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

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

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NOTE: Under Committee Rules, Mr. Obey, as Chairman of the Full Committee, and Mr. Lewis, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

DAVID REICH, NICOLE KUNKO, STEPHEN STEIGLEDER, DONNA SHAHBAZ, JOHN BARTRUM, LISA MOLYNEUX, and MIKE FRIEDBERG,
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PART 5

Printed for the use of the Committee on Appropriations

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

WEDNESDAY, MARCH 10, 2010.

DEPARTMENT OF LABOR, FY2011 BUDGET OVERVIEW

WITNESS

HON. HILDA SOLIS, SECRETARY OF LABOR

INTRODUCTION

Mr. OBEY. Welcome, Madam Secretary. I am sorry we had to delay this hearing for an hour because of the special meeting I was called to today. So, to try to put us somewhat back on schedule, I am going to forego an opening statement and simply welcome you here. I know you probably have the toughest job that any Secretary of Labor has had since the Great Depression. I wish you luck and anything else that you need to get the job done.

Mr. Tiahrt.

Mr. TIAHRT. Thank you, Mr. Chairman.

Secretary Solis, welcome back to the Committee. It is always a privilege to receive testimony from a former colleague.

During these tough times, it is an extremely important Cabinet position to hold. Madam Secretary, when I look back over this past year, I become quite anxious about where we are today, and even more concerned about where we are headed. Unemployment continues to hover around 10 percent, twice the level of structural unemployment. We are seeing record budget deficits and historic levels of debt, many State budgets are also deep in red, and households continue to tighten their belts. They are making very difficult decisions, but necessary, decisions on spending cuts, which is what they expect their Government to do.

We have to work our way through this together and do so responsibly, and that does not mean that we spend our way out of this recession, as the distinguished Majority Whip said last month. I fundamentally disagree with that approach. In order to work towards a vibrant American economy in the 21st century, Congress needs to take a comprehensive look at policies and incentives which build solid economic foundation. This will not be accomplished by Federal funds, but by private capital which spurs innovation and leads to job growth. Lasting economic growth comes from the bottom up, and not the top down.

Government does not create wealth. I think that is a misnomer in Washington today, that Government does create wealth. It does not. Government does not create wealth; the private sector does. And jobs are a byproduct of creating wealth. Our fellow Americans have been the victims of a top-down approach this past year. The Recovery Act was supposed to create 3.5 million jobs; yet 3.3 million jobs have been lost since its passage, including over 25,000 manufacturing jobs in Kansas. Kansas wants to get back to work. Kansas employers want to hire them. It is our duty to give them the tools and the opportunity to do so, not enacting policies that will only lead to a jobless recovery.

FISCAL RESTRAINT

Yet, these are macro issues, Madam Secretary, and it will take so much more than the Department of Labor alone to positively affect them. But it can start here, with this Committee, and it has to because it has not started with the Administration. President Obama promised a three-year freeze on non-defense, non-security domestic spending; yet, his request for programs under the jurisdiction of this Subcommittee have increased by $27,000,000,000.

We need to do exactly what the President promised, but has so far failed to do: apply the scalpel to this budget request and make the tough, perhaps politically unpopular, decisions.

There was an excellent article in the Wall Street Journal today about Ireland and how they are going to survive their red ink. The title of it is Irish Take Bitter Medicine to Survive the Age of Red Ink.

ETA CARRYOVER

I strongly support many of the programs funded through this bill; they are important for sustainable economic growth. But in these difficult times they call for fiscal restraint responsibility. Case in point—and I know the mere mention of this term, carryover, will cause many to sit upright, but consider the Employment and Training Administration. The entity was responsible for providing employment and training assistance programs and the administration of unemployment benefits; $2,500,000,000 of unspent funds was carried into fiscal year 2010, $700,000,000 more than you had estimated; $2,500,000,000 appropriated in fiscal year 2009 that was simply not needed.

We all know the trillion is the new billion, but these are huge, huge numbers. Just because the practice is permissible by statute does not make it an appropriate use of taxpayer dollars. Again, tough but responsible decisions must be made this year, and we have to own up to them.

CREATION OF GREEN JOBS

Lastly, your budget request is premised on the notion of creating good jobs, a simple enough concept that we all support. And as these good jobs are created, I certainly hope that we do not fall into the same nebulous void as green jobs. Not only does the definition of a green job seem to be ever-evolving, but even the process by which we now calculate green jobs growth is flawed.

Take Vice President Biden's December memo to the President entitled The Transformation of Clean Energy Economy. In it he cites that renewable energy investments would create 253,000 jobs and would "support"—I presume he means save—up to 469,000 more jobs. But he footnotes these numbers saying, "A project that employs one person for two years would count as creating two jobs." One person working for two years is two jobs.

