggert?

Mrs. BIGGERT. Thank you, Mr. Chairman.

Madam Secretary, many, many years ago I volunteered in Chicago on the Head Start program. It was the first year that it was in existence so it was a—and so I have always had a soft spot for Head Start. And I think that it has been a really good program.

And I know that there has been problems with it and, recently, the Inspector General's Office audited several of the Head Start facilities, resulting in a report that there are numerous violations of the Health and Safety requirement. In one case there were toxic chemicals that were found within reach of children. Another there was a machete; I don't know what a machete was doing there but it was found on the stairway near the children's play area.

Why are there these problems not complying with the health and safety within the Head Start Program?

Secretary SEBELIUS. Well, Congresswoman, I can assure you that we take the health and safety of the children in Head Start Programs or our childcare programs, or any place across the country, very seriously. There are thousands of Head Start Programs operating. As I say, some are enormously high-quality; others are not serving our children as well as they could, which is one of the reasons for the re-compete this year, for unannounced visits that we are making as a result of some of the issues GAO had found, programs not operating as well as they could.

We have made about 172 unannounced visits at Head Start centers to really be able to monitor more closely what is going on a regular basis with these variety of sites. We have instituted new training guidelines, new updated rules and regs. So we are trying to identify issues that either would cause children to be in unsafe conditions or, certainly, to be in conditions where they are not being well prepared for a rigorous school curriculum, and move to correct those along the way.

Mrs. BIGGERT. Thank you. Then, another issue—the diesel industry is responsible for thousands of jobs and is represented in my district. Are you concerned that incomplete information surrounding the diesel exhaust in miners study could unfairly harm this important industry?

Secretary SEBELIUS. Well, I share your concern about jobs in any industry. And, as you know, there has been an 18-year study on diesel exhaust and the impact on miners, to evaluate lung cancer from diesel. We have in an unusual situation in this study, where there has been a court intervention that allowed certain, publically released, information to only be released after it was submitted to Congress and reviewed.

We have complied with all of that information. So the studies are finally being published—peer review studies and journals. But, I think, the scope of this study is pretty extraordinary in terms of

the length of time that they followed and the peer reviewers are looking at the scientific data and reviewing that data. So I think that people will be able to make a judgment based on the publication of the data and look at what the science has found over that 18-year period of time.

Mrs. BIGGERT. Well, I hope that there will be the full transparency—I yield back, Mr. Chairman.

Chairman KLINE. Thank the gentlelady.

Mr. Kildee?

Mr. KILDEE. Thank you, Mr. Chairman and Madam Secretary. As you both know, one of the strengths of Head Start is the close involvement of parents to the program to ensure that they have the tools they need to be their child's first and best teacher.

Can you tell the committee the current status of family literacy training and technical assistance, as required by the Head Start Act? What the department and the Office of Head Start are doing to promote and support family literacy, in the context of Head Start, so that multiple generations might benefit in the years to come.

Secretary SEBELIUS. Well, Congressman, I think there is no question that the involvement of family in their child's earliest, outside the home, educational opportunities has been, as you said, one of the real strengths of Head Start from the outset. And we are, certainly, proceeding in the family literacy program and involving family members.

And I would tell you that, for the first time ever in a lot of the other early learning settings, there has been an incorporation of some of the hallmarks of the family involvement from Head Start into those programs. So we have been working closely with the Department of Education around everything from the race to the top for early learning challenges to looking at guidelines across the way.

And, I think, there is a recognition that a curriculum for young learners is important to acquire the skills for school readiness but so are social, emotional, family skills, so is health care. And that, for the first time, is being incorporated across the board, regardless of the setting where the child would be involved.

So I would say that not only is family involvement incredibly important in the Head Start Program, but it is beginning to be very recognized in all of the early childhood programs, whether they are run by the Department of Education or in a childcare setting or in a Head Start setting.

Mr. KILDEE. Thank you, Madam Secretary. Another interest of mine—I was pleased to see that the fiscal year 2013 budget included an increase of $116 million for the Indian Health Services, to improve health outcomes of American Indian communities. What steps has your department taken to implement the Indian Health Care Improvement Reauthorization and Dissention Act that was included in the health care reform law?

Secretary SEBELIUS. Well, Congressman, I know this is a strong priority of yours and one that we have taken very seriously in this Administration. The health gaps between the first Americans and the rest of the population are still staggeringly bad and we have focused additional resources, time and attention—and, I think, Dr.

Roubideaux heading the Indian Health Service has been a terrific leader.

We are now making investments in the contract service area. We have new health care facilities coming on line, and staffing coming on line, with the health services. We are continuing with some facilities construction, including an IHS facility, which comes on line this summer in Barrow, Alaska. We are doing active budget consultations and very much involved in the Indian Health Improvement Act.

It has been the involvement of tribal leaders, as we begin to implement the Affordable Care Act, because there are a number of tribal members who live on Indian land and use, and access, the Indian Health Services facilities. But there are lots of first Americans who live in urban settings, and live all over the country, who are eager to take advantage of the advantages of the Affordable Care Act that they have coming on-line.

So we are working actively on everything from diabetes control, focus on suicide prevention, which is a huge issue in Indian country, new facilities, new contract services. And, as you say, this Administration has made an historic investment in the budget for the Indian Health Service.

Mr. KILDEE. Thank you, Madam Chair, and I appreciate your commitment.

Chairman KLINE. Thank the gentleman.

Dr. Foxx?

Ms. FOXX. Thank you, Mr. Chairman.

Thank you, Madam Secretary, for the morning here today. Good morning. Madam Secretary, in February, you testified before the Ways and Means Committee about the Class Act. And you told Congressman Boustany that you had "no idea", quote—"whether HHS secretly negotiated changes to the Class Act in early 2010, because there was certainly nobody from our department involved."

But, then, when the department's report on the Class Act came out, it admitted that there were backroom negotiations with the advocacy groups to try to make the Class Act solvent. Could you tell me and this committee why you stated that the department was not involved in the backroom negotiations on Class, when your own department's report admitted those negotiations took place? I assume you weren't deliberately trying to mislead the Congress.

Secretary SEBELIUS. Congresswoman, I never misled the Congress at all. The question dealt with—were there secret negotiations during the passage of the Affordable Care Act that involved Class. And my answer is absolutely accurate.

We were charged, as you know, in the Affordable Care Act, with setting up a program that would have provided much-needed services and supports for those individuals who wanted to set aside a portion in their income and provide their own payment for home-based care. We were also charged with not beginning that program unless it was possible to certify to Congress that the program would be solvent for 75 years.

During the course of the time between the time that the Class Act was passed and the time that we announced that we could not make that certification, there were numerous negotiations with all kinds of stakeholders, not just advocacy groups but insurers and

actuaries, looking at all sorts of modeling possibilities for whether or not there was a scenario under which we had both a legal authority and could justify the financing that would, indeed, allow this program to be up and running.

They were fully reported to the committee when those studies were concluded. We did not make reports before the studies were concluded because, frankly, we didn't know what the conclusions were. I think they're very transparent, very above board. And, at the end of the day, without major legislative changes what we concluded was that the program designed to help people who wanted to stay in their own homes and provide their own care services out of a stream of income, was not able to be either certified as solvent or if, indeed, the premiums were high enough to make the program solvent, it wouldn't serve the people it was designed to serve.

So that is the report I made to Congress; it is the report I made to the President. And I don't think there is anything inconsistent about either of those statements.

Ms. FOXX. Well, I also understand that Congressman Boustany sent you a letter, which I am going to make a part of the record here, asking for a correction of the record of those statements and that you have not yet replied. It appears that you have a pattern, is this—as the Chairman said in his opening comments; it has taken us 10 months to get an answer from your department on information.

What do you see as the responsibility of the Executive Branch to respond to members of Congress? And what do you think is a reasonable time, given the huge bureaucracy that you have here, to submit answers to questions that are given to you on things that should be readily available?

Secretary SEBELIUS. Well, Congresswoman, we make every effort to respond in a fashion and, also, to gather the information requested. It probably doesn't come as a big surprise that we get hundreds and hundreds of requests, often for thousands of pages of documents, and we have a lot of staff who do nothing else but gather documents, look at documents, try and be responsive.

So we are on a full-time, 24/7, trying to be responsive as questions come in the door. And make sure that the answers that we get you are accurate information. And we will continue to do that.

Ms. FOXX. Thank you, Mr. Chairman.

Chairman KLINE. Thank the gentlelady.

I understand she was requesting to enter Dr. Boustany's letter for the record.

[The information follows:]

CHARLES W. BOUSTANY, JR., MD
7TH DISTRICT, LOUISIANA

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March 6, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health & Human Services
200 Independence Ave., S.W.
Washington, DC 20201-0007

Dear Secretary Sebelius:

I write to follow up on our dialogue at last Tuesday's House Ways and Means Committee hearing regarding your Department's role in the CLASS program. When I asked you about quotes in a journal article suggesting your Department secretly negotiated changes to CLASS in early 2010, you gave the following response:

> "I have no idea who was in the backroom with whom, and making deals, because that was certainly nobody from our Department."

However, your testimony appears to directly contradict your own Department's report on the CLASS program. Specifically, Appendix H from that report includes various options examined by your Department to make CLASS solvent. One option on pages 10 and 11 of that appendix, entitled "Employment Earnings Amount," notes that a $9,000 per year income threshold for CLASS eligibility "will be consistent with what was negotiated with most of the advocacy organizations that lobbied for CLASS during the discussion of legislative fixes (though the fixes were not included in the final bill)." Further in that section, the same document notes that a $15,000 annual income threshold would be "a 'new' number that is higher than the $9,000 that was negotiated with the advocates and the Senate."

The CLASS report makes clear individuals from within the Administration negotiated "legislative fixes" to CLASS ***before*** the law was enacted, despite the fact those changes were never incorporated into the final law. These statements are entirely consistent with Howard Gleckman's article in the December 2011 issue of Health Affairs, in which Mr. Gleckman writes: "the Obama Administration quietly negotiated a series of legislative fixes to the law...aimed at maintaining the long-run stability of CLASS."

I am greatly concerned by the yawning gap between your testimony last Tuesday and the report your Department previously released. At best it suggests your lack of familiarity with the details of your Department's operations – a troubling sign, given your integral role in implementing the

President's 2700-page health care law. At worst it is indicative of a distinct lack of candor, and potentially a desire to mislead Congress.

Therefore, in order to set the record straight, I hope you can answer the following questions:

1. Do you stand by your testimony of February 28, 2012, that no one – not a single person – from within your Department was involved in negotiations regarding a package of legislative changes to the CLASS program with outside advocacy groups, Congressional staff, or both?
2. If yes, why does Appendix H in the CLASS report specifically reference Administration negotiations "with most of the advocacy organizations" in an attempt to change the CLASS program before the health care bill was signed into law?
3. If your Department did not negotiate legislative changes with advocacy organizations and the Senate, who in the Administration did?
4. Why are these negotiations the Administration undertook regarding CLASS not mentioned ***at all*** in any of the CLASS-related documents that have thus far been provided to Congress?
5. Where are the documents germane to these secret negotiations the Administration undertook regarding the CLASS program?
6. In an internal document dated January 4, 2010, your Department noted that "it is possible the authority in the bill to modify premiums will not be sufficient to ensure the program is sustainable." When it became clear that the package of negotiated changes to CLASS would not be included in the final version of the health legislation, why did you and your Department not raise these significant concerns about CLASS' solvency publicly ***before*** Congress voted to enact the legislation?
7. Was anyone within your Department, or anyone within the Administration, instructed not to provide information to Congress about the serious solvency concerns the Administration recognized in its January 4, 2010 internal memo?

As I mentioned during last Tuesday's hearing, I find your Department's responses to our prior inquiries disconcerting. That someone within the Administration negotiated a secret package of changes to the CLASS program before the health care law was enacted shows the Administration knew all along this program was unsustainable. That the Administration chooses not to release the documents surrounding those negotiations makes me question whether there was a deliberate "conspiracy of silence" regarding CLASS, whereby HHS staff and/or outside advocacy groups were instructed not to reveal the near certainty that CLASS would prove unsustainable, for fear that doing so would jeopardize passage of the entire health care law.

It is critical that the record be set straight as soon as possible, and that the documents my

colleagues and I first requested nearly one year ago finally be transmitted at the first possible instance. Therefore, I ask you provide a response to my questions, along with ALL appropriate documentation, within two weeks.

If you have any questions, feel free to contact Mike Thompson of my staff at (202) 225-2031. Thank you in advance for your time, and I look forward to hearing from you shortly.

Sincerely,

Charles W. Boustany, Jr., M.D.
Member of Congress

Chairman KLINE. Without objection, we will do that.

Mr. Scott?

Mr. SCOTT. Thank you, Mr. Chairman.

Thank you, Madam Secretary. Madam Secretary, in the Chairman's opening remarks, he talked about the effect that the ACA has on small businesses and suggested that there would be a devastating impact on small businesses when it comes into effect. I thought small businesses were exempt from the mandates, is that right?

Secretary SEBELIUS. Yes, Congressman, certainly businesses under 50 have no employer responsibility under the Affordable Care Act but they are eligible for tax credits. So they are—many

small business owners are taking advantage of the tax credits, which allow them to pay for employee-based health care.

Mr. SCOTT. So, let us slow up a minute—first of all, they are exempt. But if they voluntarily elect to provide insurance, there are tax credits that they would not be eligible for, but for the ACA, is that right?

Secretary SEBELIUS. There not only are tax credits but, in 2014, when the new exchange markets are up and running, the estimate is that small business owners will be one of the major beneficiaries, given the fact that right now they are often paying 15 to 18 percent more in the private market for health insurance plans because they don't have the large numbers to negotiate rates.

They will be able to pick and choose out of a plan that puts them in a much larger pool, without having to change anything.

Mr. SCOTT. And, so, they are exempt. And, if they provide insurance, they have got tax credits. And, if they provide insurance, they will be able to get it at a cheaper rate because they will be in a—get the big group markets rather than the small business rate. And, if they elect not to provide insurance because they are exempt, would they have access to insurance that they would not have, since their employer doesn't provide it?

Secretary SEBELIUS. Well, currently, as you know, Congressman, if an employer chooses not to provide coverage for employees, employees are, pretty much, on their own; they and their families are shopping in the individual market, the——

Mr. SCOTT. That is today?

Secretary SEBELIUS. That is today. In the future, after 2014, those employees would be eligible, again, to participate in an exchange marketplace, be part of a larger pool, no pre-existing condition limitations, able to take advantage of tax credits, depending on their income, to pay a portion of their health plan. Right now, those employees are paying 100 percent out-of-pocket, which is often why a lot of working Americans have no coverage at all.

Mr. SCOTT. So you disagree with the idea that this is bad for small business and would, instead, say this is actually good for small business?

Secretary SEBELIUS. Well, I think, that at least the—I have an opportunity to visit with small business owners around the country. And what I hear from them is that having health insurance is often one of the best ways to recruit and retain high-quality employees. And that, time and time again, they lose those employees to either larger competitors or folks who can afford a better plan and a better package.

And I would say that the small business market has disintegrated and not because of the Affordable Care Act. But it is on a death spiral; more and more small business owners have dropped coverage as rates have skyrocketed. So that we see this as not only stabilizing of the market, but giving some advantage to the entrepreneurs and small business owners who currently are out on their own trying to negotiate rates.

Mr. SCOTT. Thank you. As you know, we are going to consider the student loan interest rate and there is a proposal to cut prevention funding. Are you familiar with that proposal?

Secretary SEBELIUS. I am.

Mr. SCOTT. And exactly what would be cut if that offset is the one chosen?

Secretary SEBELIUS. Well——

Mr. SCOTT. And why is that important? Why is that funding important?

Secretary SEBELIUS [continuing]. I think that the Prevention Fund is a long overdue investment in some of the most significant efforts to keep our country healthy and well. It is a significant program to immunize our kids. What we know is that is an investment that returns about $10.00 for every dollar invested. It is a public health investment with laboratory capacity at the state and local level.

We know that public health officials around the country would be laid off, reduce the availability of mental health and substance abuse. Some of the efforts around tobacco prevention and cessation, which can save thousands of lives, would be eliminated and discontinued. And, you know, right now, Congressman, America spends about eighty cents of every health dollar on dealing with chronic disease and illness and about eight cents of every health dollar on any kind of preventive effort.

I think we are a great country. I think we can educate our kids and invest in health at the same time. And I think failing to invest in long-term strategies that will lower our health care costs, doom future generations to paying higher and higher health bills and getting mediocre results.

Chairman KLINE. The gentleman's time has expired.

Dr. Roe?

Mr. ROE. Thank the Chairman and thank the Secretary for being here today.

And I think you and I totally agree that the single biggest issue preventing people from buying health insurance in this country, or having health insurance, is cost. I saw it in my practice. And, then, we had a group of people in our nation that couldn't afford it because it cost too much. And that has been a great concern of mine is that—does this plan reduce the health care cost spending in the country?

And we have held our Subcommittee on Health, Employment, Labor and Pensions—has held two subcommittee hearings, one in Evansville, Indiana and one in Butler, Pennsylvania, just a couple of months ago. And, let me share with you just some stories that I heard during these subcommittee hearings. And, really, someone from the Administration should attend these and listen.

Just last week in my office, a young person, Peter Demos, from Murphysboro, Tennessee,—has five restaurants in his family and he has evaluated the Affordable Care Act and the Accountable Affordable Care Act. And he believes he has about 100—150 employees per restaurant. He is thinking about opening another restaurant in Clarksville, Tennessee, where I grew up.

He said because of the cost of this—and he has had it analyzed—he is not going to open his Clarksville shop until he finds out what the Supreme Court does. And he has two restaurants that are marginal; sometimes they make a little money, sometimes they don't. But the others have supported his business. He is going to close

those two restaurants. So we are looking at three to four hundred jobs with one person that is going to go away.

Another IHOP owner in Evansville—he had 12 shops, 800 employees—"Dr. Roe," he said, "What do I do here? If I buy the essential benefits package, of which we don't know what it is just yet, and I pay for that for all of my employees, I am upside down $7,000 per employee. But if I pay the penalty of $200,000, because I have more than 50 employees, which is not tax-deductible, it costs me $2,800. In this business," he said, "I make $3,000 per employee," which is pretty good, I think, in that restaurant business, "it cost me all my profit."

I didn't have an answer for him. Do you have an answer for either one of these owners? What do they do?

Secretary SEBELIUS. Well, Dr. Roe, I think that there is no question that cost has eroded the private health insurance market over time. What we know is costs are up over the last decade about 115 percent, which is why more and more business owners have dropped coverage and, particularly, small business owners and individuals. It is why we have about 50 million uninsured Americans today.

And those costs continue to skyrocket with——

Mr. ROE. How do you——

Secretary SEBELIUS [continuing]. No end in sight.

Mr. ROE. How do you talk to these restaurant owners? We know all that—what you said are facts, I agree with that. But how do you—what do you say to these folks that own these—and I could go on and on with stories that I heard in these hearings that we held. I didn't have an answer for them.

Secretary SEBELIUS. Well, I think, first of all, there is not a cost associated yet with the plans in the new exchanges because they haven't been priced and packaged. That is—I don't know what they are estimating but there is no costs. There is no——

Mr. ROE. There is a cost but no one has said what it is yet.

Secretary SEBELIUS. Well, we don't have a cost estimate by the insurance plans who will be offering these programs. That will become clear as we move forward. But, I think, the estimate is there is—based on no cost of doing nothing, there are employees right now who are opting in and out of these programs because of health insurance benefits that, often, these employers can't compete with. There are employees who can't come to work because they don't have access to health care——

Mr. ROE [continuing]. I hate to interrupt you, but what do these folks say?

Secretary SEBELIUS. Those costs are employer——

Mr. ROE. Look, I am an employer. I have been an employer for over 30 years. I understand all that. And that is one of the things a good health insurance plan allows; people to come into your business and retract them and keep them. I certainly understand that but how do you answer these folk's questions that are going to close businesses and close down jobs?

We will go on. The question I have, also, is why do you still think the majority of Americans oppose the Affordable Care Act? And, secondly, almost 80 percent oppose the mandate, why do you think that is?

Secretary SEBELIUS. I think there are still lots of misconceptions about what the Affordable Care Act does and doesn't do that we are working to correct. I do think for a lot of people they have no idea what this is; they have health insurance, they are uncertain about how it is going to impact them and their family, and they really want to know "what happens to me."

We have had some considerable success with seniors who were, frankly, terrified during the course of the debate, told that Medicare Advantage plans would be done away with, that their premiums would skyrocket, that they would lose their doctors, that they couldn't access hospital; none of that has happened; none of that is accurate and, in fact, they are beginning to take advantage of the benefits offered. And that begins to change people's minds.

So, once people connect with the benefits—I can tell you parents across this country who have young adults who are on their family health plan know the benefits of the Affordable Care Act. There are moms I see every day who have a child born with a pre-existing health condition, who knows that that child will never be locked out of the insurance market again. And that has provided peace of mind to those parents.

So, as people begin to connect with the benefits, we are finding that their attitudes dramatically change.

Mr. ROE. Mr. Chairman, can I submit some questions to her that would be——

Chairman KLINE. For the record?

Mr. ROE. Yes, sir, for the record.

Chairman KLINE. Yes, please, that would be fine.

Mr. Tierney?

Mr. TIERNEY. Thank you, Mr. Chairman.

Thank you, Madam Secretary, for being here today.

Secretary SEBELIUS. Good morning.

Mr. TIERNEY. You are painfully aware, I am sure, this is a national debate that we are having with respect to the budget and reconciliation measures that are there, surrounded a lot about feelings that, you know, we can still give more money to the wealthy at the expense of struggling families, children and seniors. And not ask any in that category of "wealthy" to participate their fair share.

And not look at the whole budget, just look at narrow portions of it, and not really focus on growth in jobs. And some, you know, have put forth this concept of subsidiarity or try to rationalize the Republican budget and some of these reconciliation bills. So I would like to read a letter into the record, if you will indulge me, and then ask you some questions about it.

This is a letter from a sizeable number of theologians and religious scholars who were writing to the budget author for the Republican budget, Mr. Paul Ryan. They are welcoming him to Georgetown University, appreciating his willingness to talk about Catholic social teaching policy and dealing with urgent challenges facing the country.

They cite themselves as members of the academic community at a catholic university. And they saw his visit, which was on April 26 for election series, as an opportunity to discuss the Catholic social teaching in a role of public policy because he had talked about subsidiarity.

They go on to say, "However, we would be remiss in our duty to you and our students if we do not challenge your continuing misuse of Catholic teaching to defend a budget plan that decimates food programs for struggling families, that radically weakens protections for the elderly and the sick and gives more tax breaks to the wealthiest few."

This United States Conference of Catholic Bishops has wisely noted, in several letters to Congress, quote—"A just framework for future budgets cannot rely on disproportionate cuts in essential services to poor persons." Catholic bishops recently wrote that the, open quote—"The House-passed budget resolution fails to meet these moral criteria."

In short, the letter says, "your budget", referring to Mr. Ryan, "appears to reflect the values of your favorite philosopher, Ayn Rand, rather than the gospel of Jesus Christ. Her call to selfishness and her antagonism toward religion are antithetical to the gospel values of compassion and love. Cuts to the anti-hunger programs have devastating consequences. Last year, one in six Americans lived below the official poverty level and over 46 million Americans, almost half of them children, used food stamps for basic nutrition.

We also know how cuts in Pell grants will make it difficult for low income students to pursue their educations at colleges across the nation, including Georgetown. At a time when charities are strained to the breaking point and local governments have a hard time paying for essential services, the Federal government must not walk away from the most vulnerable. While you offer an appeal that Catholic teachings subsidiarity as a rationale for cutting government programs, you are profoundly misreading church teaching.

Subsidiarity is not a free pass to dismantle government programs and abandon the poor to their own devices. This often misused Catholic principle cuts both ways; it calls for solutions to be enacted as close to the level of local communities as possible, but it also demands that higher levels of government provide health subsidium, when communities and local governments face problems beyond their means, to address such an economic crisis—high unemployment, endemic poverty and hunger.

According to Pope Benedict XVI, subsidiarity must remain closely linked to the principle of solidarity and vice versa, and it is signed by almost 90 people that are theologians and people——

So, Madam Secretary, my question for you is—in the budget proposal by the Majority, I think voted on by all of their members, that would cut $1.5 billion, according to the Office of Management and Budget, from Head Start. In your estimate, would that cut 60,000 low-income children out of the program next year and 200,000 out of the program by 2014?

Secretary SEBELIUS. Yes, it would, sir.

Mr. TIERNEY. And in childcare, that budget would mean a substantial cut to childcare assistance for more than 1.8 million, low-income, working families who depend on it to try to get and keep jobs. By your estimate, would that be 60,000 families losing assistance next year alone?

Secretary SEBELIUS. I think about 65,000.

Mr. TIERNEY. And on the Social Service Block Grant, that bill eliminates funding that would provide services like Meals on Wheels and childcare to 23 million children and seniors and Americans with disabilities, is that your estimate as well?

Secretary SEBELIUS. Yes, sir.

Mr. TIERNEY. You know, the Childcare Tax Credit, which used to be a bipartisan measure, Republican bill would end the refundable tax credit for families of 3 million children and increase taxes for those families by an average of $1,800 a year. By your estimate, would that tax increase fall on the backs of children from low-income families?

Secretary SEBELIUS. I think that is correct, sir.

Mr. TIERNEY. And the Supplemental Nutrition Assistance Program, that bill—the Republican bill, would cut $33 billion from that program. Would that affect approximately 2 million individuals, disproportionately from working families and seniors?

Secretary SEBELIUS. I would have to defer to Secretary—for those numbers; that is not in our budget. But that sounds about correct.

Mr. TIERNEY. All right. And, if the health care budget were to be entirely—the Program B, be entirely repealed, as some propose, 32 fewer million Americans would get health insurance, is that right?

Secretary SEBELIUS. That is correct.

Mr. TIERNEY. And 2.5 million young adults who are now covered by their parent's plan would lose that coverage?