I do not buy this. We could say that one job per month for two years would be 104 jobs. I think it is just one job and we need to keep our calculations correct and have an accurate representation of job growth, because the American people deserve and need to know the real facts.

So, Madam Secretary, I welcome you back once again, and I look forward to your testimony today.

Mr. Chairman, thank you for your time.

OPENING STATEMENT

Mr. OBEY. Madam Secretary, why do you not proceed? Summarize your statement and proceed to the questions.

Secretary SOLIS. Thank you, Mr. Chairman, Chairman Obey and Ranking Member Tiahrt and members of the Subcommittee. It is a pleasure to be here again this year. Thank you for inviting me to discuss our fiscal year 2011 budget request, and I ask that my prepared testimony be entered into the record, as I will review the highlights with you.

First, it is not possible to discuss next year's budget without acknowledging the immediate need to put Americans back to work. I am proud of the work we have done with the Recovery Act resources, which include providing nearly $50,000,000,000 in UI benefits to unemployed workers and assisting over 190,000 of them to maintain their health care coverage under COBRA; creating summer job opportunities for nearly 318,000 low-income youth and over 18,000 wage-paying community service jobs for low-income seniors; and providing training opportunities for demand health care jobs and emerging jobs in the new green economy, renewable energy.

While these efforts are helping, they are clearly not enough, and at 9.7 percent, unemployment remains persistently and unacceptably high, and especially for those particular groups most affected. African Americans are suffering at 15.8 percent, Latinos at 12.4 percent. The situation is dire. And in the Native American communities it is even higher.

I remain hopeful, however, that Congress will reach agreement on measures that will allow us to continue to assist Americans until the labor market fully recovers.

Mr. Chairman, you recognized this need when you added funds last year for the Senior Community Service Employment Program. We moved quickly as a result and many low-income seniors did not need to wait for a jobs package to secure employment. But there is so much more that needs to be done, and some examples are:

To further extend the safety net for those displaced and dislocated workers by extension of the UI and COBRA assistance, which I believe the House and the Senate are working on; to commit to $1,200,000,000 to ensure that a robust summer jobs program

can be implemented to put the high number of unemployed youth to work to receive job training and education exposure;

To jump-start our employment through a $500,000,000 investment through on-the-job training programs that can help small businesses and hopefully be incentivized to hire and add on more workers; and

To add $300,000,000 to further support the oversubscribed Pathways out of Poverty and Energy Training Partnership programs that include employers in all of those partnerships.

Our budget request will sustain those investments through programs that give workers the tools they needed to succeed in this new economy. I want to highlight some of the measures that will allow us to increase the skills of all segments of our workforce.

For the first time in over a decade, the budget proposes a significant increase in funding for the Workforce Investment Act programs. However, the additional resources are also closely linked to reform. In keeping with the Administration's WIA reauthorization goals, a percentage of the funds appropriated for adults, dislocated workers, and youth will be reserved for two new WIA Innovation Funds to provide competitive grants to encourage the workforce system to test or replicate models that we know work to expand and improve services and results for their customers, namely, employment in the private sector.

The budget also requests an increase of $45,000,000 for the Green Jobs Innovation Fund. And I can tell you from my experience with the Recovery Act competitions that the demand for green job training has been enormous, and it has come from the private sector. We have simply not been able to keep pace with the record number of applications, submissions that came into my office; and I believe this unprecedented level of interest calls for further investment, more resources.

We are committed to linking this training with job creation efforts in green industries and expect our grantees to work with employers and other participants to gain those valuable skills and industry-recognized credentials that will help them move into better and higher paying jobs.

In addition to the Youth Innovation Fund, the budget request includes an increase in other services for youth, such as $17,500,000 in the YouthBuild program that will allow us to extend this program and serve an estimated 230 competitive grants to local organizations to serve disadvantaged youth.

We also expect to see benefits from fully integrating the Job Corps program with other youth programs and returning it into the ETA program. We are also undertaking a rigorous and comprehensive review of the Job Corps operations to identify any needed reforms that we might need to take.

Good jobs for everyone means that other vulnerable populations must not also be left behind. That is why we are doing more to target resources to areas of greatest poverty, and that is why the budget request includes increases in the Indian and Native American and Migrant and Seasonal Farm Worker Programs. Two DOL agencies, ETA and the Office of Disability Employment and Policy, known as ODEP, will also receive $12,000,000 each to continue their job disability initiative to increase the capacity at our one-

stop system to provide accessible services to individuals with disability.

We know returning veterans, including those who are disabled, can contribute greatly to the expansion of our economy. They are the most under-utilized population. For the Veterans Employment and Training Service, the budget requests $262,000,000 and includes increases for homeless veterans grants and transition assistance programs which are vitally important for those individuals that are coming back and want to be reintegrated into our society.

Our Assistant Secretary, Ray Jefferson, will be with you tomorrow to fill in any items or activities that you require more information regarding our Vets program. The ETA Assistant Secretary, Jane Oates, will also be here tomorrow to discuss any further plans and details you might have regarding partnerships that include the nursing shortage and also efforts to help provide assistance to States to pay for a paid leave program that we are now initiating.

I know you understand that it can be too easy to exploit workers when jobs are scarce. We need to remain vigilant in protecting the rights and safety of all of our workers. In fiscal year 2011 the budget continues that vigilance by hiring additional enforcement personnel and strengthening our regulatory efforts. We build upon the resources that you provided last year to return our worker protection programs to the 2001 staffing levels or greater, after years of decline.

To do so, the request includes $1,700,000,000 in discretionary funds for 10,957 FTE for our worker protection activities. This funding level is $67,000,000, 4 percent, and 177 FTE above last year's level, and the agency-by-agency details are in my prepared testimony.

In discussing worker protection, I want to point out that the request also includes increases to support the development of regulations in areas such as pensions, worker health and safety. These resources will help reinvigorate the Department's regulatory program and are critical to the success of our worker protection agenda.

The budget also includes an important interagency effort to address the issue of employee misclassification. Workers wrongly classified as independent contractors are denied access to critical benefits and protections in the workplace to which they are entitled, for example, overtime, health care coverage, worker's compensation, family and medical leave, and unemployment insurance.

In addition to denying workers these protections and benefits, misclassification results in billions, billions of dollars of losses to Government through unpaid taxes. Our budget includes $25,000,000 to hire additional enforcement personnel targeted at misclassification to fund competitive grants to boost States' incentives and capacity to address this problem.

Restoring our economy requires ensuring the world economy is also sound and balances. I firmly believe that our responsibility to promote acceptable conditions of work abroad is closely linked to our worker protection agenda here at home. It is with this goal in mind that we are requesting an increase of $22,000,000 in the ILAB program to increase the monitoring of labor provisions in trade agreements and to support programs that use innovative and

successful models to improve the labor rights of workers in our trading partner countries.

Mr. Chairman, it is thanks to your leadership that we have been able to pursue these approaches, which is based on highly successful garment industry projects that we have been working on in Cambodia. By increasing funding, we will be able to expand our reach of worker rights protections in additional countries. So I thank you for your previous support.

Before I conclude, I want to say just a few words about our commitment to ensuring accountability for the resources that you entrust us with. This is why my testimony links investments to performance outcomes and why we have new commitment to program evaluation.

Members of the Subcommittee, I think we all know that too many Americans are ready and willing to work. But we know that they cannot find a job. There are six applicants for each job that is available now. We know the urgency. The budget before you will help spur new and better job opportunities while fostering safe workplaces that respect workers' rights. That is what my goal of Good Jobs For Everyone is, and I look forward to working with you on making this vision a reality.

I am happy to respond to any questions that the members of the Subcommittee might have.

[The information follows:]

STATEMENT OF HILDA L. SOLIS
SECRETARY OF LABOR
BEFORE THE
SUBCOMMITTEE ON LABOR,
HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES
COMMITTEE ON APPROPRIATIONS
UNITED STATES HOUSE OF REPRESENTATIVES

March 10, 2010

Chairman Obey, Ranking Member Tiahrt, and members of the Subcommittee, thank you for the invitation to testify today. I appreciate the opportunity to discuss the Fiscal Year (FY) 2011 budget request for the Department of Labor.

The total request for the Department in FY 2011 is $116.5 billion and 17,800 Full-Time Equivalent employees (FTE), of which $17.1 billion is before the Committee. Of that amount, $14.0 billion is requested for discretionary budget authority. Our Budget request will build on the $4.8 billion in discretionary as well as the mandatory resources included for the Department in the American Recovery and Reinvestment Act (Recovery Act).

PUTTING PEOPLE BACK TO WORK

Workers and their families are hurting in these tough economic times. We know that job opportunities and economic security are of utmost importance to Americans. During my travels throughout the country, I have met many people who expected to be in their peak earning years, and yet were struggling to find employment and maintain retirement savings. At the Department of Labor, we are putting people back to work and assisting unemployed workers who need our help. Through the Recovery Act investments funded by the Congress, we have:

- Funded over $49 billion in benefits to unemployed workers;
- Created more than 90,000 jobs nationwide through our Recovery Act programs;
- Created more than 317,900 summer youth job opportunities;
- Invested $500 million in training and research for emerging "green jobs" and another $220 million to help workers pursue careers in health care and other high growth industry sectors;
- Created over 18,000 new community service employment opportunities for seniors;
- Provided job-related services to more than 2.9 million unemployment insurance claimants;
- Provided direct assistance to over 190,000 unemployed workers and their families seeking affordable health coverage and the COBRA subsidy.