Secretary SEBELIUS. Yes, sir.

Mr. TIERNEY. And 105 billion Americans would, once again, be subject to lifetime limit caps on their health insurance?

Chairman KLINE. The gentleman's time has expired.

Mr. Walberg?

Mr. WALBERG. Thank you, Mr. Chairman.

And welcome, Madam Secretary. NIOSH and the NCI issued a press release addressing the results of the Diesel Exhaust and Miner Study; this study has been very controversial, I think we all could agree, especially some of its conclusions. I'm going to expand on what my colleague from Illinois addressed a bit earlier.

This study concluded that diesel exhaust exposure of a surface mine produced higher risks of adverse health effects than to underground miners, with much higher levels of exposure. It also—and that is interesting that would be the case above-ground versus underground. It also concluded that heavy smokers, with the highest diesel exhaust exposures, have a lower risk for lung cancer than miners who didn't smoke; another peculiar finding of this study.

This study was also the subject of a 2001 court order that requires the agencies involved to provide all data requested by this committee. Now, to date, this still hasn't happened, including requests made by Chairman Kline and myself, on three separate occasions, including at a hearing where you were with us almost a year ago.

Furthermore, it took you an entire year to just reply, incompletely, to the question that we have asked last year. Now, these agencies have not provided all of the materials—why, Madam Secretary?

Secretary SEBELIUS. Well, Congressman, NIOSH is in compliance with both the court order and, my understanding is, what the com-

mittee has asked for. The underlying data has to be, according to the court order, submitted to the committee and then can be released. CDC and NIH will make the data publicly available after the 90-day review period of the committee is completed, in accordance with the court order.

So we have published the first set of papers, delivered the underlying data—we now have, in the committee's hands—your hands, the second data request. We cannot make it transparent and public until the committee's review is completed.

Mr. WALBERG. Well, I, respectfully, beg to differ with that. As far as the information we have requested, it has been willfully incomplete and inadequate to address the concerns that we, respectfully, submitted to you. Let me——

Ms. WOOLSEY. Will the Gentleman yield to your——

Mr. WALBERG. Briefly, I would yield.

Ms. WOOLSEY [continuing]. Ranking member?

Mr. WALBERG. Briefly, I would yield.

Ms. WOOLSEY. For the record, we do have a letter here that is dated March 26, from the department, responding to those questions, that I would like to introduce into the——

[The information follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

March 26, 2012

The Honorable John Kline
Chairman
Committee on Education and the Workforce
U.S. House of Representatives
2181 Rayburn House Office Building
Washington, DC 20515

The Honorable Tim Walberg
Chairman
Subcommittee on Workforce Protections
Committee on Education and the Workforce
U.S. House of Representatives
Washington, DC 20515

Re: National Cancer Institute/National Institute of Occupational Safety and Health Study of Diesel Exhaust Health Effects in Miners

Dear Chairmen Kline and Walberg:

This is in follow-up to my December 30 letter. As requested by the Committee, enclosed please find research data underlying the final three papers involved in the Diesel Exhaust Health Effects in Miners Study (Diesel Study) conducted by the National Cancer Institute (NCI) of the National Institutes of Health and the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention. As you know, on December 2, 2011, we provided the Committee with drafts of these papers for a 90 day review period, as required by the September 14, 2011 order issued by the Fifth Circuit Court of Appeals. The final three papers were published on March 2, after the completion of this review period. Two papers were published in the *Journal of the National Cancer Institute*, and one paper was published in the *Annals of Occupational Hygiene*. For your convenience, I have enclosed copies of these papers. As you know, the publication of these papers is the culmination of a twenty year study examining exposure to diesel engine exhaust in about 12,000 miners. The Diesel Study found an increased risk for lung cancer death with increasing levels of exposure to diesel exhaust.

The Honorable John Kline
The Honorable Tim Walberg
Page Two

Consistent with the terms of the Court orders, and to protect the privacy interests of the miners who agreed to participate in this study, we are providing the data to the Committee in de-identified form for a 90 day review period. After completion of this review period, NIOSH and NCI, consistent with standard practices, will make the data set available to all interested researchers pursuant to data use agreements to protect the subjects' privacy interests.
We appreciate the Committee's efforts to safeguard the data and draft papers that we have previously provided, and will continue to work with your staff to respond to any additional questions you may have.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Enclosure

cc: The Honorable George Miller
Ranking Member
Committee on Education and the Workforce

cc: The Honorable Lynn Woolsey
Ranking Member
Subcommittee on Workforce Protections
Committee on Education and the Workforce

Mr. WALBERG. And I re-claim my time—I indicated that we received a response but, willfully, inadequate and incomplete. Let me go on to a next issue, Madam Secretary.

I can't believe that you believe that it is appropriate for the diesel study author to travel to France to request international government organization, in this case IARC, which is International Agency for Research on Cancer, to issue a finding that diesel exhaust should be labeled as a known human carcinogen. Can I assume that to be an accurate understanding, that you wouldn't believe this would be appropriate for the author, an author of this study, to do such a thing?

Secretary SEBELIUS. Congressman, my understanding is that the World Health Organization is organizing a meeting in France. The International Agency on Research on Cancer—I have no prior knowledge about what is the testimony that will be presented but I do know that the researchers have been invited. We are very committed to sharing information and research findings with the World Health Organization. The United States is a very active member of that organization so I assume the researchers will participate.

Mr. WALBERG. Recognizing the time here, the concern would be, for me, that the IARC's findings trigger automatic U.S. government regulatory consequences for employers that cost millions of dollars to comply with. And I find it very unfair that, when those same regulated entities, like small businesses, don't have a way to comment on IARC proceedings, that they are, in fact, blocked from participating, this is really back-door rulemaking. And can you condone the practice——

Chairman KLINE [continuing]. I am sorry; the gentleman's time has expired.

Secretary SEBELIUS. But, Mr. Chairman, could I respond? Because what has just been stated is just absolutely not correct.

Chairman KLINE. Please.

Secretary SEBELIUS. There is no international finding that automatically triggers anything. We have the responsibility, under the Centers for Disease Control and NIH, to produce findings about likely carcinogens and proven carcinogens. That doesn't even trigger an automatic finding; that, really, is within another department's jurisdiction. So we do the science, we publish the science. We have the responsibility for making that available.

There are other agencies, the Environmental Protection Agency and others, who actually trigger the regulatory responses. And they are not automatically triggered; they go on that agency's line-up list. So I have no idea. The International agency for Research on Cancer, to my knowledge, Congressman, has no impact, whatsoever, on an automatic triggering on anything that would impose any regulatory requirement——

Mr. WALBERG. Mr. Chairman if you might indulge me, I disagree with that but I am willing to be proven wrong. But we will follow this up with the Secretary——

Secretary SEBELIUS. I would be happy to.

Chairman KLINE. Thank the gentleman.

Thank you, Madam Secretary.

Mr. Holt?

Mr. HOLT. Thank you, Mr. Chairman.

Thank you, Madam Secretary. It was earlier mentioned by one of our colleagues that there are so many uncertainties now in the health care field. I would just comment that the uncertainties that existed before the Affordable Care Act was passed were even greater. I mean, you know, where do 40 million people go for their health care and how will we redirect health care in America toward wellness and health outcomes? And how will we handle additional families trailing into bankruptcy by bad luck of illness or injury?

But two things that were not uncertain before the health care law was passed was health care costs in America would go up 8 percent a year, or more, and insurance companies would spend a

smaller and smaller fraction of the premiums that they collect on actually providing health care. And, with regard to the cost, there is an article by economist Peter Orszag in Bloomberg, that points out that health care spending in the past year rose by 4 percent. Now, that is high but that is half of what it used to be.

And he says that this is not just because of economic reasons but it is because of structural reasons, with doctors and hospitals cutting back on unnecessary procedures, expanding their use of information technology, switching from fee-for-service to compensation, aimed at maximizing quality of treatment, and so forth. Do you, in fact, see some changes in health care costs already because of the Act?

Two other things that I would like to ask you about on this subject is—the health care law provides assistance to states in doing rate review. And I am wondering whether State insurance commissioners and others are beginning to use that information. Further, I would like to ask if you have data that show that this medical loss ratio of 80 or 85 percent is about right or is this subject to further review.

I have other questions but if you could answer those quickly, I would appreciate it.

Secretary SEBELIUS. Well, Congressman, I can tell you that the major program that we are in charge of, probably the largest insurance program in the world, Medicare, which has about 49 million beneficiaries, was on a trend line growing at about 8 percent a year. And that rate of growth definitely has been slowed in the last two years.

We are now at about 6.3 percent and the Trustee has certified the fact that that trend line is largely due to changes in the Affordable Care Act. And I think we can monitor that very closely. We do know that the rate review efforts underway in states around the country have been very beneficial. Time and time again, not only have insurance departments taken advantage of the encouragement to use some of the rate review funding to hire additional actuary staff, go to their legislators to request additional ability.

As a former insurance commissioner, I know how important it is to have prior approval authority. So a company has to come through an insurance department process and——

Mr. HOLT. And would you say these will begin to have a——

Secretary SEBELIUS. They are having effects.

Mr. HOLT [continuing]. Noticeable effects?

Secretary SEBELIUS. We are watching rates be reconsidered, pulled back, reduced in states. And the 80-20 Rule—the medical loss ratio, I think, we will have pulled that shortly. But we have been monitoring it closely and beneficiaries will be getting rebate checks this year from companies who have not spent 80 percent of their dollars on health care costs.

Mr. HOLT. Let me change to something else. In answer to Mr. Scott's question, you talked about the Prevention Fund. It has been called, by the Speaker, a "slush fund."

Secretary SEBELIUS. Yes, yes.

Mr. HOLT. Could you specifically say what this means for CDC, what this means for actual treatment? And, I believe, there is a particular benefit for women.

Secretary SEBELIUS. I am sorry, can you——

Mr. HOLT. Prevention Fund.

Secretary SEBELIUS. Certainly. Well, I think, the Prevention Fund, again, is an enormously important effort that is long overdue. And you have talked about some of the—we have talked about some of the programs but, additionally, HIV/AIDS efforts have been enhanced; the, kind of, community transformation grants, which are really focused on systematic changes in 61 states and communities across the country; and a whole series of efforts to actually enhance critical programs to screen uninsured women for breast and cervical cancer; and tracking, and prevention of, birth defects, are part of the Prevention Fund efforts that are making a big difference.

Chairman KLINE. Thank you, Madam Secretary.

The gentleman's time has expired.

Dr. DesJarlais?

Mr. HOLT [continuing]. For the record, if I may?

Chairman KLINE. Yes, certainly.

Mr. HOLT. Thank you.

Mr. DESJARLAIS. Madam Secretary, I really appreciate your being here today and appreciate this opportunity to speak with you about some very important issues. I know we have spent a lot of time, over the past two years, arguing whether or not "Obamacare" is good, "Obamacare" is bad—you know, whose fault is it that various provisions aren't working out the way they are supposed to be.

But what I would really like to discuss with you today, and see if you would agree on one fact—that Medicare, according to CBO, Republicans, Democrats, AARP, is going broke in 10 years. Can we agree on that fact?

Secretary SEBELIUS. The Trustees Report said that the funds will be exhausted, which means they will only be about 70 percent of the finances by 2024.

Mr. DESJARLAIS. Okay, so you would say 12 years; that is not far off. We have another looming problem at the end of the year and that is the SGR, or the "doc fix." We were looking at a 27 percent cut in pay to physicians.

And I know, in my district, there are already concerns among seniors that it is getting more and more difficult to find access to physicians. And, in your opinion, what do you think will happen if that 27 percent cut is put in place next January?

Secretary SEBELIUS. Unfortunately, Congressman, those numbers are a little low too; it is a 31 percent pay cut. And I think it would be enormously devastating to Medicare beneficiaries, who would lose their doctors, which is why the President has called for, every year, a permanent, long-term, fix to the SGR and would love to work with Congress to do just that, as opposed to kicking this can——

Mr. DESJARLAIS. Okay.

Secretary SEBELIUS [continuing]. Two inches down the road.

Mr. DESJARLAIS. And it would cost about $300 billion to just bring us back to even from the plan's implementation back in 1997, is that right? We are about $300 in the hole?

Secretary SEBELIUS. Yes——

Mr. DESJARLAIS [continuing]. Okay, so we have got to come up with $300 just to pay for the past decade-plus. So, moving forward, not making that cut is going to be very expensive. We have got, about, a $500 billion cut to Medicare in the form of the IPAP. We are rapidly not looking very efficient and, yet, we have this huge, looming problem of, you know, 10,000 new Medicare recipients entering the program every day.

I am talking with you today because we need to solve this problem. It doesn't matter which side of the aisle you sit on, we all have parents, grandparents, maybe we are of Medicare age ourselves. So you said the President wants to work on an SGR fix. I would be happy to work with you. Our doctor's caucus would be happy to work with you.

We have got to solve this problem because these numbers are hard to even comprehend. And I just wondered what ideas you might have for us.

Secretary SEBELIUS. Well, Congressman, I think that that would be encouraging. I think that, as you know, the SGR well pre-dates any discussion in 2010 and 2009 about an Affordable Care Act. It has nothing to do with it. It is based on the Balanced Budget Act. And, I think, fixing that in the long-term, looking at new ways to actually pay docs, is an important thing going forward.

I would also just suggest that the $500 billion is not a cut to Medicare; it is an estimated slowdown in the growth rate, which we are seeing right now. That is where the $500 billion comes from. So Medicare costs will continue to rise, largely, as you say, because we have the beginning of the "baby boomers" coming into Medicare, more beneficiaries than ever.

Mr. DESJARLAIS. Okay, let us shift just for a minute because, you know, we are obviously not going to solve that problem. To the issue of employers dumping their employees into the insurance exchanges. I have visited with several businesses in my district and I will just give a quick example of Belmont Industries—has about 6,000 employees so they would fall into the $3,000 penalty.

Right now, they pay about $12,000, per employee, for their health care benefits. So they would, literally, save about $9,000, per employee, and $34 million. You know, clearly, they would be rewarded for dumping these employers—or these employees into the exchange. What—what do you think the impact is going to be as we see this trend moving forward?

Secretary SEBELIUS. Well, again, Congressman, the only real-life example that we have to look at has been the Massachusetts example, where the exchange program, the employer penalty and the subsidy, has provided a template for the Affordable Care Act. What happened in Massachusetts is more employers actually offer coverage today than did when the exchange started. They have not dumped employees. They have similar incentives in place.

If one would speculate—we have a totally, as you know right now, voluntary market, where insurers—I mean, employers voluntarily are participating in an increasingly expensive and hard to predict insurance market. My sense is, based on the real-life model that is up and running, based on conversations with employers as we move along, that these same kind of incentives, keeping, retain-

ing good employees around health care, will be in place in the future.

And that employers will, actually, have an incentive to come back in the market because there will be a larger pool, no pre-existing conditions, they won't be penalized for being small employers, and they will have market rates that they can control.

Chairman KLINE. The gentleman's time has expired.

Ms. Fudge?

Ms. FUDGE. Thank you, Mr. Chairman.

And, thank you very much, Madam Secretary, for being here and to continue to show your knowledge of the Affordable Care Act and why it was so important that this Congress passed it. I, certainly, am concerned, though, about the recent reductions to Medicare payments and the effect that they will have on safety net hospitals, in particular. And the people that are served by safety net hospitals, of which, certainly, I have two, fairly large, ones in my district.

The Middle Class Tax Relief and Job Creation Act was the latest piece of legislation to make it to the President's desk with significant reductions in Medicare payments for hospitals. And then there is the cut proposed in the President's budget, where the Administration proposes to reduce bad debt payment to 25 percent of the current 70 percent for all—from the current 70 percent for all eligible providers, including safety net hospitals.

And this is done in order to save some $36 million over the next 10 years. The Medicare payment cuts included in the Payroll Tax bill and the payment cuts proposed in the President's budget, come on top of the sequester, where hospitals will see a 2 percent cut in their Medicare reimbursement for the next nine years.

Safety net hospitals serve as America's first line of defense for treating low-income and uninsured patients. Without a doubt, these cuts will adversely affect already financially weak safety net hospitals and the people they serve. Metro Health, which is in my district, is a safety net hospital that needs our support and not cuts.

So my question is—why does it seem as though the Administration and this Congress are targeting the health care providers that can least afford it? And I want to ensure that safety net hospitals will be able to continue to meet the health care needs of the communities they serve. So could you just elaborate for me the thought process here and what is the plan going forward for safety net hospitals?

Secretary SEBELIUS. Well, Congresswoman, I share your interest and concern about safety net hospitals who provide critical care in some of our most underserved areas. I think that the President shares that concern and we want to find ways to both reduce health care costs but, at the same time, not jeopardize that critical safety net.

I would look forward to working with you on some specific issues that you find troubling in the budget. I do think that we are trying to find a balance of areas where there may have been opportunities to reduce overall payment levels and not jeopardize the quality of care. And that is really what we are trying to find is that right bal-

ance. But, certainly, the provision of quality health care to underserved areas continues to be a very high priority.

Ms. FUDGE. I would, certainly, look forward to continuing the conversation with you. The second question is—there were workforce demonstration projects, of course, as a part of the legislation. Now, these projects will, in fact, help low-income individuals, receiving training and entering health care professions, which you mentioned earlier in your testimony.

Can you update the committee on the progress that has been made as a result of these projects? And, if you would, please highlight any specific goals HHS has regarding increasing the number of health workforce professionals. And, finally, please update me on any other dedicated funding that will address health workforce shortages.

Secretary SEBELIUS. Certainly, Congresswoman. I think that the President, from the outset, recognized that additional health insurance and more affordable, available health insurance was a piece of the puzzle. But, without a competent, trained and appropriately placed workforce, it would be a huge misconnect between people who now have access to health care and that access.

So, from the outset, really starting with the Recovery Act, there has been an effort to look at workforce training. We have tripled the number of National Health Service Corps members in the last 3 years. And those members are nurse practitioners, docs, mental health techs, dentists, who are then placed in underserved areas in return for helping to pay down their student loans and student debt. A kind of win-win situation.

There is a stream of funding specifically to recruit health workers out of minority communities that is new, thanks to the Affordable Care Act, and one that we are actively working on under the jurisdiction of the Health Resources and Services Administration. We are re-looking at what is defined as underserved areas to make sure that we have the most accurate data.

So that, as new workers come around, we are working to re-designate graduate education slots to focus on primary care and preventive care and gerontology, areas that have been missing, so that we will be training more docs. The Affordable Care Act contains a couple of years of funding increases for doctors who serve Medicaid patients, paying them at the rate for Medicare patients, again, recognizing that the pay differential often is discouraging to health care providers serving in underserved areas.

So we are trying to look at everything from training and recruitment to slots to placement. The additional work, which is under——

Chairman KLINE. I am sorry to interrupt, Madam Secretary.

The gentlelady's time has expired.

Mr. Miller, you are recognized.

Mr. MILLER. Thank you, Mr. Chairman.

And I would just like to take a moment to recognize the presence in our hearing room today of Mr. Bill Payne, the brother of Donald Payne, our colleague on this committee and our colleague in the House.

[Applause.]

Mr. Bill Payne is a distinguished public service as—servant in his own right. Welcome, thank you so much and many of us had the opportunity—the Speaker sponsored a wonderful memorial service yesterday for Donald and many of us had the opportunity to participate with you and your family. And we grieve the loss of your brother.

Chairman KLINE. I thank the gentleman and I welcome Mr. Payne.

I agree with Mr. Miller, the Ranking Member, it was, indeed, a moving and memorable service yesterday and we are very glad to have you here today.

Dr. Bucshon?

Mr. BUCSHON. Good morning. The first question I have is can you—and, based on some previous questions, can you give me what you consider a definition of a "small business," because, based on some questioning from the other side, it seemed to me that your interpretation is that is 50 employees or less.

Secretary SEBELIUS. A small business is——

Mr. BUCSHON [continuing]. Well, because the question was asked what the effect on small businesses is with the Affordable Care Act, and you focused on the fact that employers with 50 or less employees would not be affected or have all of these credits and exemptions. So, based on that interpretation, I got the impression that you considered a small business people that have 50 employees or less. Because that is a different description of what constitutes a small business from what we all know is really the truth.

Secretary SEBELIUS. I don't have any starting place of a definition. I think I was asked were employers under that level exempted. And my answer was yes.

Mr. BUCSHON. Well, the question was small businesses and so my argument is that, yes, that is true, what you said about 50 employees or less. But I would argue that small businesses actually incorporates a much larger group of employers. And I can tell you from experience, talking to business owners in my district, that the Affordable Care Act will have a dramatic negative effect on businesses.

And I know Dr. DesJarlais' questioning about employers dropping their insurance. At least in southwest Indiana, I talk to small business people all the time that provide health insurance and they all say they don't know anyone that they have talked to in southwest Indiana, I can speak for, that is not planning to drop their private health insurance for financial reasons and pay the penalty.

The next question I have is—you talk a lot about quality when you are talking about savings rather than cuts. And, so, I wouldn't—as a physician, I would like you to, kind of, tell me how an insurance company controls quality of health care. Because in my view, the quality of health care comes at the provider level and the insurance company, essentially, pays the bill.

And, so, when you talk about quality and making—you know, with these Medicare Advantage plans, and you are looking for quality plans, and that is why you are cutting payments to those; you are not saving anything, you are cutting payments to programs that seniors really like. How are these insurance companies improving the quality of the health care, itself? That is my question.

Secretary SEBELIUS. Well, I would, certainly, not disagree that quality health care is at the provider level. I think that what we are trying to do is stop overpaying for plans that are currently paid at a rate of about 107 percent of fee-for-service, with no differentiation in the outcome of those patients. So diabetes management is no different in a Medicare Advantage.

They may get a gym membership, they may get free glasses, but there is no apples to apples comparison between patients; there is no differential. So the additional financing is not providing additional incentives to providers who, actually, manage chronic disease better or help reduce preventable hospital stays, bundle care, coordinate care.

Mr. BUCSHON. But you would have to agree that these Medicare Advantage plans provide a service that seniors want and that is why they enroll in them. So, yes, they do get more services and better—you know, as you know, a health insurance policy—one policy isn't the same as the next. They cover certain things, they have got different co-pays.

I mean, you would agree, and I know being in the health care industry, it is a very, very complicated system that most of us don't really, truly understand. But I would argue that those programs provide more services, hence the reason that they are paid more. The last question is—can you describe your position on the "doc fix," so to speak; the dramatic cuts in provider payment.

But, then again, on your controlling the cost or savings, so to speak, you plan to limit reimbursement to providers based on, and I will read this, "rate of growth and productivity in the economy at large". So, if we would allow payments to go down under the formula, the SGR formula, or we cut payments—or allow the payments to come down, by limiting the growth, based on the general economy, I don't see the difference; it is the same thing.

Chairman KLINE. Excuse me; can we take that for the record, please? We are running—I am very mindful of your time, Madam Secretary. I have got other members to answer so if you could provide an answer to that for the record, please.

Secretary SEBELIUS. Sure——

Chairman KLINE. Mrs. Davis?

Mrs. DAVIS. Thank you, Mr. Chairman.

And, Madam Secretary, thank you very much for joining us today. I wanted to turn to one area of disease prevention, where we know that trying to quantify the outcomes are very, very important. A bipartisan group of us in the House and Senate have been working on approaches to decrease instances of Type 2 diabetes.

And, as you are aware, 79 million Americans have pre-diabetes, which puts them at risk in developing Type 2. And complications cost our nation somewhere in the area of about $218 billion every single year in health care costs. With about 25 percent population at risk, there is a national interest, I think, and I believe—I know how supportive you are in addressing these issues, in reducing the incidence of diabetes and having far better outcomes for people.

The health bill included bipartisan legislation to establish the National Diabetes Prevention Program, which builds on evidence-based methods to give individuals at risk, guidelines on how to pre-

vent Type-2 diabetes. And it is eligible for funding from the Prevention and Public Health Fund at HHS.

Do you see continuing our combating instances of Type 2 diabetes as a national priority? And do you see that funding for the National Diabetes Prevention Program must come out of the Prevention Fund? And, if that is the case, is it at risk if we, essentially, scrap funding for that Prevention Fund?

Secretary SEBELIUS. Well, I think, Congresswoman, you have just identified one of the clearly looming health threats, and present health threats, that is, I think, a target of the Prevention Fund funding. And we think diabetes efforts and, certainly, focusing on pre-diabetes to try and ensure that more Americans don't end up with diabetes in the long-term, is an effort that not only lowers costs but saves lives in the long run.

So we have, actually, not only invested—a number of the community transformation grant activities are focused directly on communities where there is a high prevalence of diabetes. And a number of the Beacon Community efforts, with some of the Electronic Health funding, are focused on diabetes efforts.

We have special projects being run in tribal communities, where the diabetes rates are even higher than in the general population. And I would say that the Prevention Fund is an underlying health funding stream for just the kind of efforts that you are describing. And, of course, it would be at risk if the Prevention Fund is eliminated because there are no funds available, often, at the state and local levels. So this would continue to be a huge problem.

We also have a Million Hearts effort, where we are trying to have partnerships with not only health care providers but some of the major drug companies, and others, around disease management issues that we think could save people from strokes and heart attacks in the future if we focus on some of the underlying causes of blood pressure control and cholesterol issues, that often also present themselves in diabetes care.

So having those strategies in place, having Medicare, frankly, invest in prevention efforts—Medicare used to, you know, pay for an amputation but not for diabetes screening. Those screenings are now available without co pays and, we think, that is a huge step forward.

Mrs. DAVIS. Yes. If, in fact, we were to really target that fund, are there any other ways that those issues would be addressed?

Secretary SEBELIUS. Well, I think that it is very difficult, often, to have people in particularly difficult budget times, but even in good budget times, look at investments in longer term strategies. It hasn't happened in the past. I am not very confident it would happen in the future, in spite of the fact that we pay the health results every day and we pay the costs for them.

Mrs. DAVIS. I really appreciate that. I think one of the other things that we have seen on the Armed Services Committee is how important, just, preventive health care for young people is, actually, because if we are finding that far too many young people are not even able to be eligible for the military services today because of their health care.