While these efforts are helping Americans during these difficult times, they are clearly not enough. The unemployment rate remains persistently and unacceptably high. This Administration wants to ensure that investments in job creation will *continue until the labor market fully recovers* from the economic downturn. The president has proposed $100 billion for job creation, including the president's proposals on small business, infrastructure, and clean energy. I urge Congress to quickly pass a jobs bill. In addition, the Administration proposes additional job-creating investments in key Department of Labor initiatives:

- First, last summer the Recovery Act created over 300,000 summer jobs for at-risk youth in 2009, addressing an alarmingly high youth unemployment rate. Based on that experience, we believe that local areas can expand the program to create up to 350,000 jobs this summer, providing work experience to help young people build their futures and income their families can use in a weak economy. We can accomplish this with a $1.2 billion investment in summer and youth employment, including $150 million for competitive grants to support innovative programs and build knowledge of what strategies, including paid work experience, produce the best educational and employment outcomes for disconnected youth.

- Second, training programs that bring workers into contact with employers form key partnerships that will result in people getting jobs. We support an additional $500 million to expand on-the-job training, refresh the skills of the long-term unemployed, and link them to real employment opportunities as the economy rebounds.

- Third, through grant programs we will be prioritizing training in emerging industries where we know there are jobs, such as clean energy, an area where we see a lot of potential for additional training efforts. The Administration supports an additional $300 million to continue two Recovery Act programs -- Pathways Out Of Poverty Grants ($225 million) and Energy Training Partnerships ($75 million). For both of these programs, we received many more quality applications than we were able to fund. As a result, additional resources would allow us to quickly fund these high-quality programs.

We also believe that extending expiring unemployment benefits and health insurance coverage is a vital part of any jobs package. They ensure a continued safety net for individuals who cannot find jobs, and the benefits help stimulate the economy by putting money back in workers' pockets who then spend it in their local communities.

We must work together to respond to the plea from millions of Americans for job opportunities and assistance. That means that we need to create new and better jobs for the 21st Century economy. And because it is too easy to exploit workers when jobs are scarce, we need to be vigilant in protecting the rights and safety of workers. At the Department of Labor, my strategic vision is to provide *Good Jobs for Everyone*. Here are some of the ways that we define a good job:

- A good job can support a family by increasing incomes, narrowing the wage gap and allowing workplace flexibility.
- A good job is safe and secure and gives people a voice in the workplace.
- A good job is sustainable and innovative, for example a green job.
- A good job will help rebuild a strong middle class.
- A good job provides access to a secure retirement and to adequate and affordable health coverage.

The resources requested in our FY 2011 budget will help to make the vision of *Good Jobs for Everyone* a reality. They will build on and leverage the job creation efforts begun with the Recovery Act and continued with the FY 2010 appropriation. I am committed to doing my best to see that that the new jobs created with the economic recovery are good jobs that are open to the diverse group that represents the workers of the future.

PREPARING FOR JOBS OF THE FUTURE

The Department is looking to prepare workers with the tools they need to succeed in the 21st Century economy, and for innovative ways to promote economic recovery. The FY 2011 budget request for the Department's Employment and Training Administration (ETA) is $10.9 billion in discretionary funds and 1,080 FTE, not including the 148 FTE associated with the proposed legislation for foreign labor certification application fees. Through innovative program strategies, the budget request for ETA will allow the Department to increase the skills of the American workforce, while addressing all segments of the population.

Innovation Funds

Reflecting the urgent need to prepare workers for 21st Century jobs, for the first time in over a decade, the FY 2011 budget proposes a significant increase in funding for the Workforce Investment Act (WIA) grant programs for Adults, Dislocated Workers, and Youth. The budget requests $3.4 billion for these programs, an increase of $209 million above the FY 2010 level. However, the additional resources are inextricably linked to reform.

In keeping with the Administration's WIA reauthorization plan, a percentage of the funds appropriated for Adults, Dislocated Workers and Youth will be reserved for the budget's proposed new Partnership for Workforce Innovation, which encompasses $321 million of funding in the Departments of Labor and Education. In the Department of Labor, two new Innovation Funds would provide competitive grants to state and local entities that can demonstrate new and promising ways of preparing individuals for jobs of the future. There are funds for adults and youth. For adults, the $108 million *Workforce Innovation Fund* would be funded through a 5 percent reserve from the WIA Adult and Dislocated Worker programs. Innovation funding will be used, in part, to support and test "learn and earn" strategies like on-the-job training and apprenticeships. For youth, the $154 million *Youth Innovation Fund* will be funded by a 15 percent reserve of the funds appropriated for Youth; the funds will support summer and year-round employment opportunities and "work

experience plus" programs for out-of-school youth. We are confident that the Partnership for Workforce Innovation will create strong incentives for change that will improve the effectiveness of the Workforce Investment Act programs, and provide incentives for States and localities to break down program silos and improve service delivery.

Green Jobs

The demand for green job training opportunities is enormous – and the Department has been unable to keep pace with the record number of applications for grants. We believe that this unprecedented level of interest represents the need for resources that focus on green jobs training, which complements job creation efforts. We also believe this demonstrates the need to assist people who are already working, but who may be underemployed, to gain skills – and portable credentials – that will help them move into better, higher-paying jobs in emerging sectors.

The budget requests $85 million for the Green Jobs Innovation Fund, an increase of $45 million (89 percent) from the FY 2010 appropriation. The request will provide training opportunities for some 14,110 workers. These funds will support the Department's efforts to achieve its high priority performance goal in the employment and training arena, which is aimed at increasing opportunities for America's workers to acquire the skills and knowledge to succeed in a knowledge-based economy (and includes training over 120,000 Americans for green jobs by June 2012). The budget will also complement the competitive grant awards made through the $500 million appropriation included for high growth and emerging industry sectors under the Recovery Act, and the $40 million provided in the FY 2010 appropriation.

YouthBuild

The FY 2011 Budget includes $120 million, an increase of $17.5 million (17 percent) for YouthBuild to provide an estimated 230 competitive grants to local organizations for the education and training of approximately 7,450 disadvantaged youth age 16-24. Under these grants, youth will participate in classroom training and learn construction skills by helping to build affordable housing. In FY 2011, the Department will continue the "green" transition of YouthBuild by encouraging connections with other Federal agencies involved in creating green jobs – such as the Departments of Energy and Housing and Urban Development – in order to leverage resources and new "green" opportunities for YouthBuild participants.

Transitional Jobs

The FY 2011 budget proposes that $40 million for second-year funding to demonstrate and evaluate transitional job program models, which combine short-term subsidized or supported employment with case management services to help individuals with significant employment barriers obtain the skills needed to secure unsubsidized jobs. The initiative, which is a critical part of our jobs agenda, will target non-custodial parents to strengthen their workforce skills

and experience, and help the children who rely on them for support. The Department is carrying out this demonstration collaboratively with other Federal agencies, such as the Departments of Health and Human Services and Justice. In partnership with these agencies, we are working to develop and implement a rigorous evaluation strategy for this demonstration.

Strengthening Unemployment Insurance Integrity and Promoting Re-Employment

The severity of the recession has placed great stress on the Unemployment Insurance (UI) system, which has paid out unprecedented amounts of unemployment compensation. This Administration is committed to protecting the financial integrity of the UI system, and helping unemployed workers return to work as swiftly as possible. In addition to providing the funding that States rely on to administer this important safety net program, our approach includes:

- A package of legislative changes that would prevent, identify, and collect UI overpayments and delinquent employer taxes. We estimate that these legislative proposals would reduce overpayments by $2.632 billion and employer tax evasion by $282 million over 10 years (net of the income tax offset).

- A request of $55 million (an increase of $5 million over the FY 2010 level) in discretionary funding to support Reemployment and Eligibility Assessments, which may include in-person interviews at One-Stop Career Centers with UI beneficiaries to discuss their need for reemployment services and their continuing eligibility for benefits. In FY 2011, this investment, combined with the $10 million request included in State administration, will help 710,000 UI beneficiaries find jobs faster. It is expected to save $2.3 billion over a 10-year period.

We urge the Congress to act on these important proposals to strengthen the financial integrity of the UI system and help unemployed workers return to work.

Senior Community Service Employment Program

The FY 2011 budget proposes $600.5 million for the Senior Community Service Employment Program (SCSEP), which will support some 61,900 slots for low-income seniors in part-time, minimum wage community service jobs. The request continues funding at the base amount of the FY 2010 appropriation. As you know, in FY 2010 the Congress provided a special multi-year appropriation of $225 million to help low-income seniors facing special economic challenges, asking that we allocate those funds within 45 days of enactment. In January 2010, the Department moved quickly to award these funds to offer immediate employment opportunities.

Job Corps

The budget includes $1.7 billion to operate a nationwide network of 124 Job Corps centers in FY 2011. Job Corps provides training to address the individual needs of at-risk youth and equip them with the skills they need to enter the world of work. The FY 2011 budget sets forth an ambitious agenda to reform and improve the Job Corps program's performance. We have begun this agenda in FY 2010, which includes:

- Fully integrating Job Corps with the Department's other employment and training programs, with the return of the program to the Employment and Training Administration.
- A rigorous and comprehensive review of Job Corps center operations and management to identify areas most in need of reform.
- Remediation of program performance shortfalls at the lowest performing centers.
- Analysis of contracting practices and procedures to identify potential savings and strategies to improve cost effectiveness.