Secretary SEBELIUS. I think the data right now, which is really alarming, is about 30 percent of the age-eligible young men and

women aren't, actually, physically eligible to even consider Armed Services as a possibility.

Mrs. DAVIS. If you could help tie those issues together, I think that would be very helpful because I don't think we want to turn around and find that we really have totally ignored this problem in the future.

Secretary SEBELIUS. Well, certainly, the effort that the First Lady is leading around childhood obesity, the community efforts underway to look at what happens if you increase exercise, have more access to fresh fruits, your efforts in Congress to change the child nutrition guidelines around school breakfast and school lunch, is a start of the kind of prevention effort that would, hopefully, produce a lot fewer diabetics when they get to be 50.

Mrs. DAVIS. Thank you.

Secretary SEBELIUS. Thank you, ma'am.

Chairman KLINE. The gentlelady's time has expired.

Mr. Gowdy?

Mr. GOWDY. Thank you, Mr. Chairman.

Good morning, Madam Secretary.

Secretary SEBELIUS. Good morning.

Mr. GOWDY. With respect to the HHS mandate, the most recent mandate, you said, and I quote—"this decision was made after very careful consideration, including the important concerns some have raised about religious liberty. I believe the proposal strikes the appropriate balance between respecting religious freedom and increasing access to important preventive services." There are only three balancing tests that I am aware of when it comes to matters of Constitutional significance; there is the rational basis balancing test for economic legislation, there is the intermediate, or mid-level scrutiny for gender-related Constitutional issues, and then there is the heightened, or strict scrutiny, when fundamental rights are involved."

And, given the fact that I am sure you can see that religious liberty is a fundamental right, which of those three Constitutional balancing tests were you making reference to when you said you "balanced" things?

Secretary SEBELIUS. Congressman, I am not a lawyer and I don't pretend to understand the nuances of the Constitutional balancing tests.

Mr. GOWDY. But you would agree——

Secretary SEBELIUS. I assume you are talking about the preventive services——

Mr. GOWDY. You would agree it is a legal issue, right? I mean, are we going to wind up in this—last time I was at the Supreme Court, I think you and I were there the same day during the oral argument. This mandate is going to wind up in the Supreme Court.

To me, it is—we can talk about the politics all we want to, I want to talk about the law. I want to talk about balancing religious liberty with whatever else you think it is appropriate to balance it with because you used the word "balance." Which of those three tests is the appropriate test for us to use when considering religious liberty?

Secretary SEBELIUS. Again, Congressman, I am not going to wade into Constitutional law. I am talking about the fact that we

are implementing the law that was passed by the Congress, signed by the President, which directed our department to develop a package of preventive health services for women. We have done just that with the advice of the Institute of Medicine and promulgated that rule.

Mr. GOWDY. Do you agree with me that government cannot force certain religious beliefs on its citizens?

Secretary SEBELIUS. Yes, sir.

Mr. GOWDY. And why can they not do that?

Secretary SEBELIUS. Why can government not——

Mr. GOWDY. Yes.

Secretary SEBELIUS [continuing]. Force religious beliefs?

Mr. GOWDY. What is the basis of that?

Secretary SEBELIUS. The separation of church and state.

Mr. GOWDY. Well, it is the Constitution, right, the First Amendment? Can government decide which religious beliefs are acceptable and not acceptable?

Secretary SEBELIUS. No, sir.

Mr. GOWDY. And why can they not do that?

Secretary SEBELIUS. It is part of our Constitution.

Mr. GOWDY. It is a legal analysis. I mean, for me, this is not a political analysis; it is a legal analysis. So, before this rule was promulgated, did you read any of the Supreme Court cases on religious liberty?

Secretary SEBELIUS. I did not.

Mr. GOWDY. You would agree with me that our society has a compelling interest, not just an important interest, a compelling interest in having an educated citizenry, right?

Secretary SEBELIUS. Yes, sir.

Mr. GOWDY. Right. So when a state said you have to send your children to school until a certain age and a religious group objected because they did not want to send their children to school until that certain age, do you know who won? It went to the Supreme Court.

Secretary SEBELIUS. I do not.

Mr. GOWDY. The religious group won. I think the state has a compelling interest in banning animal sacrifice, whether it is compelling or just important is irrelevant for purposes of this discussion. When a state banned a practice of animal sacrifice and a religious group objected, it went to the Supreme Court. Do you know who won that?

Secretary SEBELIUS. I do not, sir.

Mr. GOWDY. The religious group won. I think the state has an important interest in having license tags on automobiles so law enforcement can know who they are dealing with. When a religious group objected to having a certain license tag on their cars, it went to the Supreme Court. Do you know who won?

Secretary SEBELIUS. I do not.

Mr. GOWDY. The religious group won. And, most recently, I happen to think government has a compelling interest in avoiding gender discrimination but this Administration took to the Supreme Court a case, Hosanna-Tabor, where a religious group wanted to decide who its teachers were, even if it meant gender discrimination. It was a nine to nothing opinion in favor of religious liberty.

So when you say you balanced things, can you understand why I might be seeking a Constitutional balancing instead of any other kind?

Secretary SEBELIUS. I do, sir, and I defer to our lawyers to give me good advice on the Constitution. I do not pretend to be a Constitutional lawyer——

Mr. GOWDY. Is there a legal memo that you relied on, at least when a——

Secretary SEBELIUS. I relied on discussions.

Mr. GOWDY. At least when an Attorney General Holder made his—appointments, there was a legal memo that he relied on. Is there one you can share with us?

Secretary SEBELIUS. Attorney General Holder, clearly, runs the Justice Department and lives in a world of legal memos.

Mr. GOWDY. Do you have attorney——

Chairman KLINE. I am sorry, but the gentleman's time has expired. You can ask such a question for the record.

Mr. Andrews?

Mr. ANDREWS. Thank you, Mr. Chairman.

Madam Secretary, you didn't score well on the pop Constitutional law quiz, I am sorry.

Secretary SEBELIUS. I got a kind of drift that——

Mr. ANDREWS [continuing]. But, more importantly, you did acknowledge the Constitutional principles that my friend just talked about because you put a religious exemption in the rule that you put forward. So we thank you for being sensitive to that.

We have heard a lot of dark predictions this morning about terrible things that are going to happen as a result of the Affordable Care Act. And I think it is important that we get some context and look at the sources of those predictions and how they did on some of their prior predictions about the Affordable Care Act.

We heard from your critics and critics of the Act that premiums would skyrocket in the private sector, as a result of the Act. But we hear from the Kaiser Family Health Foundation, this very morning, that the medical loss ratio provisions that you were overseeing will likely yield $1.3 billion dollars this year, in rebates to payers of health care premiums, because of the quality of the law.

We heard it this morning, that the new IPAP would result, and I am quoting, in "$500 billion in Medicare cuts." A more accurate statement is that if the growth of Medicare spending continues on the same, lower glide path that it has been on for the last 18 months, my understanding is the IPAP provisions would never kick in because we would be below the projected growth rate and there wouldn't be any IPAP decisions or recommendations.

We heard, this very morning, that Medicare Advantage is in great peril and, literally, falling apart because of the Affordable Care Act. It is my understanding that your department released a report several weeks ago that said Medicare Advantage premiums are 7 percent lower than they were last year and enrollment is 10 percent higher than it was last year.

And then, finally, although we don't hear much about them anymore, we heard for years about the death panels. Let me just ask you that question. Has your department formed a committee that

votes on whether any person in this country gets medical care or not?

Secretary SEBELIUS. No, sir.

Mr. ANDREWS. Are you obligated to do so under the law?

Secretary SEBELIUS. Absolutely not.

Mr. ANDREWS. Okay, well, we heard, you know, for months, that this was eminent. So, now, we are hearing this morning about a prediction that, unfortunately, may come true if Congress makes the wrong decision this week. And that is that the Prevention Fund that you oversee would be drained in order to make this Hobson's choice between making college more affordable and making preventive health care available to people.

Now, I want you to answer this question for us—if a young woman is at the age where she thinks it is the right time for her to start to get cervical and breast cancer screenings to take proper care of herself and she is uninsured, and she does not have a sufficiently high income in her pocket to pay for those tests and those screenings, is one of the sources that she might receive that screening from the Prevention Fund that we are talking about this morning?

Secretary SEBELIUS. Yes.

Mr. ANDREWS. What would she do if that Prevention Fund did not exist? Where would she get that cervical or breast cancer screening?

Secretary SEBELIUS. It is possible that she could qualify for a program but what we know is, right now, unfortunately, there are millions of women in the situation that you have described and they go without the screening. What we know about breast cancer is that if it is found early, it has got a 90 percent survival rate. If, indeed, it is found later in the disease progression, the survival rate drops to less than 30 percent. So she would be in a very precarious situation, not being able to identify——

Mr. ANDREWS. She, sort of, just opts for the malignancy lottery. She hopes that she gets a winning ticket and doesn't have that problem. Ten percent of the country's health care expenses are attributable to obesity and Type 2 diabetes. Are there preventive services offered for Type 2 diabetes under this Prevention Fund that we are talking about?

Secretary SEBELIUS. Yes, there are.

Mr. ANDREWS. And what would happen to people if that fund were removed? Where would they get their services to begin to manage their diet and their exercise and their blood sugar, to avoid further complications?

Secretary SEBELIUS. Again, we don't have to look very far because the Prevention Fund is relatively new. So the kind of costs that not only are imposed upon people's shortened lives and their family for loss of a loved one, and their reduced productivity to their employer, but the kind of health care costs are a part of what is driving health care in this country on an ever-increasing pace.

We pay lots of money, private insurers, public insurers, hospitals, taxpayers, for chronic disease and diabetes and obesity and smoking are underlying those chronic diseases. So we know that anything that can reduce those chronic disease onsets will, indeed, save money, save lives, save productivity, in the long run.

Mr. ANDREWS. Thank you, Madam Secretary.

Thank you, Mr. Chairman.

Chairman KLINE. I thank the gentleman.

Dr. Heck?

Mr. HECK. Thank you, Mr. Chairman.

And, thank you, Madam Secretary, for being here. I have enjoyed the discussion this morning and appreciated you acknowledging the difference between access to health insurance and the access to health care, in the answer to the question from my colleague from Ohio; certainly the two are not synonymous. And, with fewer health care practitioners, true access to health care will, obviously, be impeded.

As you know, the Association of Medical Colleges projects that, by 2020, the U.S. will be facing a shortage of 91,500 physicians, both specialists and primary care docs. I am concerned that in a time when we need to grow the physician workforce, and we have heard you reference the investments in health care workforce in the Affordable Care Act, that the Administration is actually proposing cutting Medicare support, physician training and the critical services provided by teaching hospitals.

It is estimated that the President's proposal to cut Medicare IME payments by 10 percent will cost America's teaching hospitals over $685 million annually and would severely impact their ability to train the next generation of physicians. So can you explain the Administration's rationale behind this cut when, throughout the debate on the Affordable Care Act, and here this morning, we have heard about the new investments in growing the health care workforce?

Secretary SEBELIUS. Well, again, Congressman, I think that the workforce issue is one that we have tried to focus on well before, even, the debate on the Affordable Care Act began because it is a situation that was looming in this country with an aging population and not nearly enough health care providers.

And, so, we are really reassessing all the tools that we have throughout the department with graduate medical education, with Medicare, with the National Health Service Corps, with training of community health workers around some medical home models, with a variety of strategies to try and increase the pipeline of medical providers. And, not only increase our pipeline, but try and refocus on primary care providers, gerontologists, nurse practitioners, and others, who will deliver the kind of primary and preventive care we think is so important.

Mr. HECK. Well, and I appreciate using all those tools but, the fact is, cutting IME reimbursements to teaching hospitals cuts the pipeline. We can give Pell Grants to get them through college. We can get them into the health profession's Student Loan Re-payment Program after they are done but they still need to go to a residency program. And decreasing IME funding will result in fewer residency slots, which will result in fewer doctors.

So, again, I am caught because there is a lot of talk about investing in health care workforce yet there is significant cuts to training the physicians of tomorrow.

And, with that, Mr. Chairman, I would like to yield the rest of my time to my colleague from South Carolina, Mr. Gowdy.

Chairman KLINE. Let me interrupt for just a minute. We have had, apparently, an operator error in our light system. You have about 1½ minutes.

Mr. GOWDY. I thank the gentleman.

Madam Secretary, I think the last time you were here I asked you about tort reform. And I don't think it was the most recent State of the Union, it might have been the one before that, the President mentioned tort reform, specifically, in his State of the Union address. The House just passed H.R. 5, which is our version of tort reform.

Do you know whether you or the Administration took a position on H.R. 5? And what forms of tort reform would you support?

Secretary SEBELIUS. Congressman, I did not take a position on H.R. 5. I know that the President has said, from the outset, that he certainly opposes anything that imposes caps on injured patients and is also not supportive of programs that pre-empt the state court system.

We have, underway, a series of efforts looking at strategies that both lower liability rates for practicing physicians, increase safety initiatives and compensate injured patients more promptly, that are yielding, actually, some very promising results. And I would be happy to provide that data to you. They are in place in hospital systems, in provider groups and in states across the country.

Mr. GOWDY. What about tort reform for Medicare, Medicaid, Tri-Care, Federal Bureau of Prisons; things that are inherently Federal. I understand he doesn't want to take over the state's civil justice system but what about tort reforms? If 88 percent of all the payment comes from one of the Federal providers, what about tort reform that connects Medicare, Medicaid, Tri-Care, Federal Bureau of Prisons?

Secretary SEBELIUS. I have no idea what you are putting under an umbrella of tort reform so that is an impossible question for me to answer—court claims act——

Mr. GOWDY. I am aware of that.

Secretary SEBELIUS [continuing]. Where he provides a limit on any suit that is against a Federal entity so what——

Mr. GOWDY. Are you opposed to caps for non-economic damages in all instances, pain and suffering caps?

Secretary SEBELIUS. Again, Congressman, you show me the bill and I would be happy to take——

Mr. GOWDY [continuing]. H.R. 5.

Secretary SEBELIUS. We don't really deal in the tort reform arena; that isn't our area in Health and Human Services. We are trying to avoid errors to patients, though. We are trying to help hospital systems limit the number of cases where a lawsuit would be brought.

I believe in prompt payment to victims. I, certainly, believe in helping health care providers have affordable rates in malpractice coverage. Most of that experience comes from former lives; it is not an area that I deal with day in and day out today.

Chairman KLINE. Sorry, the gentleman's time has expired.

Ms. Woolsey?

Ms. WOOLSEY. Thank you, Mr. Chairman.

Thank you, Madam Secretary, you are amazing. I know you know, and I am going to repeat what others have said; tomorrow the Republicans are going to bring to the floor legislation to postpone their student loan interest increase rate that is included in their Republican Ryan budget. That would raise the interest rate to 6.8 percent over the current 3.4 percent.

In so doing—we are glad they want to postpone it—I am. But they want to pay for it out of the Prevention Fund; that is their offset. The Democrat offset would be to end tax subsidies for big oil companies. We think that is where you go for offsets, not from the people you are trying to help in the first place.

Speaker Boehner refers to the Prevention Fund as a "slush fund." Well, that slush fund is already—it is not a slush fund. That fund, that Prevention Fund, is already being accessed. And some of the—and you know what that fund provides for us. What I would like you to talk about—the other people have, kind of, missed this one. It is increasing child immunization and screening for newborns.

What happens if these immunizations are not made available? What is going to happen to these children and our society at large? And what happens if newborns aren't screened? Why do we care?

Secretary SEBELIUS. Well, Congresswoman, what we know is that the Children's Immunization Program, which is, I think, one of the great health successes of, frankly, the last century, to get our children into a situation where they now have resistance to a lot of deadly and infectious and preventable diseases. It is an investment that the health studies show returns about $10.00 for every dollar invested.

It is significantly funded through the Prevention Fund; that plus the operators at—at the Centers for Disease Control and Prevention, who have public health laboratories in states across the country, to fund health professionals in states across the country so we can both track disease surveillance and prevent disease. It is a huge payoff. We know what happens in countries where the immunization rate is far lower and children die.

Ms. WOOLSEY [continuing]. Children die. And, if newborns aren't screened, what do you find—what do we learn when newborns are screened?

Secretary SEBELIUS. Well, again, I think the screening is advantageous because what it does is highlight, at the very beginnings of life, what are the issues that may be complicating that child's ability to succeed and have a healthy and prosperous life. So addressing it early, finding problems early is not only saving those children from potentially threatening disease but a lifetime of health issues.

Ms. WOOLSEY. Thank you, and what impact would using that fund to offset—to do away with that fund, virtually, what impact would that have on community health centers?

Secretary SEBELIUS. Well, I think that it has a significant impact across the board. And, I think, Congresswoman, your earlier issue raises just a false choice. In America, we should both invest in the education of our children and not allow student loan rates to double, as they are scheduled to do in July, which would make student loans far less affordable to working class families.

And we would have kids drop out of school and not access a college degree. And choose between that and keeping our children healthy in the first place so they can get to college. So I think there is a choice here that is not—there are, clearly, ways that student loans can be funded other than destroying the Prevention efforts, which are finally underway in this country, after decades of talking about them.

Ms. WOOLSEY. Well, thank you, because I agree with you, of course. You know, the Affordable Care Act provides states with millions of dollars in grants to strengthen statewide insurance review programs. My state of California has benefitted, with $5.3 million to fight unreasonable premiums.

And the California department insurance recently reduced four rate increases, by an average of 9.65 percent, saving 87,000 Californians; a total of $1.66 million, per month, in premium increases. I think——

Chairman KLINE. The gentlelady's time has expired.

Mr. Ross?

Mr. ROSS. Thank you, Mr. Chairman.

Madam Secretary, thank you for being here. You know, when the President started his campaign for health care reform, he talked about a health care crisis. Over time, when it didn't seem to be getting traction, it turned into a health care insurance crisis. And my question to you is—would you not agree that health insurance carriers are an indispensable party, in the aggregate, to the resolution of affordable and accessible health care in this country?

Secretary SEBELIUS. That health care insurers are indispensable——

Mr. ROSS. Correct.

Secretary SEBELIUS [continuing]. Is that the question? I think that is what the President believes, which is why he built the new system around the private health market.

Mr. ROSS. Well, I don't think he built it around the private health market because I want to make sure we understand. As much as I don't like writing my premiums and as much as I think insurance companies are their own worst enemies, health insurance, as in every insurance, is private capital backing a risk. When the government gets involved in the business, it's government dollars; it's taxpayer dollars, covering that same risk or being part of that same risk.

My question to you is, in light of where we are with this health care reform now before the Supreme Court, should we find a mandate to be un-Constitutional—and you have addressed affordability and accessibility in your opening, and you talked about market forces. But would it not be in the best interests of every American to have interstate sale of health insurance, over policies that can meet the demands of individual choice? Would that not create a competitive environment that would bring price stability and keep the government out of being in the business of funding health care?

Secretary SEBELIUS. Congressman, I have been involved in the health insurance market for decades and what we have is a private health insurance market that, frankly, is fully able to operate in market strategies and decreasing in members' year in and year out.

The health insurance rates skyrocket, fewer people, particularly, young and elderly people drop out——

Mr. ROSS [continuing]. Right. We can do assigned risk pools to take care of pre-existing conditions.

Secretary SEBELIUS. [Off mike]

Mr. ROSS. Yes, we can. We have done it in other areas. We can also require that there be more availability of choice to consumers by allowing for interstate sale. But, more importantly, we can incentivize wellness if we make it part of the choice that the consumer has.

What we are doing here is the same thing we have done to the Student Loan Program and the health—we have nationalized it, suppressed the rates, and now we are telling the American public that if you want to have a student loan at all, you have got to come to the Federal government. We have taken away competition. We have taken away choice and we have taken away market forces that are absolutely necessary if the individuals are going to want to have the coverage they deserve at the price they want.

Secretary SEBELIUS. Well, again, sir, I think you have mischaracterized what the new exchanges will do, which is offer competitive choice in a private market strategy around—it does get rid of some of the most onerous rules of insurance companies; they can't any longer kick people out because of pre-existing conditions.

They can't charge women 15 to 20 percent more than they charge males for the same disease. They cannot operate with rules that rescind an insurance plan if you make a technical mistake. They can't put a lifetime limit on caps but they will compete on the basis of price and quality.

Mr. ROSS. How do I respond to my constituents who, back home, said, "I was told I could keep my doctor but now my doctor won't keep me because of the reimbursement reductions that are being done in Medicare?"

Secretary SEBELIUS. There have been no reimbursement reductions——

Mr. ROSS [continuing]. There will be. But we just argued over this 6 months ago, in trying to do a piecemeal approach to guaranteeing that our——

Secretary SEBELIUS. A long-term approach would be much preferable and we would love to work with you around a long-term approach.

Mr. ROSS. And what are you saying about giving student loan forgiveness, then, to physicians out of school, that decide they want to sign a contract with the Federal government to handle Medicare patients?

Secretary SEBELIUS. I am sorry, say——

Mr. ROSS [continuing]. Incentivize medical students to have a loan re-payment program if they will commit so many years to taking Medicare patients.

Secretary SEBELIUS. Well, sir, right now we have 98 percent of doctors involved in Medicare and it hasn't been a problem. The problem is that there is no long-term solution to the sustainable growth rate and that looms——

Mr. ROSS [continuing]. But I won't get into that now. I want to ask you real quickly because—CBO Director, Doug Elmendorf, tes-

tified that "Obamacare" would cost 800,000 jobs. March 13th of this year, CBO released a projection that the new health care law will cost $1.76 trillion over the next 10 years, nearly double the $940 billion estimate provided when it was signed into law.

Have you or anyone in your administration discussed this with the President? And how do you reconcile this increased exponential cost, in light of the fact that this economy doesn't seem to be doing too well, either in revenue generation or in spending cuts?

Secretary SEBELIUS. Sir, I am not sure of the precise quote. I know the 800,000 job loss is not, necessarily, a job loss; it was the projection by the Congressional Budget Office that more people would have the ability to retire earlier, choose other options, who are now job locked because they are terrified of losing——

Mr. ROSS. The cost was highly——

Secretary SEBELIUS [continuing]. Health coverage. The cost differential, I can get the quote.

Mr. ROSS. [Off mike]

Secretary SEBELIUS. The CBO continues to suggest that the Affordable Care Act will, indeed, reduce the deficit by over $100 billion the first decade and close to $1.1 trillion over the second decade; that is—those numbers continue to be updated and, so, I would be happy to respond in writing to what, exactly, you have quoted there. I don't know. But the $1.1 trillion deficit reduction is an updated number from CBO.

Chairman KLINE. The gentleman's time is expired.

Mr. Hinojosa?

Mr. HINOJOSA. Thank you, Mr. Chairman.

Secretary Sebelius, over the past 2 years, the Centers for Medicare & Medicaid Services, or CMS, have been working to implement new operating systems that will allow for CMS to process claims in compliance with the new HIPAA requirement. In January of this year, CMS began the processing of those electronic claims through HIPAA Version 5010.

And it is my understanding from providers who have visited my office, that this change has been met with some reimbursement delays, in particular, for dual-eligible patients. Therefore, I would like to submit a question for the record to ask you to work with me and my staff to see what can be done to ensure these delays can be avoided in the future because they say that it has been, in some cases, taking 60 days to get paid.

Madam Secretary, the Prevention and Public Health Fund is an opportunity to invest in the health services before people are sick, instead of paying for more costly care. This is important for racial and ethnic minorities, who continue to have higher uninsured rates and are less likely to gain access to health care when they really need it. What are the specific ways in which the fund is being used to mitigate the impact of these differences in access?

Secretary SEBELIUS. Well, Congressman, first of all, we look forward to working with you around the——

Mr. HINOJOSA. Thank you.

Secretary SEBELIUS [continuing]. Delayed billing issue and take a strong look at it because, certainly, the health care to, particularly, the poorest, oldest Americans is a high priority. In terms of the Prevention Public Health Fund, you are absolutely right that

identifying early, preventing causes and, even, dealing with disease at the earliest stage, is not only saving lives but saving dollars.

So the Prevention Fund is investing in everything, as we have talked about, from immunization of kids to disease control to breast and cervical cancer screening for uninsured Americans; a whole series of strategies. Smoking cessation, which we know now that tobacco causes about 400,000 premature deaths a year in this country, has a huge toll on workforce productivity, and any effort to reduce the smoking rates pays off.

I think, in the case of particularly the minority communities, the prevalence of chronic disease is significantly higher. Diabetes rates are higher, blood pressure issues are higher, obesity rates are higher. So efforts to, really, develop strategies that work, have access to prevention and care, supporting everything that we are doing, like public housing that gives, now, residents smoke-free options so they and their kids don't have to live in situations of secondhand smoke, delivering clinical preventive services in a much more user-friendly fashion, are all ones that will save lives and lower costs.

Mr. HINOJOSA. It is clear that health reform is making a difference for communities of color. Nearly 1.2 million young adults of a racial and ethnic minority background were able to get on their parent's plan because of this Affordable Care Act. And we are very happy about that. This includes, nearly, 750,000 Latino adults under the age of 26. This is progress but we all know that an insurance card isn't always enough.

In fact, the Agency for Health Care Research and Quality reported that disparities in health care treatment between whites and minorities have worsened every year since the report was first made public. What investments does the President's budget make to eliminate racial and ethnic disparities that affect access to quality care?

Secretary SEBELIUS. Well, I think there is a series of strategies; more health centers in underserved populations, bringing health care providers to where people live, additional, I think, support for minority health workers, knowing that having culturally competent, language competent workers dealing with patients is incredibly important, certainly expanding insurance coverage.

We know minority communities are far more likely to be uninsured than insured. So, looking forward to 2014, when there will be insurance coverage available at an affordable rate and that will have a huge impact on helping the health disparity situation. Additional research is in the budget on some of the health disparity strategies and, certainly, looking at the prevention, which now is available to seniors without co-pays, with Medicare it is available, with private insurance plans. So prevention will be front and center, in terms of health care responses.