We are optimistic that our reform agenda will identify ways to produce better outcomes at a lower cost. To the extent that our efforts produce long-run cost avoidance, rather than near-term savings, the budget includes appropriations language that would allow the transfer of up to 15 percent of the $105 million appropriation for construction to meet center operational needs. This authority was first provided by Congress in the Recovery Act. Job Corps received $250 million from the Recovery Act, which it is using to fund shovel-ready construction projects that stimulate job growth in center communities. In addition, the Recovery Act funds are promoting environmental stewardship in Job Corps by supporting development of green-collar job training, technology enhancements, and fleet efficiency.

Veterans' Employment and Training Service

We know returning veterans can contribute greatly to our economy. For the Department's Veterans' Employment and Training Service (VETS), the FY 2011 budget request is $262 million and 234 FTE. The FY 2011 budget includes $41 million for the Homeless Veterans Reintegration Program (HVRP), an increase of $5 million (14 percent) above FY 2010. The request will allow the program to provide employment and training assistance to more than 25,000 homeless veterans, and increase our reach to homeless women veterans. In addition, the budget requests $8 million for the Transition Assistance Program (TAP) for spouses and family members (including those with limited English proficiency), an increase of $1 million (14 percent) from FY 2010. TAP Workshops will enroll roughly 185,000 participants worldwide in FY 2011, and play a key role in reducing jobless spells and helping service members transition successfully to civilian employment.

State Paid Leave

Workforce and workplace changes have made it increasingly difficult for working families to meet their work and family responsibilities. The vast majority of American workers have family care-giving responsibilities outside of work and no full-time caregiver at home. Nearly half of private-sector workers do not have paid sick leave to care for themselves, and even fewer have leave available to care for another family member when they are ill. Millions of workers risk losing pay – and even their jobs – when they are sick or their children are sick. No worker should be placed in that position. Similarly, most workers do not have paid family leave – for example, to care for a newborn or newly adopted or fostered child.

State programs that provide for paid leave for workers facing these challenges offer a solution for working families who cannot afford to lose a day's pay or risk loss of their job to care for themselves and their families. The FY 2011 budget requests $50 million for a State Paid Leave Fund to provide grants to help States establish paid leave programs.

PROTECTING WORKERS' RIGHTS AND SAFETY

In the jobs of the future as well as in jobs of the present, workers should be safe and their rights should be protected. To achieve our goal of rebuilding the middle class, we need to level the playing field and restore fair play for all working people. The FY 2011 budget continues our commitment to protect the rights and safety of workers by hiring additional enforcement personnel and strengthening our regulatory efforts. The request includes $1.7 billion in discretionary funds and 10,957 FTE for our worker protection activities. This funding level is $67 million (4 percent) and 177 FTE above the FY 2010 appropriation. The budget returns the worker protection programs to the FY 2001 staffing levels or greater, and builds on the progress begun in FY 2010 to restore capacity in our worker protection programs.

Employee Misclassification Initiative

Employers who misclassify their employees as independent contractors often avoid paying the minimum wage and overtime. They evade payroll taxes, and often do not pay for workers' compensation or other employment benefits. As a result, employees are denied the protections and benefits of this Nation's most important employment laws, and their employers gain an unfair advantage in the market place. Employees are particularly vulnerable to misclassification in these difficult economic times. The FY 2011 budget requests $25 million for a multi-agency initiative to strengthen and coordinate Federal and State efforts to enforce statutory prohibitions, and identify and deter employee misclassification as independent contractors.

For the Wage and Hour Division, the FY 2011 budget requests an additional $12 million and 90 new investigators to expand its efforts to ensure that workers are employed in compliance

with the laws we enforce. The funds will support targeted investigations that focus on industries where misclassification is most likely to lead to violations of the law, and training for investigators in the detection of workers who have been misclassified.

The Misclassification Initiative also will support new, targeted ETA efforts to recoup unpaid payroll taxes due to misclassification and promote the innovative work of States on this problem. This initiative includes State audits of problem industries supported by Federal audits, and $10.9 million for a pilot program to reward the States that are the most successful (or most improved) at detecting and prosecuting employers that fail to pay their fair share of taxes due to misclassification and other illegal tax schemes that deny the Federal and State UI Trust Funds hundreds of millions of dollars annually.

In addition, the Misclassification Initiative includes:

- For the Office of the Solicitor, $1.6 million and 10 FTE to support enforcement strategies, with a focus on coordination with the States on litigation involving the largest multi-State employers that routinely abuse independent contractor status.

- For the Occupational Safety and Health Administration, $150 thousand to train inspectors on worker misclassification issues.

- Legislative changes that will require employers to properly classify their workers, provide penalties when they do not, and restore protections for employees who have been classified improperly.

With these efforts, we intend to reduce the prevalence of misclassification and secure the protections and benefits of the laws we enforce. This effort strikes at the core of the Department's mission – and the hard working people of this country deserve no less.

Wage and Hour Division

I take the failure to pay workers the wages that they have earned very seriously, and I am committed to enforcing all employment laws – particularly those related to payment of the minimum wage and overtime. Workers deserve this money, and it will bring new resources to low-income households where most of it will be spent and help reinvigorate local communities. As I noted earlier, we have already increased Wage Hour enforcement staffing. At 1,672 FTE, the staffing level for the Wage and Hour Division requested in FY 2011 is 29 percent higher than the FY 2009 level. As new investigators grow into their jobs, they will be an even stronger force for securing compliance with basic labor standards protections. The FY 2011 Budget request of $244.2 million for the Wage and Hour Division will support targeted investigations, meaningful compliance assistance, and – in support of the Department's high priority performance goals – reduce repeat violations of minimum wage, overtime, and workplace safety laws.

Office of Federal Contract Compliance Programs

I am also committed to vigorously enforcing the laws that combat discrimination, for our goal is to protect workers who — ultimately — are America's most important asset. The FY 2011 request for the Office of Federal Contract Compliance Programs (OFCCP) is $113.4 million and 788 FTE, an increase of $8 million from the FY 2010 level. The 2010 appropriation has allowed OFCCP to return to 2001 staffing levels, and the 2011 request will make it possible to maintain that level.

The FY 2011 budget will allow OFCCP to broaden its enforcement efforts and focus on identifying and resolving both individual and systemic discrimination. OFCCP will focus its attention on a broad range of issues that arise in individual cases, including harassment, retaliation, termination, and failure to promote. Since federal contractors are obligated to self-audit and correct identified problems, OFCCP will step up monitoring of this element of contractor compliance. As part of OFCCP's enforcement of Executive Order 11246, *Equal Employment Opportunity*, a renewed emphasis on conducting construction reviews is planned.

Office of Workers' Compensation Programs

The FY 2011 discretionary budget request for administration of the Office of Workers' Compensation Programs (OWCP) totals $127.3 million and 921 FTE to support the Federal Employees' Compensation Act (FECA) ($103.5 million), the Longshore and Harbor Workers' Compensation program ($17.2 million) and $6.6 million for the Division of Information Technology Management and Services (DITMS). DITMS provides information technology General Services Support for the programs that were previously within the Employment Standards Administration (ESA) and was previously funded in ESA's Program Direction and Support activity. DITMS was transferred to OWCP with the understanding that it would provide the same level of IT support. The request includes an additional $3.2 million and 9 FTE to address the burgeoning workload under the Defense Base Act arising from claims associated with injuries to war-zone contract workers in Afghanistan and Iraq.

A high priority performance goal for FY 2011 will be a new, jointly-sponsored OWCP and Occupational Safety and Health Administration (OSHA) initiative entitled "Protecting Our Workforce and Ensuring Reemployment" (POWER). The new program is designed to bring a greater focus on the Federal Government as a model employer of workers injured on the job and returning to the workplace, or for employing workers with disabilities.

The OWCP budget also includes mandatory funding totaling $53.8 million and 295 FTE to administer Part B of the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), and $72.8 million and 265 FTE for Part E of the Act. EEOICPA provides compensation and medical benefits to employees or survivors of employees of the Department of Energy and certain of its contractors and subcontractors, who suffer from a radiation-related

cancer, beryllium-related disease, chronic silicosis or other covered illness as a result of work at covered Department of Energy or DOE contractor facilities.

Lastly, OWCP's FY 2011 budget includes $38.3 million in mandatory funding and 198 FTE for its administration of Parts B and C of the Black Lung Benefits Act, and $58.4 million and 127 FTE in FECA Fair Share administrative funding.

Office of Labor-Management Standards

The FY 2011 budget request for the Office of Labor-Management Standards (OLMS) totals $45.2 million and 269 FTE. This is an increase of $4 million from the FY 2010 level. OLMS administers the Labor-Management Reporting and Disclosure Act (LMRDA), which establishes safeguards for union democracy and union financial integrity and requires public disclosure reporting by unions, union officers, employees of unions, labor relations consultants, employers, and surety companies. OLMS also administers the Department's responsibilities under Federal transit law by ensuring that fair and equitable arrangements protecting mass transit employees are in place before the release of Federal transit grant funds. The FY 2011 budget includes an additional $2.5 million to allow OLMS to modernize an aging, mission-critical information technology system. This project will increase transparency to the public, reduce reporting burden and administrative costs, and improve program efficiency.