Mr. HINOJOSA. Thank you——

Chairman KLINE. I am sorry to interrupt.

We are, Madam Secretary, mindful of your hard stop at 12:30. We have three more members with questions so we are going to be almost exactly on time.

Mrs. Roby?

Mrs. ROBY. Thank you, Mr. Chairman.

Thank you, Madam Secretary, for being here. As you may know, the Catholic TV station, the Eternal Word Television Network, EWTN, is located in my home state of Alabama. And EWTN does not fall under the small umbrella of the religious exemption of a religious employer, nor do many hospitals, charitable service organizations and universities. And I understand that you, along with the Administration, are working on a, quote—"accommodation" for groups that fall in this category.

But my question is—putting aside any future accommodation, why is EWTN, and similar religiously affiliated entities, not completely exempt from covering these services, especially when these drugs, such as the "morning-after pill" and services fundamentally contradict their moral belief?

Secretary SEBELIUS. Congresswoman, the Affordable Care Act made it clear that, in the future, insurance policies should include health benefits essential to women's health care and, often, they are missing. And, so, we asked the Institute of Medicine to give us an analysis of what were the key preventive health services for women. They included everything from domestic violence screening to maternity care to contraceptive coverage.

We then looked to state law; 27 states in the country have mandatory contraceptive coverage. And we looked at the various kinds of exemptions that were currently present in the majority of states around the country——

Mrs. ROBY [continuing]. Let me, maybe, ask——

Secretary SEBELIUS [continuing]. That is why we developed the——

Mrs. ROBY. Right, let me get to it because I only have a short amount of time and this Chairman is pushing it. Why are you defining some religious organizations as acceptable for the full exemption and others as only religious enough to qualify under some other——

Secretary SEBELIUS [continuing]. Again, we were guided by the exemption that was in place; we didn't invent this exemption. The exemption that was in place in the majority of states that had any religious exemption, and a number of them don't have any, is what we proposed, with an additional issue that we, in the year and in the ANPRM that we have just issued, we will provide a series of strategies for religious employers who currently do not offer contraceptive coverage as part of their health plan, to have the opportunity to employ one of these strategies.

The mandate is not to the employer; it is to the insurance company. Insurance companies will offer preventive services to women, at no cost to those women, and religious employers will not have to purchase, or refer, or pay for, that coverage.

Mrs. ROBY. All right, well, let us—we have talked a lot this morning about the preventive care and, so, I just have, very quickly, a series of questions. And I want to make sure that we are very clear on those. And yes or no is good. Is your testimony that without the Preventative Fund, there would be no more screenings for children anywhere?

Secretary SEBELIUS. Of course that isn't.

Mrs. ROBY. Okay. Isn't it true that the statute does not direct preventive funds to any specific program?

Secretary SEBELIUS. It is the Prevention Fund and we have worked with bipartisan members of both——

Mrs. ROBY [continuing]. And isn't it also true that the President's very own budget made cuts to the Preventative Fund?

Secretary SEBELIUS. The President's budget did recommend, over 10 years, a reduction in the Prevention Fund, certainly not an elimination of the Prevention Fund.

Mrs. ROBY. But there were cuts to the Preventative Fund——

Secretary SEBELIUS [continuing]. There was a reduction in the Prevention Fund, made in the President's budget, which would still leave about a billion-plus dollars a year to invest in these critical health programs.

Mrs. ROBY. Okay. And, since I have a little bit more time, I am going to circle back. I wanted to make sure I got these questions in. All plans after 2014 are expected to include coverage for sterilization and contraception, including drugs that some believe can cause abortion, i.e. the "morning-after pill" that I have already mentioned. If an employer, such as EWTN, that I mentioned, the Catholic television station, has a moral objection to such coverage, what penalties will be imposed on the employers or, as you clarified, the insurance providers?

Secretary SEBELIUS. Again, the mandate is not on the employer; this is a direct——

Mrs. ROBY [continuing]. What penalties will they suffer if these employers do not offer these services?

Secretary SEBELIUS. Well, those plans won't be certified to be sold in the market.

Mrs. ROBY. Okay.

Mr. Chairman, I yield back.

Chairman KLINE. I thank the gentlelady.

Mr. Kelly?

Mr. KELLY. Thank you, Chairman.

Ms. Sebelius, thanks for being here today. I had a question—early on, Dr. Roe had asked you some questions. We held a hearing, back in western Pennsylvania, regarding lawyers and their approach to the Patient Protection Affordable Care Act and the costs that were going to be involved.

And maybe I misunderstood, but you said that the reason that there is a—that the people don't know—there is a lot of misconceptions that are still out there. You still do believe there are a lot of misconceptions about the protection plan of the Affordable Care Act?

Secretary SEBELIUS. I do.

Mr. KELLY. Okay, why do you think there are so many misconceptions?

Secretary SEBELIUS. Well, I think that there was about a year-and-a-half of mistruths and erroneous debate, that was driven by 24/7 news coverage, and people still believe that there are elements of the law that not only were never part of the law in the first place, but they believe that those will come to pass. I find people every day who——

Mr. KELLY [continuing]. Yes, and I also do. And, maybe, part of reason is the rules haven't been written yet. Let me read to you a part of the testimony from Will Knetch, who is the President of

Wendell August Forge: "I believe that we, as a nation, are about to walk into an unknown abyss that, humbly, I believe our country will face with full force and effect, the implementation of the 2010 health care bill in 2013 and 2014. The sheer monstrous size of the bill intimidates most Americans and provides so many unknowns for the business community that it is scary." And to verify it, he quoted Speaker Pelosi, during the voting on the bill, "We have to pass it so we can read it."

In other words, nobody really knows all the tentacles of this bill and that is bad for America and it is bad for business. Now, I would just contend to you that there is a lot of misconceptions, especially for people who have never run a business and, especially, for people who come here thinking that they know what is best for everybody at every step of the way.

Is there some reason that, after 2 years, we still don't have the rules and regulations because you really—if there is a misconception, it would be because this Administration never really made it clear what the rules and regulations are going to be. So that is not a matter of people sticking pins in a voodoo doll; this is a matter of an Administration that has never clearly, never clearly, put out what the rules are and never, really, clearly told employers what it was going to cost.

Now, I know a little bit about that because every 2 weeks I do have to make a payroll. And it is not funded by the American taxpayers; it is funded by the success of my business. I can't tell you how uncertain most employers are today as to what is it going to cost them as employers, as business owners. We still don't know, do we?

Secretary SEBELIUS. Sir, I would just——

Mr. KELLY [continuing]. Answer will be "yes" or it will be "no."

Secretary SEBELIUS. We are writing rules and regulations——

Mr. KELLY [continuing]. So we still don't have the rules and regulations 2 years after the bill was passed?

Secretary SEBELIUS. Excuse me, we do not have every rule——

Mr. KELLY [continuing]. Do not have the rules, is that the answer?

Secretary SEBELIUS. We don't have 100 percent of the rules——

Mr. KELLY. Okay, so we don't really know what the costs are going to be?

Secretary SEBELIUS. That is exactly what——

Mr. KELLY. So the misconceptions are based on the fact that the Administration has not yet come up with the rules and regulations? Passed the law, didn't need one Republican vote to get it passed—and I hear how terrible the Republicans have been——

Secretary SEBELIUS. Well, there was a Republican vote but——

Mr. KELLY. Okay, all right. You and I can, maybe, agree on a lot of things. I would agree on this and I would say that any business owner is scared to death of this. They have absolutely no idea what it is going to cost them. Now, it is going to cost the business owner one of two ways; either increased costs to him or increased taxes. Is that a given? I mean, this money isn't just going to fall out of the sky; this increased cost—this health care bill is going to cost an awful lot of money.

Secretary SEBELIUS. I think for any small business owner who currently is providing health coverage, the estimates are, by every economist who has looked at this, CBO, et cetera, is that costs will go down, not up.

Mr. KELLY. We don't have the rules yet. We don't have the finals rules. We don't know. You can't draw a conclusion on something you don't know——

Secretary SEBELIUS. I understand, but I keep being cited all kinds of people who have drawn all kinds of conclusions. We are working——

Mr. KELLY [continuing]. My question to you is if there are no rules and regulations, how can you——

Secretary SEBELIUS [continuing]. There are plenty of rules and regulations——

Mr. KELLY [continuing]. Excuse me, I am in the automobile business. Do you know what you are asking people to do?

Secretary SEBELIUS. I do——

Mr. KELLY. You are asking people—I said I am in the automobile business. I would imagine that somewhere in your life you bought an automobile. Can you imagine walking into a place of business and saying, "I want to buy a car," and the dealer saying, "Okay, fine, I have got a car for you, can't tell you what is in it, can't say how much it is going to cost you, can't tell you how much the monthly payment's going to be. But I want to go ahead and start paying for it today and 4 years from now you can take delivery."

Secretary SEBELIUS. And, well before people have access to the health care changes, they will know what they cost.

Mr. KELLY [continuing]. I understand, but they don't know. It is 2 years later. I got to tell you, this is either inept, an inept Administration, or people who truly don't actually know at all how to treat the American people fairly. This is going to fall on the backs of the American taxpayers; that is who it is going to fall on.

This is not some benevolent monarchy that supplies all these wonderful services to people. The American taxpayers are the ones that pay for this. And I have only been here 15 months but I have never seen such a disconnect to the real world, in the way that things work inside the Beltway. There is such a lack of understanding as to what people have to do, in order to pay their fair share, play within the rules, and live within their means. So——

Chairman KLINE. The gentleman's time has expired.

Mr. Petri?

Mr. PETRI. Thank you very much, Mr. Chairman.

I have a couple of questions. First, I have heard from a number of constituents, including employers, in the area that I represent in Wisconsin, about the importance of health savings accounts. And health savings accounts offer a more affordable option that puts the consumer in control of their health care plan decisions. So I am concerned that some of the regulations being written to implement the Affordable Care Act, most importantly the medical loss ratio regulations, could jeopardize consumer access to these types of plans.

Do you think consumer access to health savings account-type plans is important? And, as you write regulations for medical loss ratio and other components of the Affordable Care Act, are you tak-

ing steps to ensure that health savings account plans are able to compete on a level playing field with other, more comprehensive, plans?

Secretary SEBELIUS. Well, I think, Congressman, the impact that you may be referring to is on the so-called "mini med" plans, some of which are offered along with an HSA. There are no direct implications on the health savings account. But the "mini med" plans, which do not offer a full package of health insurance, are not currently subject to the medical loss ratio but they will no longer be insurance plans post-2014.

Mr. PETRI. In another area, Section 9010 of the Act includes an annual fee on health plans. And I am concerned about two, possibly unintended, consequences of this fee. First, there are many managed care plans in my state and I am sure in others that serve exclusively to low-income individuals who are on Medicaid or who are dually eligible for Medicaid and Medicare.

These types of plans were created to help coordinate care for these individuals, both to lower costs and to improve quality. Because the plan revenue comes directly from state Medicaid programs, the tax, as applied to these plans, will ultimately be paid by the state government and by the Federal government. So we are taxing ourselves, raising the costs of Medicaid. Are you concerned about this, sort of, anomalous situation?

Secretary SEBELIUS. Well, certainly, Congressman, the access to health insurance for low-income Americans is in jeopardy. And we, certainly, don't want to compound that situation. I think that the fee that is being looked at is a partial offset to the millions of new customers that health insurers are looking forward to serving through the insurance exchanges.

So, we think, on balance, the number of new customers will far outweigh the modest fee going into the plans, because currently they are really on a situation where they are losing customers day in and day out as health costs spiral. But they are looking forward to, you know, 15, 17 million Americans who will be signing up for health insurance.

Mr. PETRI. And, secondly, in connection with the fees, we have a lot of integrated health care providers in our state who offer their own health plans; Marshall Clinic and so on. These providers have been very effective at using their plans to coordinate care for patients to reduce costs and to improve quality.

Concern is that this health plan fee will be disproportionately harmful to these plans because they are smaller and may be less able to absorb these additional costs. Do you have any concerns in that area?

Secretary SEBELIUS. Well, I think that the kind of coordinated care strategy that often is available in an integrated health plan is exactly the kind of best practice that we are trying to encourage in systems across the country. And I have visited a number in your home state, which are some of the best, I think, in the country.

On balance, I really think that the kind of more efficient care delivery is a strategy that, not only will pay off but—right now, we have got the financial incentives in the wrong places for the very plans you have described. We pay on volume and not on outcome.

So if you coordinate care, if you keep people healthier in the first place, if you reduce hospital admissions, you get penalized.

I think what you will find is that those plans are exactly the strategies we are—in fact, they will be receiving enhanced payment through Medicare, through other strategies, going forward. So we are shifting a payment system that, I think, again, will not penalize those plans but, in fact, will appropriately pay for those plans for the first time.

Chairman KLINE. The gentleman's time has expired. It looks like the morning has expired.

I want to thank the Secretary, again, for being here and sharing her time and expertise with us.

I will recognize Mr. Miller for any closing remarks he may have.

Mr. MILLER. Thank you very much. I am sorry Mr. Kelly left the room. This year, the automobile manufacturers put 15 million new cars on the road. I assume they didn't just simply dump those on the automobile dealers. I assume they took time to ramp up the service department, to ramp up the sales department, to ramp up the warranties, to change their policies, and they knew that those cars were going to come on line in a period of time.

Had we dumped 40 million uninsured people into this system on one day after we passed the legislation, I think there would have been a howl. The fact of the matter is, I think your department has done an amazing job in working with patients, with insurance companies, with hospitals, with doctors, with specialty people, with general practitioners, with all the health services, with the education institutions, so that, hopefully, in 2014, this nation will be ready for this. I can't tell you, I hear all the time from people who are telling me, "Why did you wait until 2014?" because they want to go start their own business but they can't risk health care for their spouse and their families. Maybe that is just in California, where we have a lot of innovative start-up companies, but I hear it all of the time from young people about job lock and that side. So I think you have done a very prudent job on that.

We are out of time. You are out of time. I would just like to ask if I could prod you, in writing, for an update on how we are doing on complying with, and managing, mental health parity? I am getting more and more questions in the mental health community, and in my general community, about this. There is a great deal of concern. As you know, this was a very long struggle——

Secretary SEBELIUS. You bet.

Mr. MILLER [continuing]. In the Congress to get this into——

Secretary SEBELIUS. And I would be glad to respond in writing. Thank you.

Mr. MILLER. Thank you very much, Madam Secretary. Thank you for being here today.

Chairman KLINE. I thank the gentleman.

Again, I thank the Secretary——

Secretary SEBELIUS. Thank you.

Chairman KLINE [continuing]. For being with us today. I think we have made it with——

Secretary SEBELIUS. It is brilliant.

Chairman KLINE [continuing]. Twelve seconds to spare. There being no further business, the committee stands adjourned.

[Additional submissions of Chairman Kline follow:]

United States Senate
WASHINGTON, DC 20510

March 8, 2012

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Secretary Sebelius:

We write to request the results of the Head Start "Third Grade Follow-Up Study" that had been scheduled to be completed in September 2011, as well as information about the reasons why the release of that study has been delayed until September 2012.

Congress and the American people deserve the opportunity to review the evidence about whether the Head Start program is benefiting the children that it serves. In 1998, Congress mandated that the Department of Health and Human Services conduct a national evaluation of the impact of Head Start on children served. In 2006, the Department awarded a follow-up contract to continue the evaluation of Head Start's impact through students' third grade year.

We understand that the data collection for the "Third Grade Follow-Up" study was completed in the spring of 2008. Four years seems to be a sufficient period of time for the Department and the researchers that conducted the data collection to analyze the results.

Given the critical importance of understanding whether the Head Start program is benefitting the children it serves, we request the following information:

- Any reports (including drafts) that Westat or any other researchers involved with the project have conducted about the Third-Grade Follow Up study results.
- Any reports (including drafts) that the Department has written analyzing the results of the Third Grade Follow-Up Study results.
- An explanation why the Department decided to extend the Head Start study project period to September 2012 and further delay the release of this evaluation.

We also request that the Department brief our staffs about the status of this study and our questions.

The American people—including the families of the estimated 904,000 children currently enrolled—deserve to understand how this program is affecting the children it serves.

We request an answer to this inquiry by March 16, 2012. Thank you for your assistance.

Sincerely,

Tom Coburn, MD
U.S. Senator

Mike Enzi
U.S. Senator

Lamar Alexander
U.S. Senator

Richard Burr
U.S. Senator

John McCain
U.S. Senator

DEPARTMENT OF HEALTH & HUMAN SERVICES

ADMINISTRATION FOR CHILDREN AND FAMILIES
Office of the Assistant Secretary, Suite 600
370 L'Enfant Promenade, S.W.
Washington, D.C. 20447

March 27, 2012

The Honorable Tom Coburn, M.D.
United States Senate
Washington, D.C. 20510

Dear Senator Coburn:

Thank you for your letter concerning the follow-up of the Head Start Impact Study. Secretary Sebelius asked that I respond on her behalf. As noted in your letter, we anticipate a fall 2012 release date for the third grade report.

Congress gave us an ambitious mandate for evaluating Head Start, calling for an independent study that would be nationally representative, use rigorous random-assignment methods, and collect longitudinal data on a broad range of children's and families' outcomes. Congress directed us to assess not only the overall impact of Head Start but also variations in impacts among programs and children with different characteristics.

The study first collected data on three- and four-year-old children entering Head Start in the fall of 2002. The children completed one year in Head Start by summer of 2003, and we provided impact findings based on data from that spring in a report to Congress in 2005. The children completed their first grade year by the spring of 2006, and the study completed first grade data collection in summer 2006. Impact findings in the final required report to Congress were provided in January 2010.

Data from the study are rich, and we have encouraged and supported the use of these data by other researchers, by placing the data collected through children's first grade year in a repository (http://www.researchconnections.org/childcare/resources/19525) for use by researchers. A number of researchers have begun to use the data and publish their own analyses. In September 2011, we awarded a grant to a consortium of researchers at New York University, MDRC, and Harvard University to conduct analyses of the data focusing on questions that have posed particularly difficult methodological challenges.

The Administration for Children and Families places a high value on transparency and openness in research and evaluation, as demonstrated by the comprehensive reports from this study already published (http://www.acf.hhs.gov/programs/opre/hs/impact_study/index.html). We have ensured that reports from the study fully document methods used and comprehensively report findings. These detailed reports receive careful review to ensure that they are accurate, complete, and clear.

While Congress specifically required studying children only through first grade, we have undertaken the third grade follow-up to continue learning from this important study. The follow-

up study completed collecting data on children's third grade experiences and progress in the summer of 2008. Analyses of the third grade data are not complete for several reasons. The analyses of the first grade data took longer than anticipated, delaying the start of work on the third grade data. Analyses of large, complex data sets typically require a number of steps such as analyzing sample attrition, constructing statistical weights and developing composite measures, among others.

There are also considerations specific to this study. As one of only a few studies ever conducted with a nationally representative randomized control design, this study has broken new ground and the researchers have had to explore new techniques to analyze the data. The collection of longitudinal data over several years further complicates the study. The researchers have taken time to consult with statisticians and other experts about how to address analytic challenges. As part of a serious effort to answer the questions Congress posed for the study, my agency supports this careful approach.

The Administration for Children and Families is committed to rigor and transparency in the conduct of this study, as in all research and evaluation studies sponsored by the Department of Health and Human Services. We will contact your staff to arrange a briefing for them, as you requested in your letter. I will also provide this response to Senators Enzi, Alexander, Burr, and McCain who co-signed your letter.

Sincerely,

George H. Sheldon
Acting Assistant Secretary
for Children and Families

[Additional submission of Mr. Roe follows:]

Demos' Restaurant was started by my parents 22 years ago, and now has four locations in Middle Tennessee and one in Northern Alabama. Three of the restaurants do very well, one is marginal and one does not do well at all, but not bad enough to close as the other restaurants support it. My sister and I came back into the family business a few years back with the intention of growing it. We opened three locations in 7 years with each location employing about 100-150 people. After the Affordable Care Act was passed, we spoke with several people on estimates of the costs it would have on our business. The range of costs was $250,000 to $600,000. If we take the low estimate, we would have to close down two of our locations putting about 200 people out of job. If it is on he high range, we may have to close a third location down.

Further, we have wanted to add another restaurant in the Clarksville area, but since we have seen these costs, we have held off any expansion. It is too risky to invest money in a building that we may not be able to afford to keep open after a few months due to the increase costs from the Affordable Care Act.

To summarize, the Affordable Care Act in its current form will cost us 300 jobs in small markets, and has kept us from adding 100-150 jobs to the local economy.

Peter

Peter Demos
President
Demos' Restaurants
1119 NW Broad St
Murfreesboro TN, 37129
615-225-8797

[Questions submitted for the record and their responses follow:]

COMMITTEE ON EDUCATION
AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES
2181 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6100

May 18, 2012

The Honorable Kathleen Sebelius
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Sebelius:

Thank you for testifying at the committee's recent hearing entitled, "*Reviewing the President's Fiscal Year 2013 Budget Proposal for the U.S. Department of Health and Human Services.*" I appreciate your participation.

Enclosed are additional questions submitted by committee members following the hearing. Please provide written responses no later than Friday, June 8, 2012 for inclusion in the official hearing record. Responses should be sent to Cristin Datch of the committee staff.

Thank you again for your contribution to the work of the committee.

Sincerely,

JOHN KLINE
Chairman
Committee on Education and the Workforce

Enclosures

Rep. John Kline (R-MN)

1. The president's FY 2013 budget included a $111 billion increase for health insurance subsidies, a 30 percent increase from last year's budget. Given that there has been no significant change in law or economic assumptions, is this increase due to an assumption that more people will lose their employer provided coverage and claim a subsidy than previously believed?

2. Secretary Sebelius, we are all aware the Supreme Court recently heard oral arguments regarding the constitutionality of PPACA. On the last day of oral arguments, Justice Kennedy alluded to the fact that it could be judicial overreach to strike some parts of the law and leave others intact. The Court's opinion is expected in June. It is possible the individual mandate, and potentially the entire law, could be found unconstitutional. Without debating the merits of the case, has the department begun to prepare contingency plans for the possibility that the court will strike down all or part of PPACA?

3. Recently, HHS announced the creation of the new Administration for Community Living that will focus on strengthening assistance to seniors and people with disabilities. The committee has concerns regarding the efficacy of new offices. How will this new office help streamline service delivery or reduce duplication within the department? Will there be fewer federal employees working in these offices?

4. The new Administration for Community Living proposes to consolidate the Administration on Aging, the Office on Disability, and the Administration on Developmental Disabilities. The president's FY 2013 budget includes $1.95 billion for the Administration on Aging (AoA), an increase of $457 million over last year. The funding levels support 135 Full-Time Equivalents, an increase of 14 employees. Why is HHS requesting more funding and more FTEs if these offices are being consolidated?

5. How will the new Administration for Community Living be funded? How will the funds be allocated amongst the various aging and disability programs? Does HHS have the authority to create and fund this new agency without language in an appropriations bill?

6. We understand the new Administration for Community Living will share an administrator with the subordinate Administration on Aging. How will the administrator serve effectively in these dual, overlapping roles?

7. How will the new Administration for Community Living affect the department's plan for Older Americans Act reauthorization? How will it affect the reauthorization of the Developmental Disabilities Assistance and Bill of Rights Act of 2000?

8. How can the department work to better coordinate services for the elderly across all federal agencies?

9. The president's FY 2013 budget proposal requests to move the Senior Community Service Employment Program (SCSEP) to HHS. This program was one of 47 duplicative workforce development programs identified by GAO in early 2011. Why has the

administration proposed to further fragment job training by moving this program out of the Department of Labor? Is the administration proposing this change because it believes SCSEP is more about community service than workforce development?

10. The 2010 reauthorization of the Child Abuse Prevention and Treatment Act (CAPTA) included a requirement that ACF conduct a study relating to immunity from prosecution for professional consultation in reporting instances of child abuse and neglect and submit a report to Congress. What is the status of this study? When will the report be submitted to Congress?

11. What type of guidance does the department provide to Head Start and Early Head Start grantees on the appropriate use of funds for conferences and events? How does the department monitor the use of funds for these activities?

12. As you know, GAO released a report that highlighted egregious examples of waste and fraud in the Head Start program in 2010, after which your department announced several reforms. Can you tell us how the department is implementing the promised changes? Can you tell us with confidence that enrollment fraud has been eradicated in the program?

13. As you mentioned in your testimony, the department finally issued re-competition rules for Head Start grantees as called for by the 2007 reauthorization of the Head Start Act. Despite being almost two years behind schedule, the committee supports this effort to increase program quality. Last month, the re-competition process began for 97 service areas and is expected to include 100 additional areas in the coming weeks. Can you tell us how the implementation is going thus far?

14. The 2010 Head Start Impact Study found the advantages children gained from Head Start yielded only a few significant outcomes that lasted through the end of first grade. The "Third Grade Follow-Up Study" was set to be completed last September, but has now been delayed until later this year. Considering data collection for the third grade study was completed in the Spring of 2008, what is the cause for delay? Does it have anything to do with the implications of the study's results for Head Start?

15. Both you and Secretary Duncan have requested $850 million for Race to the Top, including "an unspecified amount" that will be used for the Early Learning Challenge competitive grant program. What portion of Race to the Top do you foresee going to the Early Learning Challenge? Why wasn't that included in your budget?

16. How does the Race to the Top-Early Learning Challenge work with existing early learning programs at the state level? How does it work with Head Start?

17. The administration's budget requests again call for increased spending on most health and human services programs. What efforts are you undertaking to make the department more efficient? Can you point to any real reductions in offices or staffing that reflect this effort?

18. In recent years, Congress has received numerous reports highlighting fraud and abuse in many health and human services programs. How are you working to prevent waste and protect taxpayer dollars?

19. How much money has ACF and/or AoA spent on all conferences and events over each of the previous four fiscal years? Please provide a breakdown of each event or conference planned by ACF and/or AoA since January 20, 2009, and indicate which program the conference was associated with, what program office was the lead for the event, whether the department contracted out planning or management for either all or part of a conference or event, how much the contract for these services was for, whether the department has employees to plan events and conferences, and, if so, why the services were contracted out rather than planned by staff.

Rep. Joe Wilson (R-SC)

1. During your testimony, you indicated that "it is absolutely not correct" that IARC findings trigger automatic regulatory consequences for regulated entities in the United States. Do you stand by that response, in light of the fact that if IARC does find that diesel exhaust represents a known human carcinogen, the Occupational Safety and Health Administration (OSHA) regulations (C.F.R. § 1910.1200(d)(3), 1910.1200(d)(4)(ii)) require employers that utilize diesel engines to communicate this finding to employees via material safety data sheets (MSDS)?

Rep. Virginia Foxx (R-NC)

1. In your FY 2013 budget request, you call for increased funding for new and duplicative programs, such as the Race to the Top-Early Learning Challenge and Child Care Quality Initiative. At the same time, programs like Head Start are faced with examples of waste and fraud and revelations of horrific safety violations among grantees. How can you justify requesting funding for new programs while your department is having a difficult time overseeing its current programs?

2. GAO has identified 69 separate early childhood education and child care programs, totaling more than $25 billion and littered across 10 different federal agencies. What steps has the administration taken to ensure that the larger number of programs isn't making it more difficult for low-income families to access services and that the federal government isn't funding duplicative and inefficient programs?

Rep. Duncan Hunter (R-CA)

1. Private for-profit organizations participate in state preschool programs across the country. Many of these commercial organizations have a proven reputation of delivering high-quality early child care and educational services. These providers, however, are deterred from participating in Head Start because grantees aren't allowed to keep administrative profits. Would you support allowing for-profit organizations to receive a marginal profit on Head Start grants as part of a broader effort to encourage greater competition and

improve quality within the program? How about if they can show an increase in student outcomes?

Rep. Tim Walberg (R-MI)

1. What is the operating status of the Lake Lynn mine testing facility?

2. In your testimony regarding the Diesel Exhaust in Miners Study (DEMS) conducted by NIOSH and NCI, you indicated to me that that the Department of Health and Human Services has complied with the committee's previous requests. However, the department has not yet fully complied with the committee's multiple requests. When will the department release the following information to the committee and the representatives of the study participants?

   A) All information on vital status of each cohort member, including follow-up, date of death and cause of death.

   B) All information obtained in interviews, including smoking history (both active and passive), lifetime occupational history, medical history, family medical history, usual adult diet, and use of respiratory protective equipment.

   C) The exposure data files referred to in the file, "DEMS_DATA_FILES".

   D) An identification of each lung cancer case used in the case control study and the controls that were matched to the case.

   E) An identification of the specific cases included in each of the cohort study analyses.

   F) All data on exposures to other air contaminants including radon, asbestos, silica, respirable dust, and PAHs from non-diesel sources, in a form that would permit reproducing the results in Table 1 of Silverman et al. (2012) and Table 2 of Attfield et al. (2012).

   G) The state mortality rates used in the SMR analysis in Attfield et al. (2012).

3. Occupational Safety and Health Administration (OSHA) regulations (C.F.R. § 1910.1200(d)(3), 1910.1200(d)(4)(ii)) require American employers utilizing diesel engines to take specific actions if the French based International Agency for Research on Cancer, finds that diesel exhaust is a known human carcinogen. Do you believe American employers should be permitted to have a voice in these IARC proceedings? If so, will you commit to taking a leadership role at IARC to insist that U.S. employers be able to comment on this issue?

4. I understand that the Department of Health and Human Services, through the Centers for Disease Control and/or other agencies have awarded a number of grants and/or funds to the International Agency for Research on Cancer (IARC) over the past several years.

Please provide a complete account of any such grants in aid, or other transfers of funds originally obligated to the department or its agencies, since 2009. In accounting for this information, please provide a summary of each project or projects undertaken by IARC as a result of the funding provided by the department or its agencies and documentation requested by the department and its agencies provided by IARC during 1) the solicitation process for such funding and 2) federal oversight of the projects undertaken by IARC, as a result of the grants in aid or other funding provided by the government.

Rep. Lou Barletta (R-PA)

1. Recently, the 2012 Medicare Trustee Report concluded that Medicare will go bankrupt by 2024. Doctors, hospitals, and patients in the 11th district are concerned about these results. With an aging population, increased technology, and more complex medications there continues to be a strong demand for medical services. In addition, the President's healthcare reform law reduced Medicare expenditures by more than $500 billion and the Health and Human Services' FY13 budget request calls for over 300 billion more in cuts from Medicare and Medicaid. How do you expect providers to address these cuts?

2. How is the U.S. Department of Health and Human Services planning for the estimated mandatory cuts that will take place under the current sequestration rules contained in the Budget Control Act? What process will the agency use in determining the necessary cuts? Will you start with the programs that cost the most? What analysis has been done to estimate the impact on access to care?

3. My district is home to one of the largest vaccine companies in the world, and as such I have a concern about the proposed cuts to the 317 immunization program which provides the federal infrastructure funding for state and local immunization programs. What is the rationale for cutting this program and how will that impact the states' ability to purchase and distribute vaccines?

Rep. Martha Roby (R-AL)

1. As part of the universal health insurance reform passed in 2010, all health plans must now provide—at no out-of-pocket cost to the recipient—certain "preventative services." Many of these services are routine; however, it is the tenth government-mandated service that puts various groups in a moral bind. Specifically, the mandated coverage must include "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity."

   Due to public uproar, in February, HHS finalized the narrowly defined exemption for the "religious employer"—ensuring that some, but not all religious institutions, will not have to cover contraceptive services or refer employees to organizations that provide such services. This exemption only applies to a religious entity if it primarily serves people of their own faith. It does not apply to faith-based organizations that serve people of all or no faith.

The Catholic TV Station, The Eternal Word Television Network (EWTN), is located in the state of Alabama. EWTN does not fall under the small umbrella of this religious exemption—nor do many hospitals, charitable service organizations, and universities. I understand that the Administration is working on an "accommodation" for groups that fall under this category.

Putting aside the future "accommodation," why is EWTN, and similar religiously affiliated entities, not exempt from covering these services—especially when these drugs and services fundamentally contradict their moral beliefs? Why is the administration defining some institutions as religious enough for a full exemption, others as only religious enough to qualify for a yet undefined accommodation and leaving still others with no religious protection at all?

2. After 2014, all health care plans are expected to include coverage for sterilization and contraception, including drugs that some believe can cause an abortion (e.g. the morning after pill). If an employer such as EWTN has a moral objection to such coverage, and their moral objections remain even under the accommodation that you have said will be proposed at a later date, what penalties will be imposed on employers and insurance providers for not covering these services?

   A) What will happen to an employer who cannot find an insurance plan that matches their values? If they were to fail to provide insurance, will that employer be fined or otherwise penalized? How much are the fines imposed? How will entities such as EWTN be penalized as a self-insured entity?

   B) What if an employer that objects to certain coverage self-insures (as in the case of EWTN) or otherwise provides insurance to their employees and fails to include the coverage that they oppose? What would the fines be in that case? If they refuse to pay the fines will they be arrested? What actions will be taken?

3. The US Conference of Catholic Bishops (USCCB) was recently denied a HHS grant to provide assistance to victims of human trafficking. For the first time in the history of the program, the funding opportunity announcement stated that "strong preference" would be given to applicants that are willing to direct clients to medical providers who can provide or refer for the "full range of legally permissible gynecological and obstetric care." This language appeared to be an effort to make it more difficult for the USCCB to receive a grant under this program—even though they were the incumbent applicant and had received outstanding reviews throughout the years that they received funding for this program. An investigation conducted by the House of Representatives Oversight and Government Reform Committee revealed that even with this "preference" in the request for proposals, independent reviewers gave USCCB one of the highest scores on their application: 89 out of 110. Still, HHS denied funds to the USCCB while funding proposals that received significantly lower scores, including scores of 69 and 74. Only one of the three awardees received a score higher than USCCB.

This question is regarding the HHS grant to fund care for victims who have been rescued from human trafficking. I am referring to the funding that was denied to the USCCB as an entity.

Were you briefed on the reproductive health language in this request for proposals? Did you request or approve the reproductive health language? Were you briefed on the scores awarded to each applicant under this program? Did you approve the decision to pass over USCCB even though they had one of the highest scoring applications? Could you please clarify how an entity that offers a "full range" of services but at a lower quality level more effectively assists trafficking victims and protects taxpayer dollars than an organization that is more qualified and does not fit HHS's new definition of reproductive health? Did HHS base its decision to redefine reproductive health and give preference to such organizations on evidence-based research?

As a result of the reproductive health requirement, have any trafficking victims been referred to Planned Parenthood? Have any of the new funding recipients indicated that they have, or intend to, refer victims to Planned Parenthood clinics?

Rep. Lynn Woolsey (D-CA)

The National Institute for Occupational Safety and Health (NIOSH) in conjunction with the National Cancer Institute (NCI) conducted the Diesel Exhaust in Miners Study (DEMS), which was designed to evaluate the risk of death associated with diesel exhaust exposure, particularly as it may relate to lung cancer.

1. What was the main result of the DEMS study?

2. At the hearing it was asserted that this study found "that diesel exhaust exposure of a surface mine produced higher risks of adverse health effects than to underground miners, with much higher levels of exposure." Is this a correct characterization of what this study found?

3. At the hearing it was asserted "that heavy smokers, with the highest diesel exhaust exposures, have a lower risk for lung cancer than miners who didn't smoke…" Is this an accurate characterization of the study findings?

4. What mines and how many workers were covered in this study?

5. This study was also the subject of a 2001 court order that requires the agencies involved to provide all data requested by this committee. Are there any requests for information submitted to the department from this committee that have not been completely fulfilled? Are you aware of any willful non compliance with these requests?

6. NIOSH leases the Lake Lynn Experimental Mine in southwest Pennsylvania. This facility, in which the U.S. government has invested more than $40 million, is essential for conducting mine safety research such as large-scale explosion trials. However, the lease

The Honorable Kathleen Sebelius
May 18, 2012
Page 9

is expiring and NIOSH will have to vacate this facility in September. What steps are being taken to acquire this property? Has an appraisal been completed?

7. The Occupational Safety and Health Act requires the Secretary of Health and Human Services, after consultation with the Secretary of Labor and other agencies, to conduct directly, or by grants and contracts, education programs to provide an adequate supply of qualified personnel to carry out the purposes of this Act. However, the department's Fiscal Year 2013 budget eliminated all funding for the NIOSH Education and Resource Centers (ERCs), which is one of the key means by which HHS fulfills this mandate.

   A) Did the Secretary of Labor or the Assistant Secretary for the Occupational Safety and Health Administration agree that that funding for ERCs was no longer necessary to assuring an adequate supply of occupational safety and health professionals?

   B) In December 2011, the Millbank Quarterly published the "Economic Burden of Occupational Injury and Illness in the United States" which estimates that the annual direct and indirect costs of occupational disease and injury are at least $250 billion per year. This amount exceeds the individual cost of cancer, coronary heart disease, stroke, and diabetes. In view of this economic burden, will the department reconsider the priority it is giving to training programs for qualified personnel to help prevent occupational injury and disease, as part of its budget for Fiscal Year 2013 or its development of the Fiscal Year 2014 budget?

Rep. Rubén Hinojosa (D-TX)

1. Over the past two years, the Centers for Medicare and Medicaid Services have been working to implement new operating systems that will allow for CMS to process claims in compliance with ICD10 and HIPPA 5010 requirements. On January 1, 2012, CMS began the processing of electronic claims through HIPPA Version 5010 and it is my understanding from providers and their trade organizations that this change has been met with some problems.

   I have received reports that this change has led to physicians in Texas experiencing substantial reimbursement delays, in particular for dual eligible patients. I have received further reports that presently, the Texas Medicaid Program is having some problems interfacing with CMS' claims software due to technical difficulties prompted by the 5010 change over. This gives me great concern as dual eligible patients are some of our most distressed and medically needy individuals.

   I applaud your agency responding to these challenges by postponing full 5010 implementation until June 30. However, I have serious concerns about any program that leads to delays in payments and could endanger our nation's safety net of care. So my question for you is can you outline what can be done to ensure these delays will be avoided in the future? Additionally, can you please give me a brief report on any other changes, requirements or proposed pilot programs that are or could delay provider payments due to technical difficulties?

Questions Submitted for the Record by Mr. Miller

Secretary Sebelius, each year an estimated 40 million American adults suffer from some type of mental illness. That is why passage of the Mental Health Parity was so critical.

1. Can you give me an update on what the Department is doing to ensure that health plans are complying with Mental Health Parity?

2. Can you please provide an update on guidance HHS has or will prepare for states to assist them implementing and enforcing Mental Health Parity?

During the April 26th hearing you were asked about the Diesel Exhaust in Miners Study that was conducted by the National Cancer Institute and the National Institute for Occupational Safety and Health.

1. Could you please clarify when the peer reviewed study was published in scientific journals?

Lastly, subsequent to the hearing on May 24, 2012, the Fifth Circuit Court of Appeals vacated and remanded a lower court order regarding the obligations of the Secretary to produce to the Committee certain documents and studies pertaining to the Diesel Exhaust in Miners Study.

1. What did the Appeals Court find with regards to the Secretary's compliance with the previous court orders to provide studies to this Committee?

[Secretary Sebelius' response to questions submitted follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

December 17, 2012

The Honorable John Kline
Chairman
Committee on Education and the Workforce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for the opportunity to complete the record for the April 26, 2012, hearing at which Secretary Sebelius testified on the FY 2013 Budget for the Department of Health and Human Services. Enclosed you will find the answers to your questions.

I hope this information is helpful. If I may be of further assistance, please do not hesitate to contact me at 202-690-7627.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Enclosure

Secretary Sebelius Questions for the Record
House Committee on Education and the Workforce
April 26, 2012

The Honorable John Kline

1. The president's FY 2013 budget included a $111 billion increase for health insurance subsidies, a 30 percent increase from last year's budget. Given that there has been no significant change in law or economic assumptions, is this increase due to an assumption that more people will lose their employer provided coverage and claim a subsidy than previously believed?

Answer: The increase does not reflect any fundamental change in our underlying assumptions regarding utilization of premium tax credits or the cost of providing coverage for a given person in the Exchanges.

Instead about half of the change is attributable to legislative changes enacted in 2011, primarily the "Three Percent Withholding repeal and Job Creation Act" (P.L. 112-56) and, to a lesser extent, the "Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011" (P.L. 112-9). As you will recall, P.L 112-56 changed the Affordable Care Act by including certain Social Security income when determining eligibility for premium tax credits and Medicaid. Both CBO and the Administration scored a net decrease in overall health-related outlays due to this legislation. Health insurance premium tax credit outlays are projected to increase by about $60 billion over 10 years as a result of the health provisions of P.L. 112-56. However, looking only at the premium tax credit outlays is incomplete since savings accrue to Medicaid as well.

The remaining difference is attributable to technical changes in the revenue estimating model that are designed to improve its accuracy. These changes inform all of the individual income tax modeling and were not implemented just for purposes of calculating the cost of the premium tax credit.

2. Secretary Sebelius, we are all aware the Supreme Court recently heard oral arguments regarding the constitutionality of PPACA. On the last day of oral arguments, Justice Kennedy alluded to the fact that it could be judicial overreach to strike some parts of the law and leave others intact. The Court's opinion is expected in June. It is possible the individual mandate, and potentially the entire law, could be found unconstitutional. Without debating the merits of the case, has the department begun to prepare contingency plans for the possibility that the court will strike down all or part of PPACA?

Answer: We are confident that the law will be upheld. There is clear and well-established legal precedent that Congress acted within its constitutional authority in passing the Affordable Care Act.

3. Recently, HHS announced the creation of the new Administration for Community Living that will focus on strengthening assistance to seniors and people with disabilities. The

committee has concerns regarding the efficacy of new offices. How will this new office help streamline service delivery or reduce duplication within the department? Will there be fewer federal employees working in these offices?

Answer: Establishing a single HHS organization focused on community living will enhance and strengthen HHS efforts to support seniors and people with disabilities in their efforts to live independently, with dignity, in their communities. This action simply mirrors actions that many States have long since taken at their level to address the same needs. Including the Administration on Aging, the Administration on Developmental Disabilities and the Office on Disability in the new entity establishes a single organization to ensure consistency and coordination in community living policy across the Federal government. This is the next step following establishment of President Obama's Community Living Initiative "to ensure the fullest inclusion of all people in the life of our nation."

The reorganization will strengthen our efforts to support community living, regardless of age. Existing programs intended to serve both older Americans and persons with disabilities, such as the Lifespan Respite Care program and the National Clearinghouse for Long Term Care Information, will benefit from this integrated organization, while initiatives designed to meet the unique needs of seniors or people with disabilities will retain their distinct programs.

The creation of ACL was carried out to improve HHS's ability to address the common needs of seniors and individuals with disabilities who seek to continue living independently in their communities. It was not an attempt to achieve efficiencies by reducing existing staff. As such, overall Federal staff levels for the new Administration for Community Living are equal to the sum of the staffing levels for its predecessor agencies.

4. The new Administration for Community Living proposes to consolidate the Administration on Aging, the Office on Disability, and the Administration on Developmental Disabilities. The president's FY 2013 budget includes $1.95 billion for the Administration on Aging (AoA), an increase of $457 million over last year. The funding levels support 135 Full-Time Equivalents, an increase of 14 employees. Why is HHS requesting more funding and more FTEs if these offices are being consolidated?

Answer: The FY 2013 President's Budget for the AoA includes $1,978 million in budget authority. This represents a net increase of $7 million. The difference from your estimate reflects the comparable display of programs such as the Senior Community Service Employment Program and the State Health Insurance Assistance Programs, which were first proposed for transfer in last year's President's Budget and are continued in this year's. The reorganization which resulted in the creation of ACL occurred after the FY 2013 President's Budget was submitted to Congress. The funding level for ACL includes the AoA budget and the $174 million requested for ADD and OD, the same amounts that were requested in the Adminstration for Children and Families and the Office of the Secretary.

The Administration is not proposing significant increases in funding or staff in the establishment of ACL, but rather aligning programs and staff from AoA, ADD, and OD to ACL.

5. How will the new Administration for Community Living be funded? How will the funds be allocated amongst the various aging and disability programs? Does HHS have the authority to create and fund this new agency without language in an appropriations bill?

Answer: As in prior years, ACL will be funded by a mix of discretionary and mandatory appropriations. The Secretary has the authority to administratively organize her department. ACL was created using the same authority that was used in the creation of the Administration for Children and Families. HHS first published a Federal Register notice creating an entity in the current year, followed by an administrative delegation of authority to that entity to draw from allocation accounts created to mirror existing activities. The Department will continue to achieve the purposes identified in the appropriations bill.

6. We understand the new Administration for Community Living will share an administrator with the subordinate Administration on Aging. How will the administrator serve effectively in these dual, overlapping roles?

Answer: The role of the Assistant Secretary for Aging (ASA) has always been two-fold as outlined by Congress in Title II of the Older Americans Act, as the ASA administers Older Americans Act (OAA) programs, while collaborating across all federal agencies to broadly impact national policy that affects older adults. This second role will be emphasized with the new structure where the ASA in her role as the Administrator of ACL, will advise the Secretary on long-term care policy matters that impact older adults as well as individuals with disabilities. The ASA will continue to give equal priority to administering OAA programs.

7. How will the new Administration for Community Living affect the department's plan for Older Americans Act reauthorization? How will it affect the reauthorization of the Developmental Disabilities Assistance and Bill of Rights Act of 2000?

Answer: The Department is not recommending any proposed language changes related to the creation of the Administration for Community Living and the reauthorizations.

8. How can the department work to better coordinate services for the elderly across all federal agencies?

Answer: The ACL plans to build on existing coordination efforts such as the Partnership for Patients (to reduce hospital acquired conditions and preventable hospital readmissions); the Fraud Task Force and other elder rights initiatives; Multiple Chronic Conditions Framework; Aging and Disability Resource Centers; Veterans Directed Home and Community Based Services (VDHCBS); and Medicare outreach and enrollment efforts.

9. The president's FY 2013 budget proposal requests to move the Senior Community Service Employment Program (SCSEP) to HHS. This program was one of 47 duplicative workforce development programs identified by GAO in early 2011. Why has the administration proposed to further fragment job training by moving this program out of

the Department of Labor? Is the administration proposing this change because it believes SCSEP is more about community service than workforce development?

Answer: The Senior Community Service Employment Program is the only title of the Older Americans Act not administered by the Administration for Community Living. By transferring this program, ACL will both better coordinate this program with nutrition services, caregiver supportive services, and home and community based supportive services as well as realize better integration within the aging services network resulting from the transfer to ACL. In addition to creating jobs, this program empowers the elderly to take charge of their livelihoods and incorporates training and job counseling to improve seniors' job marketability.

10. The 2010 reauthorization of the Child Abuse Prevent ion and Treatment Act (CAPTA) included a requirement that ACF conduct a study relating to immunity from prosecution for professional consultation in reporting instances of child abuse and neglect and submit a report to Congress. What is the status of this study? When will the report be submitted to Congress?

Answer: Section 118 of the CAPTA Reauthorization Act of 2010 requires a study to be conducted, in consultation with certain experts, that examines how provisions for immunity from prosecution under state and local laws and regulations facilitate and inhibit individuals cooperating, consulting, or assisting in making good faith reports, including mandatory reports, of suspected or known instances of child abuse or neglect and to submit a report on the study by December 20, 2011. We appreciate the value of such a study and report and are committed to meeting the requirement. However, as no funds were appropriated for these activities, additional time has been needed to identify existing resources and develop a workable approach to move forward. We anticipate completing this work and issuing a report in 2013.

11. What type of guidance does the department provide to Head Start and Early Head Start grantees on the appropriate use of funds for conferences and events? How does the department monitor the use of funds for these activities?

Answer: During the review of the annual refunding application, federal staff reviewed the grantee's budget narrative which should include an explanation of the proposed uses of federal funds for travel and conference fees. Federal staff are particularly interested in assuring that grantees' proposed travel funds are reasonable and that the conferences are relevant to improving staff knowledge and skills related to their jobs. If the proposed travel costs are not reasonable or the location of the conference appears unreasonably far from the grantee's home then federal staff would also question and resolve any issues with those costs before the grant award was cut.

During onsite monitoring visits the fiscal reviewer looks at budgeted cost such as travel or conference attendance to determine allowability and reasonableness. If those cost exceed appropriate thresholds then the evidence is sent to OHS for further evaluation.

12. As you know, GAO released a report that highlighted egregious examples of waste and fraud in the Head Start program in 2010, after which your department announced several

reforms. Can you tell us how the department is implementing the promised changes? Can you tell us with confidence that enrollment fraud has been eradicated in the program?

Answer: In FY 2010, GAO found that employees at 8 of 13 Head Start grantees disregarded applicant procedures and determined erroneously that families were below the poverty line. In response to GAO's study, ACF made a series of commitments to strengthen its oversight of eligibility:

- Implement a system of unannounced triennial reviews for 10 percent of grantees reviewed in FY 2011;
- Develop an on-line complaint system for reporting waste and fraud in Head Start programs;
- Draft regulations that require grantees to retain source documentation for children enrolled in the Head Start program; and
- Improve the risk management process.

ACF is implementing the changes as follows:

- ACF strengthened the monitoring protocol to contain more detailed evaluation of eligibility data and strengthened the interviews of parents and staff to determine if programs had fraudulently or erroneously enrolled families.
- ACF also strengthened the erroneous payment study conducted randomly for 50 grantees each year by looking more closely at source documentation, thereby giving reviewers a broader spectrum to determine eligibility than before.
- ACF conducted 11 percent of the reviews for FY2011 as unannounced—exceeding the target of 10 percent.
- ACF opened the line for public complaints and received 289 complaints from the public, 16 of which were related to eligibility. ACF instituted an internal control unit which handled and reviewed all complaints received.
- ACF developed a standardized form for conducting eligibility checks that could be used voluntarily by Head Start grantees.
- ACF issued proposed regulations for eligibility that are scheduled to be final this fall.

ACF believes that the heightened focus on erroneous payments and fraud related to eligibility was a warning for all grantees, and greater attention has been given to monitoring program integrity. Strengthening many of our systems has given us an increased ability to detect and resolve problems with eligibility in Head Start programs. We will continue to add improvements for detecting problems with eligibility moving forward.

13. As you mentioned in your testimony, the department finally issued re-competition rules for Head Start grantees as called for by the 2007 reauthorization of the Head Start Act. Despite being almost two years behind schedule, the committee supports this effort to increase program quality. Last month, the re-competition process began for 97 service areas and is expected to include 100 additional areas in the coming weeks. Can you tell us how the implementation is going thus far?

Answer: The process for Head Start grantees required to compete as a result of the Designation Renewal System (DRS) has begun with the publication of 95 funding opportunity

announcements in April. An additional 100 funding opportunity announcements will be posted in mid-May. Competitions will be open for 90 days, and the panel review process will begin in August. As the result of extensive grant reviewer recruitment efforts, OHS has selected approximately 500 highly-qualified reviewers to attend a comprehensive three day training in July.

In order to minimize disruption of services to children, families, and staff, OHS plans to extend funding to the end of the 2012-2013 school year for all current grantees required to re-compete under the DRS. This plan promotes continuity of services for children and families, and minimizes disruptions in communities by taking advantage of natural program breaks. The plan provides an opportunity for OHS to negotiate new awards and work with both incumbents and incoming grantees to ensure seamless transitions for children and families.

14. The 2010 Head Start Impact Study found the advantages children gained from Head Start yielded only a few significant outcomes that lasted through the end of first grade. The "Third Grade Follow-Up Study" was set to be completed last September, but has now been delayed until later this year. Considering data collection for the third grade study was completed in the Spring of 2008, what is the cause for delay? Does it have anything to do with the implications of the study's results for Head Start?

Answer: We anticipate a fall 2012 release date for the third grade report. As in all research and evaluation studies sponsored by the Department of Health and Human Services, the Administration for Children and Families (ACF) is committed to rigor and transparency in the conduct of this study.

As background, Congress gave us an ambitious mandate for evaluating Head Start, calling for an independent study that would be nationally representative, use rigorous random-assignment methods, and collect longitudinal data on a broad range of children's and families' outcomes. Congress directed us to assess not only the overall impact of Head Start but also variations in impacts among programs and children with different characteristics.

The study first collected data on three- and four-year-old children entering Head Start in the fall of 2002. The children completed one year in Head Start by summer of 2003, and we provided impact findings based on data from that spring in a report to Congress in 2005. The children completed their first grade year by the spring of 2006, and the study completed first grade data collection in summer 2006. HHS provided first grade impact findings in January 2010 in the final required report to Congress.

Data from the study are rich, and we have encouraged and supported the use of these data by other researchers, by placing the data collected through children's first grade year in a repository (http://www.researchconnections.org/childcare/resources/19525) for use by researchers. A number of researchers have begun to use the data and publish their own analyses. In September 2011, we awarded a grant to a consortium of researchers at New York University, MDRC, and Harvard University to conduct analyses of the data focusing on questions that have posed particularly difficult methodological challenges.

ACF places a high value on transparency and openness in research and evaluation, as demonstrated by the comprehensive reports from this study already published (http://www.acf.hhs.gov/programs/opre/hs/impact_study/index.html). ACF has ensured that reports from the study fully document methods used and comprehensively report findings. These detailed reports receive careful review to ensure that they are accurate, complete, and clear.

While Congress specifically required studying children only through first grade, we have undertaken the third grade follow-up to continue learning from this important study. The follow-up study completed collecting data on children's third grade experiences and progress in the summer of 2008. We look forward to the results of this follow-up. However, analyses of the third grade data are not complete for several reasons. The analyses of the first grade data took longer than anticipated, delaying the start of work on the third grade data. Analyses of large, complex data sets typically require a number of steps such as analyzing sample attrition, constructing statistical weights and developing composite measures, among others.

There are also considerations specific to this study. As one of only a few studies ever conducted with a nationally representative randomized control design, this study has broken new ground and the researchers have had to explore new techniques to analyze the data. The collection of longitudinal data over several years further complicates the study. The researchers have taken time to consult with statisticians and other experts about how to address analytic challenges. As part of a serious effort to answer the questions Congress posed for the study, the Department supports this careful approach.

15 . Both you and Secretary Duncan have requested $850 million for Race to the Top, including "an unspecified amount" that will be used for the Early Learning Challenge competitive grant program. What portion of Race to the Top do you foresee going to the Early Learning Challenge? Why wasn't that included in your budget?

Answer: We think it is critical to continue to invest in innovative approaches to education reform—including Race to the Top—Early Learning Challenge. FY 2013 funds for Race to the Top would be used to deepen the Administration's investments (in the form of new competitions or continuation grants) in the program's five core reform areas and to address the unmet demand of States and districts that have demonstrated a commitment to implementing comprehensive and ambitious plans in these areas. The Department is continuing to consider the appropriate type of grant and award ranges, which will depend in part on the level of FY 2013 appropriations. Because we had not yet made final decisions on the funding levels, we did not include that information in the budget request.

16. How does the Race to the Top-Early Learning Challenge work with existing early learning programs at the state level? How does it work with Head Start?

Answer: The RTT-ELC grant competition focuses on improving early learning and development for young children by supporting states' efforts to increase the number and percentage of low-income and disadvantaged children in each age group of infants, toddlers, and preschoolers enrolled in high-quality early learning and development programs; and designing and

implementing an integrated system of high-quality early learning and development programs and services.

At its core, RTT- ELC represents an opportunity for states to focus deeply on their early learning and development systems for children from birth through age five. It is an opportunity to build a more unified approach to supporting young children and their families--an approach that increases access to high-quality early learning and development programs and services, and helps ensure that children enter kindergarten with the skills, knowledge, and dispositions toward learning they need to be successful.

The RTT-ELC competition does not create new early learning and development programs, nor is it a vehicle for maintenance of the status quo. Rather, the RTT-ELC program supports the integrating and aligning of resources and policies across all of the state agencies that administer public funds related to early learning and development. This includes Head Start.

Many early learning and development programs and services, such as child care providers, family child care homes, state preschool programs, Early Head Start and Head Start programs, Home visiting services, etc., co-exist within States. For states, the challenges to be addressed by RTT-ELC are to sustain and build on the strengths of these programs, acknowledge and appreciate their differences, reduce inefficiency, improve quality, and ultimately deliver a coordinated set of services and experiences that support young children's success in school and beyond.

Each state will involve representatives from Participating Early Learning Programs including Head Start, Early Childhood Educators or their representatives, parents and families, including parents and families of Children with High Needs, and other key stakeholders in the planning and implementation of the activities carried out under the grant.

17. The administration's budget requests again call for increased spending on most health and human services programs. What efforts are you undertaking to make the department more efficient? Can you point to any real reductions in offices or staffing that reflect this effort?

Answer: HHS is committed to improving the Nation's health and well-being while simultaneously contributing to deficit reduction. The FY 2013 discretionary request demonstrates this commitment by maintaining ongoing investments in areas most central to advancing the HHS mission while making reductions to lower priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the FY 2013 request includes over $2.1 billion in terminations and reductions to fund initiatives and provide net deficit reduction. Many of these reductions, such as the $452 million cut to the Low Income Home Energy Assistance Program, the $177 million cut to the Children's Hospital Graduate Medical Education Payment Program, and the $327 million cut to Community Services Block Grants, are necessitated by the current fiscal environment. The budget reflects the careful review we gave to every program, looking for opportunities to make them leaner and more effective, and includes some difficult cuts we would not have made if our nation's fiscal health and tight budget times did not require them.

HHS has also presented a package of legislative proposals for Medicare and Medicaid that would save over $300 billion over 10 years. Medicare savings would accrue by adjusting the structure of the Medicare benefit to encourage beneficiaries to seek value in their health care choices, and encouraging high-quality, efficient care, and increasing the availability of generic drugs and biologics. The Budget also includes proposals to make Medicaid more flexible, efficient, and accountable while strengthening Medicaid program integrity.

Further, HHS continually seeks to identify and eliminate unnecessary costs, in the interest of ensuring that our resources are deployed in the most efficient manner. For instance, as part of the Administration's broader efforts to promote efficient spending, HHS is undertaking new measures to further reduce our spending on items such as travel, printing, professional services, supplies and materials, and employee information technology devices. Reducing spending in these categories will enable us to redirect resources to mission critical investments that more directly benefit our programs' targeted populations.

18. In recent years, Congress has received numerous reports highlighting fraud and abuse in many health and human services programs. How are you working to prevent waste and protect taxpayer dollars?

Answer: Preventing improper payments before they occur is a high priority of the Administration. Recovery audits help CMS identify and address common causes of improper payments. Due largely to vulnerabilities uncovered by Recovery Auditor Contractors (also known as RACs), CMS is in the process of implementing Medicare payment system edits that will stop the payment of claims after a beneficiary's date of death, stop the payment of durable medical equipment while the beneficiary is receiving care in an inpatient setting, and stop the payment for individual services that should have been bundled into another payment.

In addition, Medicare's claim processing contractors have been able to implement automated computer system edits to stop wasteful improper payments relating to medically unlikely claims and reimbursement for medications that exceed recommended dosages.

Since passage of the Affordable Care Act, CMS has implemented numerous new tools Congress provided to reduce waste, eliminate fraud, and recover improper payments. We have already put in place new provider screening and enrollment criteria to help CMS keep unscrupulous providers and suppliers out of our federal health care programs in the first place, quickly remove wrongdoers from the program when they are detected, and recover improper payments early in the process. We have also been using predictive analytics to prevent fraud and eliminate systemic vulnerabilities. We are confident these new tools will support us as we prevent fraud, waste, and abuse, and protect taxpayer dollars for years to come.

ACF leadership is committed to building a culture of program integrity and has set the tone which depicts program integrity as a high priority. At the administration-level, ACF continues to strengthen its program integrity infrastructure by increasing communication, collaboration, and sharing best practices across HHS and ACF. At the program- level, ACF programs continue to strengthen its program integrity activities through monitoring of its grantees and information-

sharing with its stakeholders. ACF remains committed to preventing waste and protecting taxpayer dollars.

Examples of program integrity activities at the administration-level:

- ACF formed its Program Integrity Internal Control Senior Assessment Team (PIIC SAT), which consists of leaders and staff from each office/program. The PIIC SAT fosters an environment that supports candid and constructive sharing of issues and solutions, where offices/programs are encouraged to proactively reach out to their peers across ACF that operate similar programs and face similar challenges.

- ACF established a Program Integrity Core Team to facilitate Department-wide program integrity initiatives, serve as a liaison with the Department, and share information and best practices with other HHS Divisions and ACF offices/programs.

- ACF continued to take a proactive role in the OMB/HHS improper payment initiatives and negotiated plans and deliverables with HHS and OMB for Foster Care, Head Start, and Child Care). ACF's contribution to the Improper Payments initiative has been significant within ACF and to HHS' overall progress toward eliminating improper payments.

- ACF conducted annual internal control assessments to determine the likelihood and impact to the ACF mission, if identified risks were to occur. Programs assess the effectiveness of its internal controls and financial management systems in compliance with the Federal Managers Financial Integrity Act and OMB Circular A-123. ACF also conducts annual assessments of its Grant Administration Tracking and Evaluation System to comply with applicable requirements.

- ACF conducted program integrity risk assessments across high-priority programs to identify and address program vulnerabilities. Through this process, programs are gaining insight into the types and potential severity of risks within their programs and are beginning to re-evaluate, develop, and implement response strategies.

- ACF has piloted the Single Audit Metrics Initiative. The objective of the initiative is to hold grantees accountable to ensure the deficiencies contained in Single Audits with unclean audit opinions are properly addressed and corrected in a timely manner. The metrics provide a tool to measure our success in improving ACF program integrity. In achieving this goal, ACF uses the Office of Management and Budget's MAX Data Collection System as a central repository to store and share audit-related information across ACF. ACF staff continued to conduct careful analyses of single audit findings within and across ACF grant programs, as well as across ACF grantees, to develop strategies for addressing chronic and pervasive internal control and compliance weaknesses in ACF grant programs and the entities that administer them.

- ACF has initiated a pilot using the Office of Head Start re-designation process to implement an additional phase to the application review process. Following the existing

grant application review processes, which may identify applicants that pose a potential risk for administering a Head Start or Early Head Start program, the additional phase involves a financial review of grant applications to better inform the funding decision-making and assure that funding is made available to grantees who are financially able to perform work under the grant. The results of the financial review are to either 1) stop awarding grants to applicants with viability and/or capacity concerns regarding the administration of federal funds or 2) for ACF to impose special conditions upon a grantee to protect the taxpayer dollars.

- As of the second quarter of FY 2012, ACF reduced its outstanding debt collections by $13 million. These collections were derived from cash collections, settlements and other adjustments as a result of A-133 audits and program disallowances. In a continuous effort to reduce the outstanding debt owed to ACF, we are working closely with the Department of Health and Human Services Office of Program Support Center and the Office of General Council to aggressively pursue the remaining outstanding debt.

Examples of program integrity activities at the program-level:

- ACF Office of Head Start (OHS)
    - Increased its focus on grantees by conducting 159 unannounced, on-site monitoring reviews. ACF found grantees that had unannounced reviews, compared to grantees that had announced reviews, were more commonly found to be noncompliant (findings that could easily be corrected) or deficient (findings that were more systemic or serious). ACF found that grantees with unannounced reviews had more findings per review, including a higher average number of deficiencies. Finally, ACF also found that over 35 percent of grantees with unannounced reviews had six or more findings, compared to approximately 18 percent of grantees with announced reviews.
    - In 2010, implemented new reporting features on the Early Childhood Learning and Knowledge Center (ECLKC) website, which provides Head Start communities and the public an easy way to contact OHS. A direct link to the HHS Office of Inspector General (OIG) is also located on the website. OHS encourages anyone who suspects fraud, waste, misuse, or abuse of federal funds to submit their concerns directly to the OIG Hotline.
    - Conducted an additional 11 targeted fiscal reviews resulting in 8 pending disallowances.
    - Strengthened its partnership with the OIG resulting in 24 additional program reviews to be conducted this fiscal year. On one year, the OHS took adverse actions on three grantee reviewed by the OIG that resulted in one termination and two relinquishments.

- Established the final rule for the Designation Renewal System that will limit Head Start grant awards to a five year project period and will require grantees to re-compete for funds, if they are not providing high-quality services.

- ACF Office of Child Care (OCC)
  - Initiated a National Program Integrity Conference Call Series with its state partners to address fraud prevention and internal controls, as well as provide a forum for state-to-state sharing of best practices.
  - Implemented a Program Integrity Self-Assessment tool for various grantees. During site visits, OCC provides technical assistance and facilitates collaboration between program staff, fiscal staff and quality control units to assist grantees in fully evaluating the integrity of their programs and to address measures to reduce errors.
  - Published the "Program Integrity, Financial Accountability, Access to Child Care" program instruction to provide guidance to Child Care and Development Fund Lead Agencies on their roles and responsibilities in preserving program integrity and to provide recommendations to strengthen accountability.
  - Streamlined the Error Rate Review process, which allows the grantees to conduct a more efficient and consistent review.
  - Expanded the Program Integrity and Accountability questions on the State/Territory/Tribal application for Federal funding to gain specific information regarding grantees' accountability measures and program administration.
  - Revised the CCDF section of the government's guide for auditors (i.e., the OMB Circular A-133 Compliance Supplement) to strengthen financial and program integrity.
  - Convened a workgroup to consider revisions to the grantee financial report to capture data and track the efforts of grantees in detecting and recovering expenditures resulting from fraudulent activities.

- ACF Office of Community Services (OCS)
  - In June 2010, delivered several presentations about the GAO's findings concerning LIHEAP errors and recommendations for LIHEAP program integrity and conducted the "Program Integrity: Internal Controls and Fraud Prevention Workshop" at the National Energy and Utility Affordability Conference (NEUAC). The goal of the workshop was to increase program integrity awareness among ACF grantees, particularly as it relates to ACF's Low Income Housing Energy Assistance Program (LIHEAP). This Conference was attended by over 600 participants representing nonprofit and government agencies, utilities

and other institutions which provide, among other things, utility and fuel bill assistance for families in need. A similar session is planned for the June 2011 NEUAC.

- Issued a formal memo strongly encouraging grantees to require social security numbers (SSNs) for all LIHEAP applicants and to verify those recipient identities through external databases, such as the Social Security Administration's database(s).

- Released new programmatic guidance, a LIHEAP plan supplement documenting State program integrity systems, and initiated a new program integrity work group.

- In 2010, released an Action Transmittal (AT) with a Model Plan format for grantees to use in submitting additional information on plans and strategies for ensuring program integrity. More recently, OCS released an AT in April 2011 to provide guidance for FY 2012 plans. The AT requires all LIHEAP grantees to supplement their LIHEAP plans with a Program Integrity Assessment that discusses the program integrity protocols and systems currently in place and what expected changes will be made to them in the upcoming year.

- Convened a working group on LIHEAP program integrity in January 2011 to allow grantees and other stakeholders a forum to exchange best practices, propose implementation strategies, and develop metrics for evaluating success in addressing the GAO recommendations. The group has conducted monthly conference calls since January, and held the first in-person meeting in Washington, DC in May 2011.

- Convened webinars and teleconferences with LIHEAP grantees to discuss the GAO report and OCS guidance on LIHEAP program integrity.

- Consulted with the HHS OIG about the OIG investigation of LIHEAP and is working expeditiously to follow up on serious OIG audit findings from the A-133 process.

- In FY 2010, conducted five on-site compliance reviews, and as many are expected to be completed in FY 2011. OCS also updated its compliance review manual to include the new ACF guidance and GAO recommendations on program integrity. ACF staff provides additional one-on-one training and technical assistance to LIHEAP grantees on the program integrity guidance.

19. How much money has ACF and/or AoA spent on all conferences and events over each of the previous four fiscal years? Please provide a breakdown of each event or conference planned by ACF and/or AoA since January 20, 2009, and indicate which program the conference was associated with, what program office was the lead for the event, whether the department contracted out planning or management for either all or part of a

conference or event, how much the contract for these services was for, whether the department has employees to plan events and conferences, and, if so, why the services were contracted out rather than planned by staff.

Answer: Please see attached spreadsheets which list the AoA and ACF conferences over the past four years.

The Honorable Joe Wilson

1. During your testimony, you indicated that "it is absolutely not correct" that IARC findings trigger automatic regulatory consequences for regulated entities in the United States. Do you stand by that response, in light of the fact that if IARC does find that diesel exhaust represents a known human carcinogen, the Occupational Safety and Health Administration (OSHA) regulations (C.F.R. § 191 0.1200(d)(3), 191 0.1200(d)(4)(ii)) require employers that utilize diesel engines to communicate this finding to employees via material safety data sheets (MSDS)?

Answer: Questions related to the Department of Labor would best be directed to the Secretary of Labor, who is best able to present the views of that Agency.

The Honorable Virginia Foxx

1. In your FY 2013 budget request, you call for increased funding for new and duplicative programs, such as the Race to the Top-Early Learning Challenge and Child Care Quality Initiative. At the same time, programs like Head Start are faced with examples of waste and fraud and revelations of horrific safety violations among grantees. How can you justify requesting funding for new programs while your department is having a difficult time overseeing its current programs?

Answer: The Administration is deeply committed to ensuring that high-need children from birth to age five enter kindergarten ready to succeed. This commitment is reflected in the FY 2013 budget request, which invests in high-quality early education to help put children on the path to school success and bolster our Nation's competitiveness. The Administration is also committed to strong oversight of early education programs, and the quality investments in child care, Head Start designation renewal, and Early Learning Challenge grants will further strengthen the integrity of such activities.

The FY 2013 budget request for the Department of Education (ED) requests $850 million for the Race to the Top, including Early Learning Challenge competitive grants to States and local communities to deepen the Administration's investments in ambitious improvements to early learning access and quality, and to address the unmet demand for these funds. The Department of Health and Human Services (HHS) budget request also includes a $300 million child care quality initiative to build on existing quality infrastructure investments in the Early Learning Challenge by directly investing in programs and teachers to help them meet and maintain higher quality standards.

In November of 2011, the President announced important new steps to improve the quality of services and accountability at Head Start programs across the country. Head Start grantees that do not meet quality benchmarks are required to compete against other organization in their community for continued funding. Of the additional $85 million requested for Head Start in the FY 2013 budget request, $40 million would be used to support this effort by minimizing potential service disruptions in the transition between incumbent and new grantees. The request also includes funds for monitoring of new grantees to ensure that they meet Head Start's critical mission – to help children from low-income families achieve their full potential and help our country build tomorrow's workforce.

2. GAO has identified 69 separate early childhood education and child care programs, totaling more than $25 billion and littered across 10 different federal agencies. What steps has the administration taken to ensure that the larger number of programs isn't making it more difficult for low-income families to access services and that the federal government isn't funding duplicative and inefficient programs?

Answer: Cross-program coordination to ensure that children have access to high quality early learning and child care programs has been a priority and key focus for the Administration. Over the last three years, ACF has developed and implemented an integrated early childhood unit under the leadership of the Office of the Deputy Assistant Secretary for Early Childhood

Development, which has become the focal point within HHS for early childhood activities at the Federal level. Within this structure, the Administration has taken several steps to improve coordination between the Office of Child Care (OCC) and Office of Head Start (OHS), such as establishing the National Center on Child Care Professional Systems and Workforce Initiatives (funded by both OCC and OHS) and implementing the Early Head Start for Family Child Care Demonstration Project, jointly coordinated by OCC and OHS.

As you are aware, Head Start and the Child Care and Development Fund (CCDF) vary in structure, administration, and regulation that help Head Start and CCDF provide complementary and not duplicative services. To further focus on the issue of preventing duplicative services and reducing barriers to access, the OCC and the OHS have worked together to encourage collaboration at the grantee level in a variety of ways. By issuing guidance on aligning eligibility policies and providing technical assistance to States and communities, our offices are working to ensure that more low-income children have access to high quality early learning.

In addition to the Race to the Top – Early Learning Challenge, which is jointly administered by ED and HHS and supports the integration and alignment of resources and policies across all of the State agencies that administer public funds related to early learning and development, the Administration has many interagency and interdepartmental efforts to coordinate federally funded early care and education programs:

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

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

- ACF/Child and Adult Care Food Program (CACFP) Workgroup: Convened by the Office of Management and Budget, the ACF/CACFP Workgroup brings together staff from the Food and Nutrition Services (in USDA), OCC, and OHS to discuss possible collaboration around the CACFP. The workgroup has identified the following areas of collaboration:

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

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

The Honorable Duncan Hunter

1. Private for-profit organizations participate in state preschool programs across the country. Many of these commercial organizations have a proven reputation of delivering high-quality early child care and educational services. These providers, however, are deterred from participating in Head Start because grantees aren't allowed to keep administrative profits. Would you support allowing for-profit organizations to receive a marginal profit on Head Start grants as part of a broader effort to encourage greater competition and improve quality within the program? How about if they can show an increase in student outcomes?

Answer: The newly implemented regulation on the designation renewal system (DRS) will provide for-profit organizations an opportunity to apply for Head Start grants. There is adequate room for a for-profit organization to compete within the existing structure, and while they should not be disadvantaged, nor should they receive different incentives than a non-profit organization.

While for-profit organizations are allowed to make a profit while they are a Head Start grantee, no portion of their profits can come directly from Department of Health and Human Services grant funds. Further we believe that a profit allowance as an incentive for their participation is not appropriate. In this difficult fiscal environment, we cannot prioritize using limited Federal dollars for organizations to keep profits rather than investing in quality improvements and increasing access for children from low-income families.

We believe this new rule will lead to robust competition – we have estimated that roughly one third of current grantees will be required to compete under the DRS in the next several years in order to continue receiving Head Start funding. In addition, the DRS system was required by Congress as a means to improve quality within the Head Start program.

The Honorable Tim Walberg

1. What is the operating status of the Lake Lynn mine testing facility?

Answer: The underground facility at Lake Lynn has been closed since the roof fall that occurred in October 2008. The surface testing labs, including the fire gallery and the detonation tube, have continued to operate.

2. In your testimony regarding the Diesel Exhaust in Miners Study (DEMS) conducted by NIOSH and NCI, you indicated to me that that the Department of Health and Human Services has complied with the committee's previous requests. However, the department has not yet fully complied with the committee's multiple requests. When will the department release the following information to the committee and the representatives of the study participants?

> **A) All information on vital status of each cohort member, including follow-up, date of death and cause of death.**
> **B) All information obtained in interviews, including smoking history (both active and passive), lifetime occupational history, medical history, family medical history, usual adult diet, and use of respiratory protective equipment.**
> **D) An identification of each lung cancer case used in the case control study and the controls that were matched to the case.**
> **E) An identification of the specific cases included in each of the cohort study analyses.**
> **F) All data on exposures to other air contaminants including radon, asbestos, silica, respirable dust, and PAHs from non-diesel sources, in a form that would permit reproducing the results in Table I of Silverman et al. (2012) and Table 2 of Attfield et al. (2012).**

Answer: Requests A, B, D, E, and F are grouped together because they represent detailed information that could potentially identify individual participants in the study. Thus, the information can only be released with appropriate safeguards in place to protect the confidentiality of individual study participants. The Committee's 90-day review of data underlying the cohort mortality and case-control study papers will end on June 24, 2012. NIOSH and NCI will make detailed datasets underlying these papers (NIOSH: cohort mortality study; NCI: case-control study) available to researchers pursuant to the execution of data transfer agreements. These datasets will not contain personal identifiers but will contain adequate detail to make replication of previously published findings possible. The level of individual data in the datasets could make specific subjects identifiable by certain parties (such as employers). Therefore, researchers who apply for access to these datasets through data transfer agreements will need to have projects that are documented to have appropriate local human subjects protections in place, e.g., as evidenced by approval of local Institutional Review Boards (IRBs).

> **C) The exposure data files referred to in the file, "DEMS_DATA_FILES."**

Answer: Item C was previously provided with data underlying the first four papers in the Diesel Study, which focused on assessment and reconstruction of exposures.

G) The state mortality rates used in the SMR analysis in Attfield et al. (2012).

Answer: The state mortality rates used in the SMR analysis in Attfield et al. (2012) are available to the public at the following link: http://www.cdc.gov/niosh/LTAS/rates.html

3. Occupational Safety and Health Administration (OSHA) regulations (C.F.R. § 1910.1200(d)(3), 1910.1200(d)(4)(ii)) require American employers utilizing diesel engines to take specific actions if the French based International Agency tor Research on Cancer, finds that diesel exhaust is a known human carcinogen. Do you believe American employers should be permitted to have a voice in these IARC proceedings? If so, will you commit to taking a leadership role at IARC to insist that U.S. employers be able to comment on this issue?

Answer: IARC is part of the World Health Organization (WHO) and operates through the participation of many countries. It conducts reviews through a structured process that seeks out a diversity of opinion. http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf IARC posted a list of attendees for its June 5 – June 12 meeting on Diesel and Gasoline Engine Exhausts and Some Nitroarenes http://monographs.iarc.fr/ENG/Meetings/vol105-participants.pdf The attendees that IARC has listed includes a number of very capable experts representing American employers. Aaron Cohen is an invited specialist. He is a principal scientist of the Health Effects Institute (HEI) which conducts research worldwide on the health effects of air pollution. The Institute's core funding comes in equal part from the U.S. Environmental Protection Agency and the makers of motor vehicles for sale in the United States. http://www.healtheffects.org/sponsors.htm John Gamble, Thomas Hesterberg (a full-time employee of Navistar, Inc.), Roger McClellan, and John Carson Wall (Vice President – Chief Technical Officer of Cummins Inc., a manufacturer of diesel engines) were observers representing "The IARC Review Stakeholder Group," which represents the AAM (Alliance of Automobile Manufacturers), ACEA (European Automobile Manufacturers Association), AECC (Association for Emissions Control by Catalyst), API (American Petroleum Institute), CONCAWE (Conservation of Clean Air Water and Environment, the oil companies European association for environment, health, and safety in refining and distribution), EMA (Truck and Engine Manufacturers of America), IPIECA (International Petroleum Industry Environmental Conservation Association), MECA (Manufacturers of Emission Controls Association), and OICA (International Organization of Motor Vehicle Manufacturers). Another observer, Timothy L. Lash, represents the Association of American Railroads. Thus, it appears American employers are well represented in the IARC evaluation of diesel exhaust.

4. I understand that the Department of Health and Human Services, through the Centers for Disease Control and/or other agencies have awarded a number of grants and/or funds to the International Agency for Research on Cancer (IARC) over the past several years. Please provide a complete account of any such grants in aid, or other transfers of funds originally obligated to the department or its agencies, since 2009. In accounting for this information, please provide a summary of each project or projects undertaken by IARC as

a result of the funding provided by the department or its agencies and documentation requested by the department and its agencies provided by IARC during 1) the solicitation process for such funding and 2) federal oversight of the projects undertaken by IARC, as a result of the grants in aid or other funding provided by the government.

Answer: Since 2009, two components of the National Institutes of Health (NIH) have provided research funding to the International Agency for Research on Cancer (IARC). They are the National Institute on Dental and Craniofacial Research (NIDCR) and the National Cancer Institute (NCI). Below are descriptions of the research that is being funded and other details relevant to each project.

NIDCR

In fiscal years 2010 and 2011, NIDCR provided research funding to the International Agency for Research on Cancer (IARC) in support of two separate projects. The research abstract and public health relevance statements included in the summaries below were submitted by each applicant.

The first project, supported by grant number R03DE020116, titled, *Investigation of Genetic Variation in the Alcohol Metabolism Genes and Other Key Candidates in the IARC Multicenter Oral Cancer Study* was submitted in response to Parent Announcement-07-418; NIDCR Small Grant Program for New Investigators (R03). The project was awarded to Dr. James Dowling McKay at the IARC. The solicitation process followed NIH policies and procedures, as does NIDCR oversight of the project. The research grant provides support for two years. The National Advisory Dental and Craniofacial Research Council was advised of the foreign component of this grant application at the September 24, 2009 meeting, and had no concerns or recommendations. State Department clearance for the foreign component was approved March 9, 2011. The Institutional Review Board at the University of Iowa approved the study on December 30, 2011.

About 413,000 cancers of the oral cavity and pharynx are estimated to occur each year world-wide. While exposure to tobacco and alcohol are the major oral cancer risk factors, there is clear evidence that genetic susceptibility, with variation in the genes involved in metabolism of alcohol, also plays a role. The IARC Multicenter Oral Cancer Study was initiated in 1996 and has developed a multicenter case-control study of approximately 1600 cases and 1600 control individuals from nine different countries and three major ethnicities (European, Asian and African) to investigate oral risk factors, notable exposure to human papillomavirus (HPV), tobacco and alcohol. Investigators associated with this study, and others, have shown that the genes involved in metabolism of alcohol, particularly the ADH gene, cluster on human chromosome 4, and may potentially play an important role in upper aerodigestive tract (UADT) cancers, and important subset of cancers affecting the oral cavity and pharynx.

The specific aims for this project are: 1) Complete isolation of DNA from the stored biological material of the IARC multicenter oral cancer study and develop a working DNA bio-repository; 2) Select key genetic variants relevant to UADT cancer; 3) Genotype genetic variants in the IARC multicenter oral cancer study; and 4) Describe variant effects in the IARC multicenter oral

cancer study. This study will also confirm that genetic markers are associated with oral cavity and pharynx cancer susceptibility across the diverse ethnicities and investigate how these effects are modified by different environmental exposures in IARC multicenter oral cancer study, in particular exposure to HPV, alcohol and tobacco.

PUBLIC HEALTH RELEVANCE: This study will provide more information about the role of key risk factors and genetic variations in the susceptibility to cancers of the oral cavity and pharynx. Such findings will provide significant benefits to efforts to prevent these devastating cancers in the U.S. population and world-wide.

Budget Data:

Project #	**Amount (Dollars)**	**FY**
1R03DE020116-01	87,375	2010
5R03DE020116-02	87,375	2011

The second project is supported by the NIDCR grant R03DE021098-01A1, "Risk Factor Differences by HPV Serology and Tumor DNA Among INHANCE Participants," which was awarded to Dr. Elaine Smith at the University of Iowa. This application was submitted in response to NIDCR PAR-09-182 "Small Grants for Data Analysis," to support research that involves secondary data analyses using existing databases that contain information about oral health conditions. The research grant provides support for two years. The solicitation process followed NIH policies and procedures, as does NIDCR oversight of the project. The National Advisory Dental and Craniofacial Research Council was advised of the foreign component of this grant application at the January 24, 2011 meeting, and had no concerns or recommendations. State department clearance for the foreign component was approved 3/09/2011. The Institutional Review Board at the University of Iowa approved the study on 12/30/2011.

The purpose of the grant is to examine data collected through the International Head and Neck Cancer Epidemiology (INHANCE) Consortium established by the National Cancer Institute/IARC in response to limitations in research of rare tumors, including head and neck cancer (HNC). INHANCE is composed of large molecular/genetic epidemiology studies of HNC worldwide. The investigators will examine the associations of HNC and human papillomavirus (HPV), a known risk factor for a significant proportion of HNC cases. There are several issues that remain unclear about HPV's relationship to HNC, tobacco use and alcohol use, which the INHANCE pooled analysis will better clarify. The aims of this study are to: 1) Examine the association between HPV, tobacco, alcohol and risk of HNC to determine whether there are two HNC diseases, i.e., one risk group related to HPV infection and the other risk group related to tobacco/alcohol use; and 2) Compare tumor tissue HPV DNA+ findings in HNC cases for E6/E7 antibodies, evaluating tumor HPV DNA+/sero- to HPV DNA+/sero+ and DNA-/sero- cases. This aim will determine whether there are HPV-driven and HPV-independent HNC cases and whether HPV DNA+/sero- cases have risk factors similar to or different from HPV DNA+/sero+ or HPV DNA-/sero- cases. The rationale for this aim is that some patients with HNC HPV DNA+ tumors do not mount an immunologic response, suggesting that these cases have different risk factors and clinical outcomes than do HPV antibody positive cases.

PUBLIC HEALTH RELEVANCE: This study will provide more information about treatment and prognosis of HPV-driven tumors, and help clarify whether there are two or more risk factor profiles for HNC. The findings will benefit the efforts to improve treatment efforts for the U.S. population.

Budget Data:

Project #	**Amount (Dollars)**	**FY**
1R03DE021098-01A1	150,750	2011
5R03DE021098-02	151,000	2012

NCI

NCI has awarded a total of eight different grants (two of which had multiple funding years) to the IARC from FY 2009 through FY 2012. The following table provides the project title, core grant number, and funding by fiscal year for each of the eight core grants.

In addition, the NCI also provides a small amount of support to IARC for training and the support of the development of cancer registries through other partners.

Information regarding the solicitation process for each identified grant is provided in the summary of each project, which includes the title, grant number, Request for applications/ Program Announcement (RFA/PA), start and end dates, and project description for each funded year. Therefore, the two projects (core grant numbers 5U01CA033193 and 5R01CA092039) with multiple funding years have multiple summaries, one for each funded year, which vary slightly in description as well as start and end dates.

Each summary includes a link to the RFA/PA that each competitive application was submitted in response to by IARC. Several of the projects were unsolicited or investigator-initiated applications. In these cases, a link to the parent announcement is provided.

The research abstract and public health relevance statements included in the summaries below were submitted by each applicant.

Project Title: Evaluation of Carcinogenic Risk to Humans
Grant#: 5U01CA033193-30
RFA/PA: Unsolicited or Investigator-Initiated
Project Start: 9/1/1985
Project End: 8/31/2015

Abstract

DESCRIPTION (provided by applicant): The IARC Monographs on the Evaluation of Carcinogenic Risks to Humans represent an international expert-consensus approach to carcinogen hazard identification. The long-term objective is to critically review and evaluate the published scientific evidence on carcinogenic hazards to which humans are exposed. These include chemicals, complex mixtures, physical agents, biological agents, occupational exposures, and lifestyle factors. National and international health agencies use the IARC Monographs as a source of scientific information and as the scientific basis for their actions to prevent exposure to known, probable, and possible carcinogens. Each IARC Monograph contains a critical review of the published scientific literature and an evaluation of the weight of the evidence that an agent can increase the risk of cancer. Agents are selected for evaluation based on evidence of human exposure and some evidence of carcinogenicity. Agents can be re-evaluated if significant new data become available. The program also collaborates on scientific workshops to determine how to make the best use of contemporary studies to identify agents that play a role in cancer development and to understand their mechanisms. The Preamble to each volume of IARC Monographs describes the principles and procedures that are followed, including the scientific criteria that guide the evaluations. Each IARC Monograph is developed by a Working Group of experts who conducted the original research, avoiding real or apparent conflicts of interests. Working Groups typically consist of 20-25 scientists from 8-12 countries, with expertise in cancer epidemiology, experimental carcinogenesis, and related disciplines. The Working Group meets to review and reach consensus on drafts prepared by the experts before the meeting, and to develop and reach consensus on the evaluations. Later, IARC scientists review the text and tables to ensure their scientific accuracy and clarity, and the volume is edited and published. Funds are requested to support two of the three volumes produced each year.

Project Title: Evaluation of Carcinogenic Risk to Humans
Grant#: 5U01CA033193-29
RFA/PA: Unsolicited or Investigator-Initiated
Project Start: 9/1/1985
Project End: 8/31/2015

Abstract

DESCRIPTION (provided by applicant): The IARC Monographs on the Evaluation of Carcinogenic Risks to Humans represent an international expert-consensus approach to carcinogen hazard identification. The long-term objective is to critically review and evaluate the published scientific evidence on carcinogenic hazards to which humans are exposed. These include chemicals, complex mixtures, physical agents, biological agents, occupational exposures, and lifestyle factors. National and international health agencies use the IARC Monographs as a source of scientific information and as the scientific basis for their actions to prevent exposure to known, probable, and possible carcinogens. Each IARC Monograph contains a critical review of the published scientific literature and an evaluation of the weight of the evidence that an agent can increase the risk of cancer. Agents are selected for evaluation based on evidence of human exposure and some evidence of carcinogenicity. Agents can be re-evaluated if significant new data become available. The program also collaborates on scientific workshops to determine how

to make the best use of contemporary studies to identify agents that play a role in cancer development and to understand their mechanisms. The Preamble to each volume of IARC Monographs describes the principles and procedures that are followed, including the scientific criteria that guide the evaluations. Each IARC Monograph is developed by a Working Group of experts who conducted the original research, avoiding real or apparent conflicts of interests. Working Groups typically consist of 20-25 scientists from 8-12 countries, with expertise in cancer epidemiology, experimental carcinogenesis, and related disciplines. The Working Group meets to review and reach consensus on drafts prepared by the experts before the meeting, and to develop and reach consensus on the evaluations. Later, IARC scientists review the text and tables to ensure their scientific accuracy and clarity, and the volume is edited and published. Funds are requested to support two of the three volumes produced each year.

Project Title: Evaluation of Carcinogenic Risk to Humans
Grant#: 5U01CA033193-28
RFA/PA: Unsolicited or Investigator-Initiated
Project Start: 9/1/1985
Project End: 8/31/2010

Abstract
DESCRIPTION (provided by applicant): The IARC Monographs on the Evaluation of Carcinogenic Risks to Humans represent an international expert-consensus approach to carcinogen hazard identification. The long-term objective is to critically review and evaluate the published scientific evidence for all carcinogenic hazards to which humans are exposed. These include chemicals, complex mixtures, occupational exposures, lifestyle factors, and physical and biological agents. National and international health agencies use the IARC Monographs as an authoritative source of scientific information and as the scientific basis for their efforts to control cancer. Each IARC Monograph includes a critical review of the pertinent scientific literature and an evaluation of the weight of the evidence that an agent or exposure may be carcinogenic to humans. Agents are selected for evaluation based on evidence of human exposure and some evidence of carcinogenicity. Agents can be re-evaluated if significant new data become available. The program also collaborates on scientific meetings on mechanisms of carcinogenesis and other topics pertinent to evaluations of carcinogenicity. A written Preamble to each volume of IARC Monographs describes the principles and procedures that are followed, including the scientific criteria that guide the evaluations. Each IARC Monograph is developed by a working group selected on two principles: to invite the best-qualified experts and to avoid real or apparent conflicts of interests. Working groups typically consist of 20-25 scientists from 10-12 countries, with expertise in cancer epidemiology, experimental carcinogenesis, and related disciplines. The working group meets to review and reach consensus on drafts prepared by the experts before the meeting, and to develop and reach consensus on the evaluation. Later, IARC scientists review the text and tables to ensure their scientific accuracy and clarity, and the volume is edited and published. Funds are requested to support two of the three volumes produced each year.

Project Title: Genetics of Tobacco and Alcohol Related Cancers
Grant#: 5R01CA092039-07
RFA/PA: Unsolicited or Investigator-Initiated
Project Start: 10/1/2001
Project End: 4/30/2012

Abstract
PUBLIC HEALTH RELEVANCE: Large genetic epidemiology studies have the potential to identify individuals at particularly high risk of developing cancer, as well as helping identify why these cancers develop. By incorporating multiple large studies of cancers related to tobacco and alcohol (specifically lung, and UADT cancer) we aim to provide knowledge that will inform future prevention efforts.

DESCRIPTION (provided by applicant): During the first 30 months of the original grant (R01 CA 092039-01A2), we have successfully contributed to our understanding of the genetic epidemiology of lung cancer and upper aerodigestive tract (UADT) cancer by identification of several genes that are very strongly associated with them, including CHEK2 and ADH1B. We have also demonstrated how genetic variants interact strongly with dietary and environmental exposures for these cancers. Given the enormous increase in genetic information over the last 3 years we plan to build on our initial results and comprehensively evaluate the role of genes in 5 specific pathways for these cancers. To test the robustness of the positive associations observed, we will conduct independent replication of findings in other large studies. We therefore propose a multistage study with the following specific aims: Stage 1 will involve a comprehensive evaluation of 5 candidate gene pathways among 2200 European case-control pairs of lung cancer and 1000 case-control pairs of UADT cancer, involving over 1500 informative variants as well as inclusion of biologically relevant variants. Stage 2 will involve rapid replication of important positive results in other large independent European studies including (i) EPIC lung cancer based on 1200 lung cancer cases and 2400 controls, and (ii) the 'ARCAGE' Western European study of 2000 case-control pairs of UADT cancer. The choice of variants passing from Stage 1 to Stage 2 will be based on hierarchical bayes approach incorporating genomic information such as sequence conservation. Important confirmed genes will be resequenced and further replicated in a third IARC study of UADT cancer from Latin American study comprising 2000 case-control pairs of head and neck cancer. As an important component of this proposal, we will conduct functional studies of the genes that are replicated including differential mRNA expression. All results will be made available to the research community of tobacco and alcohol related cancers via collaboration within 2 international consortia of lung cancer and head and neck cancers.

Project Title: Genetics of Tobacco and Alcohol Related Cancers
Grant#: 5R01CA092039-06
RFA/PA: Unsolicited or Investigator-Initiated
Project Start: 10/1/2001
Project End: 4/30/2011

Abstract
PUBLIC HEALTH RELEVANCE: Large genetic epidemiology studies have the potential to identify individuals at particularly high risk of developing cancer, as well as helping identify why these cancers develop. By incorporating multiple large studies of cancers related to tobacco and alcohol (specifically lung, and UADT cancer) we aim to provide knowledge that will inform future prevention efforts.

DESCRIPTION (provided by applicant): During the first 30 months of the original grant (R01 CA 092039-01A2), we have successfully contributed to our understanding of the genetic epidemiology of lung cancer and upper aerodigestive tract (UADT) cancer by identification of several genes that are very strongly associated with them, including CHEK2 and ADH1B. We have also demonstrated how genetic variants interact strongly with dietary and environmental exposures for these cancers. Given the enormous increase in genetic information over the last 3 years we plan to build on our initial results and comprehensively evaluate the role of genes in 5 specific pathways for these cancers. To test the robustness of the positive associations observed, we will conduct independent replication of findings in other large studies. We therefore propose a multistage study with the following specific aims: Stage 1 will involve a comprehensive evaluation of 5 candidate gene pathways among 2200 European case-control pairs of lung cancer and 1000 case-control pairs of UADT cancer, involving over 1500 informative variants as well as inclusion of biologically relevant variants. Stage 2 will involve rapid replication of important positive results in other large independent European studies including (i) EPIC lung cancer based on 1200 lung cancer cases and 2400 controls, and (ii) the 'ARCAGE' Western European study of 2000 case-control pairs of UADT cancer. The choice of variants passing from Stage 1 to Stage 2 will be based on hierarchical bayes approach incorporating genomic information such as sequence conservation. Important confirmed genes will be resequenced and further replicated in a third IARC study of UADT cancer from Latin American study comprising 2000 case-control pairs of head and neck cancer. As an important component of this proposal, we will conduct functional studies of the genes that are replicated including differential mRNA expression. All results will be made available to the research community of tobacco and alcohol related cancers via collaboration within 2 international consortia of lung cancer and head and neck cancers.

Project Title: International Lung Cancer Consortium: Pooled Analysis of Genetic Determinants
Grant#: 5R03CA133939-02
RFA/PA: PAR06-294
Project Start: 3/10/2008
Project End: 2/28/2010

Abstract
DESCRIPTION (provided by applicant): While it is apparent that lung cancer is predominantly caused by exposure to tobacco products, only a minority of heavy smokers will develop this disease. Familial aggregation has been observed in lung cancer with familial relative risk of 2-fold and a recent linkage analysis has revealed a possible susceptibility locus at 6q23-25. However, the exact inheritance mechanism of lung cancer is still largely undefined. Major gaps

remain in knowledge of lung cancer genetics including (i) the effect of positive family history of lung cancer, particularly by histological type and among never smokers, and (ii) the contribution of low and moderate penetrance genetic variants. Single studies are unlikely to be sufficiently powered to provide robust answer to these questions highlighting the need for international collaboration across studies. The International Lung Cancer Consortium (ILCCO) is an international group of lung cancer researchers established in 2004 with the aim of sharing comparable data from ongoing lung cancer case-control and cohort studies. The overall objectives are to achieve greater power, especially for subgroup analyses, reduce duplication of research effort, replicate novel findings, and afford substantial cost savings through large collaborative efforts. We propose to conduct pooled analyses to evaluate the effect of family history among never smokers, and conduct coordinated genotyping to investigate the contribution of low to moderate penetrance genetic variants. Our hypotheses are (i) positive family history of lung cancer may differ by histological type and also by smoking status, and ii) common genetic variants influence lung cancer risk and attributable to at least part of the lung cancer cases. Our specific aims are (i) to combine data from 21 lung cancer studies to evaluate the contribution of positive family history of lung cancer to the risk of developing lung cancer overall, as well as by age of the proband, in never smokers and by histological subtype. We will also (ii) conduct coordinated genotyping on potential lung cancer susceptibility variants, which are nominated by ILCCO members and chosen based on the strength of the evidence, biological plausibility, and previous independent replications. Finally we will (iii) conduct pooled analysis of genotyping data, in order to confirm or refute the effect of these sequence variants on lung cancer overall, as well as in rare subgroups of interest including never smokers, young age of onset, familial cases and on histological subtypes.

Project Title: One-carbon metabolism biomarkers and lung cancer risk
Grant#: 1U01CA155340-01A1
RFA/PA: PA10-067
Project Start: 9/23/2011
Project End: 8/31/2015

Abstract
PUBLIC HEALTH RELEVANCE: In the US over 225,000 lung cancer cases are diagnosed every year representing approximately 15% of all new cancer cases, and 28% of cancer deaths. Although the main risk factor of lung cancer is tobacco exposure, nearly half of all lung cancer cases in the US occur among former and never smokers. We recently identified strong protective effects of elevated circulating levels of B- vitamins (in particular vitamin B6, folate, and also methionine) in a large cohort including pre-diagnostic blood samples in participants from eight European countries. The proposed study includes equal numbers of never, former and current smokers, aims to clarify a potentially strong beneficial role of B-vitamins and related factors in lung cancer development. The study will be conducted in collaboration with over 20 cohorts, and may identify important biomarkers for lung cancer risk prediction, over and above that afforded information on tobacco exposure.

DESCRIPTION (provided by applicant): We have recently identified strong associations between circulating biomarkers of one-carbon metabolism (OCM) and lung cancer within the European Prospective Investigation and Cancer (EPIC) cohort, based on prospectively collected blood samples from 900 cases and 1,800 controls. The study strongly implicated important protective effects for both vitamin B6 and methionine independently of smoking status, resulting in 2.5-fold risk differences between the top and bottom 25% of the population for these vitamin measures combined (p=10-12). Repeat measures indicated that these effects were substantially under-estimated because of regression dilution. The main objectives of this expanded study are two-fold: i) to clarify the role of B-vitamins and related factors (the one-carbon metabolism pathway) in lung cancer etiology in a study population large enough to allow robust risk analyses stratified by smoking status, using both molecular epidemiology and genetic approaches, and ii) to measure the role of OCM biomarkers in lung cancer risk prediction in multiple cohorts. We have initiated a lung cancer consortium in collaboration with over 20 cohorts participating in the NCI Cohort Consortium, including in total 11,500 prospectively collected lung cancer cases with blood samples. This study will include equal proportions of 1,200 never, former, and current smoking case-control pairs recruited in US/European/Australian cohorts, as well as 1,500 case-control pairs recruited in Asian cohorts. We will also include 1,000 repeat samples from a subgroup to allow for correction of regression dilution bias, resulting in biochemical analysis of 11,200 serum/plasma samples. Circulating levels of up to 40 biomarkers of one-carbon metabolism will be measured in the whole study population, and we will quantify their association with subsequent lung cancer risk. Important analyses of a priori interest will include measuring the association with risk among never and former smokers separately. These risk estimates will subsequently be used in risk prediction models, also taking regression dilution into account. Preliminary data from the EPIC cohort indicate that serum measures of methionine and vitamin B6 may identify up to 7-fold differences in life-time risk of lung cancer. Lung cancer remains a major health problem world-wide, and is responsible for 28% of all cancer deaths in the US. As well as elucidating the association between OCM biomarkers and lung cancer, this initiative will create more detailed risk prediction models, over and above that afforded by detailed information on tobacco exposure alone. The important work that will go into the construction of this consortium will also result in opportunities to initiate additional studies concerning lung cancer etiology.

Project Title: A New Approach to Identify Rare Genetic Variants Influencing Melanoma Risk
Grant#: 1R03CA156624-01A1
RFA/PA: PAR08-237
Project Start: 3/1/2012
Project End: 2/28/2014

Abstract

PUBLIC HEALTH RELEVANCE: Malignant melanoma is a rare tumor of melanocytes that, because of its aggressive nature, causes the majority of deaths related to skin cancer. Since the mid-20th century, melanoma has become an important health problem in fair-skinned populations worldwide, since its incidence has climbed faster than any other type of malignancy. The goal of this study is the identification of new melanoma susceptibility genes and the

characterization of the pathogenic sequence variants associated with increased risk of developing melanoma. Identification of susceptible individuals may aid in increasing sun protection and early detection of melanocytic tumors at the precancerous stage of the disease, altering attitudes toward sunlight and suntans, and protecting the skin from UV damage in populations at risk.

DESCRIPTION (provided by applicant): A number of genome-wide association studies (GWAS) have successfully implicated common SNPs in the etiology of complex traits. Most variants identified so far confer relatively small increments in risk (1.1-1.5-fold), and explain oly a small proportion of familial clustering. Recent studies have demonstrated that common diseases can be due to dysfunctional variants with a wide spectrum of allele frequencies. So far, rare variants studies have been limited to a handful of phenotypes and genes, but the advancement of sequencing technologies should lead to widespread association studies of candidate genes and genomes. If rare variants have larger effects than common variants, this should aid in their detection. Also their identification should have a greater impact on risk assessment, disease prevention and treatment. However, the analysis of rare variants is challenging since methods used for common variants are underpowered. Previously, we used data from mutation screening of breast cancer patients and controls to demonstrate the ability to detect evidence of pathogenicity from both truncating and splice junction variants and rare missense substitutions. The method involves stratifying rare missense substitutions observed in cases and/or in controls into a series of grades ordered from least to most likely to be evolutionarily deleterious, followed by a logistic regression trend test to compare the frequency distributions of the grades of variants in cases versus controls. The original model was developed to assess the pathogenicity of missense substitutions in breast cancer-related genes. Here we propose to test the efficiency of our analysis strategy to cutaneous malignant melanoma (CMM). To identify novel risk alleles, we will mutation screen the strongest candidate genes of the pigmentation pathway in over 1,300 cases and 1,300 matched controls from 10 European countries enrolled in the EPIC cohort. CMM provides a unique model for studies of gene-gene and gene-environmental interactions in the development of multifactorial diseases, since relationships between the major environmental factor (exposure to solar UV radiation) and known susceptibility genes are reasonably well understood. High-risk mutations in CDKN2A and CDK4 are carried by about 20-25% of melanoma-prone families. In contrast, some missense substitutions in the pigmentation gene MC1R have been proven to be modest-risk or intermediate-risk susceptibility alleles, and also to increase the penetrance of CDKN2A mutations. Finally, two recent GWAS identified low- penetrance SNPs in MC1R or in genes of the same pathway. Associated SNPs will account for no more than 12% of the Familial Relative Risk. Thus, the majority of the genetic susceptibility to CMM remains to be explained. After validation of our method on strong candidates, massive parallel sequencing of genes of entire biochemical pathways is envisaged to generate a comprehensive picture of the risk-frequency spectrum for pathogenic sequence variants involved in susceptibility to melanoma.

Project Title: Genetic Analysis of a Large Multiplex Nasopharyngeal Carcinoma (NPC) Family
Grant#: 1U01CA165037-01
RFA/PA: PAR08-237
Project Start: 5/25/2012

Project End: 4/30/2014

Abstract
PUBLIC HEALTH RELEVANCE: Genetic susceptibility, along with environmental factors such as suboptimal food preservation and exposure to EBV, are likely to play a role in the etiology of nasopharyngeal carcinoma (NPC). However, the identity of the genes involved in NPC susceptibility, particularly genes that confer an important genetic risk, remain elusive. This application aims to perform in depth genetic analysis of a large multiplex Malaysian pedigree to identify new genes involved in the susceptibility to NPC, with the genes of interest that arise to be validated and replicated in additional populations.

DESCRIPTION (provided by applicant): Nasopharyngeal carcinoma (NPC) has an extremely heterogeneous geographical and ethnic distribution. Environmental factors such as suboptimal food preservation and exposure to EBV appear involved in the etiology of NPC. Genetic susceptibility is also likely to be involved but the identity of the genes involved in susceptibiliy to NPC remains elusive. Isolated populations, particularly those with unusually high diseases prevalence, offer rare opportunities to investigate the genetic cause of human disease. The Bidayuh ethnic subgroup of Sarawak Malaysia has unusually high prevalence of NPC. We have identified one exceptionally large Bidayuh multiplex pedigree in which 26 NPC cases can be traced back to a single founding village. We have focused extensive recruitment of the NPC cases allowing the collection of blood samples from 11 of the NPC cases, and can to infer genetic information for an additional 7 NPC cases. This application aims to perform comprehensive genetic analysis of this pedigree using a combination of high density genotyping and direct whole exome DNA sequencing. The genes of interest identified in this exceptionally large pedigree will be validated and replicated in additional populations.

Project Title: Pooled Genome-Wide Analysis of Kidney Cancer Risk
Grant#: 1U01CA155309-01A1
RFA/PA: PA10-067
Project Start: 9/14/2011
Project End: 8/31/2015

Abstract
PUBLIC HEALTH RELEVANCE: The incidence of kidney cancer has been increasing over the past decades and the disease has a very poor prognosis when diagnosed at an advanced stage (20% of the cases in the US). Apart from smoking, obesity and hypertension, much of the etiology of this disease remains to be identified. We propose to investigate genetic factors associated with kidney cancer onset and survival, looking at the genetic variants across the whole genome, and combining this with gene expression analysis of the tumor tissue.
DESCRIPTION (provided by applicant): Renal cell carcinoma (RCC) is the 8th most common cancer in the US and the 10th most common form of cancer death, with over 34,000 cases and 12,000 deaths each year. A sharp increase in the incidence of RCC was observed in recent decades with some of the greatest increases happening in Central Europe and among the black

population in the US. Apart from smoking, obesity and hypertension, much of the etiology of this disease remains to be identified. There is increasing evidence that genetic factors influence susceptibility to RCC, although this hypothesis has been understudied. We have recently completed a genome-wide association study (GWAS) of RCC comprising 3,800 cases and 8,500 controls. We now propose to extend this study by incorporating an additional 3,800 cases and 4,800 controls from a series of population based case-control and cohort studies. Inclusion of cohort studies has been facilitated via the NCI cohort consortium initiative. In addition to its size, our study will be unique in several ways: (1) extensive clinicopathological information and survival of cases will be collected; (2) genome-wide analyses for the association between genetic variants and RCC will be conducted for both disease onset and survival; (3) a comprehensive biorepository of germline DNA and tumor DNA and RNA on at least 2,000 cases will be developed; (4) whole-genome gene expression profiling on fresh renal tissue and tumor tissue will be obtained to complement results obtained from the germline genotyping analyses.

Project Title: Common and Rare Sequence Variants in Breast Cancer Risk
Grant#: 5R01CA121245-03
RFA/PA: Unsolicited or Investigator-Initiated
Project Start: 9/30/2007
Project End: 7/31/2010

Abstract
DESCRIPTION (provided by applicant): Combining data from segregation analyses and mutation screening studies, the established breast cancer susceptibility genes are responsible for an estimated 20%-25% of the genetic component of this disease. The genes and/or sequence variants responsible for the remaining genetic component of breast cancer risk have yet to be identified. Most of the current enthusiasm for SNPs and haplotype mapping are predicated on the assumption that common modest risk variants are most important. However, few candidate associations between common SNPs and breast cancer risk have been independently reproduced. Thus the central question of this study: What is the relative contribution of common (usually modest-risk) sequence variants vs. rare (potentially higher-risk) sequence variants to the genetic attributable fraction of breast cancer? U Using an ethnically diverse series of 1,250 genetically high-risk breast cancer cases and 1,250 frequency-matched population controls, we propose a novel study designed to make a direct comparison between the common disease/ common variant and common disease/ rare variant models of genetic susceptibility. The study has two arms. In the first, we will genotype the cases and controls with all of the common- sequence variants that are known, or are found over the course of this study by the breast cancer genetics research community, to predict increased risk of breast cancer. In the second arm, we will mutation screen the open reading frames of strong candidate susceptibility genes in both the cases and the controls. Analysis of the genotype and mutation screening data should provide an answer to the central study question. Our focus on early onset and familial cases will substantially increase power to detect risk conferred by deleterious sequence variants as compared to a study of similar size without these criteria, fl Results from this study are relevant to public health in three ways: (1) This study will provide a hypothesis test of genes, and mutations in them, that appear to confer moderately to dramatically increased risk of breast

cancer. Measuring risk due to mutations in these genes is a key step that lies between initial indications that the gene plays a role in breast cancer susceptibility and bringing the gene into the clinical practice of cancer genetics. (2) Results from this study will bear on the future direction of clinical cancer genetics. The relative contribution that moderate risk versus modest risk sequence variants make to the attributable risk of breast cancer will have an impact on how the genetic information enters clinical practice. (3) Analysis of the genotype and mutation screening data will provide a comparison of risk attributable to the common variant and rare variant genetic models of cancer susceptibility. This is a question of major current interest and importance within the genetics research community. If we observe that the rare sequence variants account for as much or more risk than do common SNPs, it may be necessary to expand mutation screening from the realm of genetic epidemiology/ family studies into larger scale population-based studies.

The competitive applications for each funded project were subject to federal oversight, including Just-in-Time procedures. These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information for senior/key personnel; certification of Institutional Review Board (IRB) approval of the project's proposed use of human subjects; verification of Institutional Animal Care and Use Committee (IACUC) approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants' requirement. Other program-specific information may also be requested using this procedure. In addition, progress reports were required annually as part of the non-competing continuation award process. NIH also requires all financial expenditure reports to be submitted using the Federal Financial Report (FFR). An annual FFR is required for awards to foreign organizations. Additional information on the NIH Policy on Grants to Foreign Institutions can be found at: http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch16.htm#_Toc271265275

The Honorable Lou Barletta

1. Recently, the 2012 Medicare Trustee Report concluded that Medicare will go bankrupt by 2024. Doctors, hospitals, and patients in the 11th district are concerned about these results. With an aging population, increased technology, and more complex medications there continues to be a strong demand for medical services. In addition, the President's healthcare reform law reduced Medicare expenditures by more than $500 billion and the Health and Human Services' FY 13 budget request calls for over 300 billion more in cuts from Medicare and Medicaid. How do you expect providers to address these cuts?

Answer: There's no doubt that slowing the growth of Medicare spending will be a challenge. But doing so is essential in order to meet our collective commitments to our seniors and address our long-term budget deficits. The payment modifications included in Affordable Care Act targeted areas where spending was in excess of the cost of efficient, high-quality care and where payment incentives are expected to encourage providers to improve health care delivery. The President's Budget builds on the Affordable Care Act to encourage better health care delivery systems and to further address excess spending. This constitutes a sound, sustainable, and cautious approach to slowing the growth of Medicare.

Experts agree that there is significant inefficiency in the health care sector. By attacking this inefficiency, providers will be able to absorb the relatively modest Medicare spending restraints included in the Affordable Care Act. Provisions in the Affordable Care Act that promote delivery and payment innovations will further support these efforts and help providers realize additional productivity gains.

In addition, the Affordable Care Act will vastly reduce the number of Americans without health insurance. As a result, providers will deliver far less uncompensated care, giving a major boost to their bottom lines.

2. How is the U.S. Department of Health and Human Services planning for the estimated mandatory cuts that will take place under the current sequestration rules contained in the Budget Control Act? What process will the agency use in determining the necessary cuts? Will you start with the programs that cost the most? What analysis has been done to estimate the impact on access to care?

Answer: The Administration believes that Congress should pass balanced deficit reduction legislation consistent with the President's Budget to avoid sequestration. In the event that Congress fails to pass bipartisan balanced deficit reduction legislation, the Congressional Budget Office (CBO) estimates that automatic sequestration would reduce non-defense discretionary programs by 7.8 percent on January 2, 2013, which would be applied to most HHS accounts. The deep discretionary cuts projected by CBO would have profound consequences on the Department's ability to protect Americans' health and safety and provide critical services to vulnerable populations.

3. My district is home to one of the largest vaccine companies in the world, and as such I have a concern about the proposed cuts to the 317 immunization program which provides the federal infrastructure funding for state and local immunization programs. What is the rationale for cutting this program and how will that impact the states' ability to purchase and distribute vaccines?

Answer: The FY 2013 budget request includes funds for vaccine purchase to continue outreach to the hardest to serve populations, and critical immunization operations and infrastructure that supports national, state, and local efforts to implement an evidence-based, comprehensive immunization program. The request also specifically directs $25 million towards continuation of the Billables Project, which allows public health departments to vaccinate and bill for fully-insured individuals in order to maintain Section 317 vaccines for the most financially vulnerable and respond to time-urgent vaccine demands, such as outbreak response. The FY 2013 Budget will sustain the national immunization program vaccine purchase and immunization infrastructure. The Budget does not continue funding for one-time enhancements planned for FY 2012 to modernize the immunization infrastructure through funding to the grantees for improving immunization health IT systems and vaccine coverage among school-age children and adults; expansion of the evidence base for immunization programs and policy; and enhancements to national provider education and public awareness activities to support vaccination across the lifespan. Health reform expansion will further increase access to immunizations and decrease the number of uninsured and underinsured individuals served by the Section 317 Program, resulting in cost savings.

The Honorable Martha Roby

1. As part of the universal health insurance reform passed in 2010, all health plans must now provide—at no out-of-pocket cost to the recipient—certain "preventative services." Many of these services are routine; however, it is the tenth government-mandated service that puts various groups in a moral bind. Specifically, the mandated coverage must include "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity."

Due to public uproar, in February, HHS finalized the narrowly defined exemption for the "religious employer"—ensuring that some, but not all religious institutions, will not have to cover contraceptive services or refer employees to organizations that provide such services. This exemption only applies to a religious entity if it primarily serves people of their own faith. It does not apply to faith-based organizations that serve people of all or no faith.

The Catholic TV Station, The Eternal Word Television Network (EWTN), is located in the state of Alabama. EWTN does not fall under the small umbrella of this religious exemption—nor do many hospitals, charitable service organizations, and universities. I understand that the Administration is working on an "accommodation" for groups that fall under this category.

Putting aside the future "accommodation," why is EWTN, and similar religiously affiliated entities, not exempt from covering these services---especially when these drugs and services fundamentally contradict their moral beliefs? Why is the administration defining some institutions as religious enough for a full exemption, others as only religious enough to qualify for a yet undefined accommodation and leaving still others with no religious protection at all?

Answer: After considering the many comments received on the amendment to the interim final rules providing for a religious exemption, the Departments issued final rules on February 10, 2012, retaining the same exemption authority announced in August 2011. At the same time, we released guidance providing a one-year enforcement safe harbor for group health plans sponsored by certain non-profit organizations (and any associated group health insurance coverage) that, for religious reasons, do not provide contraceptive coverage and do not qualify for the current exemption.

In announcing this policy, the Administration committed to rulemaking during this one-year enforcement safe harbor period to ensure women have access to these important preventive services in fully insured and self-insured group health plans while protecting the religious beliefs of additional religious organizations.

On March 21, 2012, HHS published an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register. The comment period was open until June 19, 2012. During this transition period, the Administration will continue to work with faith based organizations, insurers, and

other interested parties to develop rules that respect religious liberty and ensure access to preventive services for women.

2. After 2014, all health care plans are expected to include coverage for sterilization and contraception, including drugs that some believe can cause an abortion (e.g. the morning after pill). If an employer such as EWTN has a moral objection to such coverage, and their moral objections remain even under the accommodation that you have said will be proposed at a later date, what penalties will be imposed on employers and insurance providers for not covering these services?

> **A) What will happen to an employer who cannot find an insurance plan that matches their values? If they were to fail to provide insurance, will that employer be fined or otherwise penalized? How much are the fines imposed? How will entities such as EWTN be penalized as a self-insured entity?**
>
> **B) What if an employer that objects to certain coverage self-insures (as in the case of EWTN) or otherwise provides insurance to their employees and fails to include the coverage that they oppose? What would the fines be in that case? If they refuse to pay the fines will they be arrested? What actions will be taken?**

Answer: On February 10, 2012, we issued regulations finalizing last summer's interim final regulations on the exemption from the contraceptive coverage requirement for churches and similar organizations. The Federal Register publication also discusses the one-year transition period, which is detailed in separate guidance from the Departments.

On March 21, 2012, an Advance Notice of Proposed Rulemaking (ANPRM) was published in the Federal Register, marking the next step in the Administration's effort to implement the policy announced by the President on February 10, 2012. This ANPRM presents potential policies and identifies questions to guide rulemaking that is intended to amend the preventive services regulations to guarantee women's access to recommended preventive services—including contraceptives—without cost sharing, while ensuring that additional religious organizations are not forced to pay for, provide, or arrange the provision of any contraceptive item or service to which they object on religious grounds. We intend to develop a proposed and final policy through a collaborative process.

3. The US Conference of Catholic Bishops (USCCB) was recently denied a HHS grant to provide assistance to victims of human trafficking. For the first time in the history of the program, the funding opportunity announcement stated that "strong preference" would be given to applicants that are willing to direct clients to medical providers who can provide or refer for the "full range of legally permissible gynecological and obstetric care." This language appeared to be an effort to make it more difficult for the USCCB to receive a grant under this program---even though they were the incumbent applicant and had received outstanding reviews throughout the years that they received funding for this program. An investigation conducted by the House of Representatives Oversight and Government Reform Committee revealed that even with this "preference" in the request for proposals, independent reviewers gave USCCB one of the highest scores on their

application: 89 out of 110. Still, HHS denied funds to the USCCB while funding proposals that received significantly lower scores, including scores of 69 and 74. Only one of the three awardees received a score higher than USCCB.

This question is regarding the HHS grant to fund care for victims who have been rescued from human trafficking. I am referring to the funding that was denied to the USCCB as an entity.

Were you briefed on the reproductive health language in this request for proposals? Did you request or approve the reproductive health language? Were you briefed on the scores awarded to each applicant under this program? Did you approve the decision to pass over USCCB even though they had one of the highest scoring applications? Could you please clarify how an entity that offers a "full range" of services but at a lower quality level more effectively assists trafficking victims and protects taxpayer dollars than an organization that is more qualified and does not tit HHS's new definition of reproductive health? Did HHS base its decision to redefine reproductive health and give preference to such organizations on evidence-based research?

As a result of the reproductive health requirement, have any trafficking victims been referred to Planned Parenthood? Have any of the new funding recipients indicated that they have, or intend to, refer victims to Planned Parenthood clinics?

Answer: HHS is committed to ensuring that trafficking victims receive the high quality, comprehensive case management services that they need to be healthy and supported as they re-take control over their own lives. In light of the particular health risks posed to victims of human trafficking, HHS specified in the 2011 funding announcement that it would give a strong preference to applicants willing to offer all the services and referrals delineated in the program objectives, including offering "all victims referral to medical providers who can provide or refer for provision of treatment for sexually transmitted infections, family planning services and the full range of legally permissible gynecological and obstetric care, including but not limited to exams, tests, and pre-natal services and non-directive health-related counseling."

This preference reflects two realities. First, trafficking victims, many of whom are sex trafficking victims or have been sexually assaulted, can have a heightened interest in and need for the full range of medical referrals. For example, multiple studies have found that trafficked women and adolescents report sexual and reproductive health needs as their most common and most prioritized health need (Zimmerman, C. (2003) *The health risks and consequences of trafficking in women and adolescents: Findings from a European study.* London: London School of Hygiene & Tropical Medicine. Zimmerman , c., Hossain, M., Yun, K., Roche, B., Morison, L., & Watts, C. (2006). *Stolen smiles: A summary report on the physical and psychological health consequences of women and adolescents trafficked in Europe.* London: London School of Hygiene & Tropical Medicine.)

Second, HHS funds only one grantee per geographic area. Therefore, we believed it was important that the single grantee serving human trafficking victims in a given area be able to provide the population access to information about the full scope of services and the referrals they might need to take control of their own lives. In FY 2011, HHS received applications from several organizations that had both the strong capacity to provide comprehensive case

management services and a willingness to ensure that all of the specified referrals and services would be provided. As a result, HHS made awards to grantees that are able to provide the full set of health-related information and referrals, consistent with the stated preference. These three organizations will enable trafficking victims to re-take control of their lives by making informed health care decisions, in consultation with their doctors, based on the victim's own circumstances, values, and faith.

We do not collect data on individual service referrals. Accordingly, we do not know whether victims have been referred to Planned Parenthood.

On September 12, 2011, Acting Assistant Secretary George Sheldon briefed me on the evaluation of the applications and the preliminary award decisions. As the Acting Assistant Secretary of ACF, of which the Office of Refugee Resettlement is a part, Mr. Sheldon made the final decision on grant awards.

The Honorable Lynn Woolsey

The National Institute for Occupational Safety and Health (NIOSH) in conjunction with the National Cancer Institute (NCI) conducted the Diesel Exhaust in Miners Study (DEMS), which was designed to evaluate the risk of death associated with diesel exhaust exposure, particularly as it may relate to lung cancer.

1. What was the main result of the DEMS study?

Answer: DEMS showed a strong and consistent relationship between quantitative exposure to diesel exhaust and increased risk of dying of lung cancer after adjustment for smoking and other risk factors for lung cancer. This effect was strongest for underground workers, who had far greater exposure to diesel exhaust than surface-only workers.

2. At the hearing it was asserted that this study found "that diesel exhaust exposure of a surface mine produced higher risks of adverse health effects than to underground miners, with much higher levels of exposure." Is this a correct characterization of what this study found?

Answer: The Diesel Study did not evaluate surface mines. It evaluated workers at 8 U.S. non-metal mining facilities with at least 50 employees and separately reported lung cancer mortality for workers at these mines who worked at the surface (always or prior to going underground) or who had ever worked underground. For ever-underground workers (who had heavier exposures), there was strong evidence of an exposure-response relationship, with the cohort mortality and nested case-control studies showing statistically significant increases in lung cancer risk with increasing exposure. Surface-only miners had lower levels of exposure and lower numbers of lung cancer cases, so the statistical power to evaluate for exposure-response relationships was less for this group. Still, the cohort mortality study showed some evidence for a relationship between exposure and lung cancer in this group, even at the lower levels of exposure that were present on the surface. In contrast, the case-control study did not confirm the presence of consistent exposure-response relationships for surface-only workers after adjustment for smoking and other lung cancer risk factors.

3. At the hearing it was asserted "that heavy smokers, with the highest diesel exhaust exposures, have a lower risk for lung cancer than miners who didn't smoke ..." Is this an accurate characterization of the study findings?

Answer: This question refers to the nested case-control study, which was the DEMS component that evaluated information about smoking. Among nonsmokers and low-to-moderate smokers, the risk of lung cancer increased with increasing diesel exposure. In contrast, among miners who were heavy smokers (two or more packs per day), the risk of lung cancer death for those with the highest levels of exposure to diesel exhaust was attenuated. Their risk remained elevated but tapered off with increasing levels of exposure. As noted in the paper, this observation will require confirmation since little is known about the interaction between cigarette smoking and diesel exhaust exposure on lung cancer risk. The paper discusses a number of possible explanations for the tapering off of risk at high levels of diesel exhaust exposure. First, it is

possible that smokers are more likely to clear diesel exhaust particulate matter from their lungs than nonsmokers. This phenomenon has been reported among coal miners who are heavy smokers. Second, carcinogens in diesel exhaust and cigarette smoke may operate in the same metabolic pathway in the body. If so, they may compete with each other, resulting in a saturation of the pathway, thus diminishing the effects of either component. Additional research will be needed to confirm this finding and learn more about its mechanistic implications.

4. What mines and how many workers were covered in this study?

Answer: Ten mining facilities were originally selected for study after an extensive feasibility study of U.S. non-metal mining facilities with at least 50 employees. Two facilities were later rejected because of incomplete personnel records. The remaining eight comprised one low-silica limestone, three potash, one salt (halite), and three trona ($Na_3H(CO_3)_2 \cdot 2H_2O$ – a primary source of sodium carbonate) facilities. The facilities were located in Missouri (limestone), New Mexico (potash), Ohio (salt), and Wyoming (trona). Workers evaluated in the cohort mortality study included all non-administrative workers with 1+ years of tenure after dieselization. This came to a total of 12,315 individuals, of which 8307 worked ever-underground and 5848 worked at the surface only.

5. This study was also the subject of a 2001 court order that requires the agencies involved to provide all data requested by this committee. Are there any requests for information submitted to the department from this committee that have not been completely fulfilled? Are you aware of any willful non compliance with these requests?

Answer: The Department has complied with the court order.

6. NIOSH leases the Lake Lynn Experimental Mine in southwest Pennsylvania. This facility, in which the U.S. government has invested more than $40 million, is essential for conducting mine safety research such as large-scale explosion trials. However, the lease is expiring and NIOSH will have to vacate this facility in September. What steps are being taken to acquire this property? Has an appraisal been completed?

Answer: HHS has been working diligently for many years to acquire the property, but has not yet found a viable pathway to complete this effort. Multiple appraisals have been completed, and HHS has made multiple offers to the property owners – all of which have been rejected. Absent any further developments, NIOSH will need to vacate the property in September.

7. The Occupational Safety and Health Act requires the Secretary of Health and Human Services, after consultation with the Secretary of Labor and other agencies, to conduct directly, or by grants and contracts, education programs to provide an adequate supply of qualified personnel to carry out the purposes of this Act. However, the department's Fiscal Year 2013 budget eliminated all funding for the NIOSH Education and Resource Centers (ERCs), which is one of the key means by which HHS fulfills this mandate.

> **A) Did the Secretary of Labor or the Assistant Secretary for the Occupational Safety and Health Administration agree that that funding for ERCs was no longer**

necessary to assuring an adequate supply of occupational safety and health professionals?

Answer: We have no knowledge of statements by the Secretary of Labor or the Assistant Secretary for the Occupational Safety and Health Administration regarding the funding of the ERCs.

B) In December 2011, the Millbank Quarterly published the "Economic Burden of Occupational Injury and Illness in the United States" which estimates that the annual direct and indirect costs of occupational disease and injury are at least $250 billion per year. This amount exceeds the individual cost of cancer, coronary heart disease, stroke, and diabetes. In view of this economic burden, will the department reconsider the priority it is giving to training programs for qualified personnel to help prevent occupational injury and disease, as part of its budget for Fiscal Year 2013 or its development of the Fiscal Year 2014 budget?

Answer: We acknowledge the continuing burden of occupational disease, death, and injury as demonstrated in the December 2011 study cited above. However, given the limited federal resources in a resource-constrained environment, the ERCs have been designated as a low-priority program. Although the federal portion of these grants was eliminated in CDC's FY 2013 budget request, CDC will continue to provide technical assistance to the ERCs as requested.

The Honorable Ruben Hinojosa

Over the past two years, the Centers for Medicare and Medicaid Services have been working to implement new operating systems that will allow for CMS to process claims in compliance with ICD10 and HIPAA 5010 requirements. On January 1, 2012, CMS began the processing of electronic claims through HIPAA Version 5010 and it is my understanding from providers and their trade organizations that this change has been met with some problems.

I have received reports that this change has led to physicians in Texas experiencing substantial reimbursement delays, in particular for dual eligible patients. I have received further reports that presently, the Texas Medicaid Program is having some problems interfacing with CMS' claims software due to technical difficulties prompted by the 5010 change over. This gives me great concern as dual eligible patients are some of our most distressed and medically needy individuals.

I applaud your agency responding to these challenges by postponing full 5010 implementation until June 30. However, I have serious concerns about any program that leads to delays in payments and could endanger our nation's safety net of care. So my question for you is can you outline what can be done to ensure these delays will be avoided in the future? Additionally, can you please give me a brief report on any other changes, requirements or proposed pilot programs that are or could delay provider payments due to technical difficulties?

Answer: We are cognizant of the challenges faced by the health care industry in fully implementing Accredited Standards Committee (ASC) X12 Version 5010 electronic health care transaction standards (Version 5010).

To address these issues, the Department of Health and Human Services, through CMS, extended its enforcement discretion period from the compliance date of January 1, 2012, to June 30, 2012. This allows providers, vendors and other affected entities the opportunity to complete their end-to-end system testing and software installations without being subject to CMS enforcement action or penalty. CMS has been monitoring the industry's use of Version 5010, providing extensive outreach and education regarding Version 5010, and working diligently to make sure providers are able to bill and payers are able to pay using Version 5010. CMS is also working closely with State Medicaid agencies to ensure that they have either a minimum level of compliance or contingency plans in place to keep reimbursements flowing. We believe that this enforcement discretion period has provided the industry with sufficient time to complete the transition to Version 5010 and avoid any delay in payment. Lessons learned from this experience will be analyzed and applied to future standards implementations. Therefore, we do not anticipate any other changes, requirements or proposed pilot programs that are or could delay provider payments due to technical difficulties.

[Whereupon, at 12:31 p.m., the committee was adjourned.]

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