Employee Benefits Security Administration

The Department's Employee Benefits Security Administration (EBSA) protects the integrity of pensions, health plans, and other employee benefits for more than 150 million people. The FY 2011 budget request for EBSA is $162 million and 941 FTE, an increase of $7.1 million (5 percent) and 31 FTE compared to the FY 2010 level. The additional resources will support a significantly greater demand for regulatory guidance, research, outreach, education and assistance. The budget will improve EBSA's ability to ensure America's workers, retirees and their families have access to a secure retirement and affordable health insurance. I am very proud of the work this agency has done under the Recovery Act, implementing a new appeal program related to an individual's appeal of the denial of his or her COBRA premium assistance, and responding to over 190,000 inquiries and complaints from unemployed workers and their families seeking affordable health coverage and the COBRA subsidy; hosting over 2.5 million visitors to our dedicated COBRA website; and conducting 826 outreach events related to the new program, including compliance assistance webcasts and seminars and on-site visits with workers facing layoff at their place of employment.

Occupational Safety and Health Administration

I am proud that OSHA is restoring its capacity to strongly enforce statutory protections, provide technical support to small businesses, promulgate safety and health standards, strengthen the accuracy of safety and health statistics, and ensure that workers know about the hazards they face and their rights under the law. The FY 2011 budget request for OSHA is $573.1 million and 2,360 FTE, an increase of $14.5 million and 25 FTE over the FY 2010 level. The budget redirects 35 FTE from compliance assistance to enforcement and supports the Department's high priority performance goal to reduce workplace injuries by targeting establishments and industries with the highest injury, illness, and fatality rates – with the goal of reducing by two percent per year the number of fatalities associated with the four leading causes of workplace death in OSHA's jurisdiction: falls; electrocution; caught in or between; and struck by. The request also includes an additional $4 million to expand OSHA's regulatory program, $1 million for consultation programs focused on small businesses, and $1.5 million for State Plans. These additional resources will support a vigorous enforcement presence in the nation's workplaces and ensure that hard-to-reach workers know about their rights and the hazards they face.

Mine Safety and Health Administration (MSHA)

MSHA is celebrating 40 years of legislation aimed at improving working conditions for America's workers, and last year, MSHA recorded the safest year in mining in U.S. history. The FY 2011 Budget requests $360.8 million and 2,430 FTE and supports MSHA's comprehensive strategy to curb debilitating and potential fatal diseases caused by coal mine dust. The budget includes an increase of $2.3 million and 21 FTE for the Metal and Nonmetal Mine Safety and Health budget activity to bolster enforcement and conferencing. The Budget will ensure a 100 percent completion rate for all mandatory safety and health inspections; support MSHA's enhanced enforcement initiatives, which target patterns of violation, flagrant violators, and scofflaws; and allow MSHA to promulgate new standards related to reducing health hazards associated with exposure to coal mine dust and crystalline silica. The request also allows MSHA to continue its work to enhance mine rescue and emergency operations and will support the Department's high priority performance goal – which targets the most common causes of fatal accidents and is aimed at reducing workplace fatalities at mining sites by five percent per year based upon a rolling five-year average.

Office of the Solicitor

The Solicitor's Office provides the legal services that support the Department, including the Department's enforcement programs. The FY 2011 budget includes $130.4 million and 658 FTE for the Office of the Solicitor (SOL), an increase of $5.2 million and 22 FTE from FY 2010. This amount includes $122.5 million in discretionary resources and $7.9 million in mandatory funding. The budget includes an increase of $2 million to support an additional 12

FTE to handle increased Mine Safety and Health enforcement litigation resulting from the substantial increase in the number of cases at the Federal Mine Safety and Health Review Commission (FMSHRC). The FY 2011 budget will support SOL's enforcement litigation, issuance of timely legal opinions, legal support for rulemaking, and increased efficiency through its acquisition of legal technology.

Pension Benefit Guaranty Corporation

For administrative expenses of the Pension Benefit Guaranty Corporation (PBGC), the FY 2011 budget requests $466.3 million and 942 FTE. The budget includes an increase of $14.7 million for the PBGC's benefit determination process to cover the projected long-term costs of absorbing participants of several very large pension plans that terminated in late FY 2009. In addition, $200,000 and one FTE are requested to increase the capacity of the Office of Inspector General to support its audit, investigation, and training activities.

ENSURING ACCOUNTABILITY AND TRANSPARENCY

Spending tax dollars wisely helps the Department achieve our mission on behalf of America's workers, and builds trust among our stakeholders. We are committed to ensuring a sense of responsibility, accountability, and transparency at the Department of Labor. Our FY 2011 budget supports those goals.

Built around my vision of *Good Jobs for Everyone*, the Department is currently updating its strategic plan, which will be published by September 30, 2010 and cover FYs 2010-2016 – a span during which the Department will mark its one hundredth anniversary of service to America's workers.

Over the next several months, we will be reaching out to a broad range of stakeholders – including Congress – to solicit their input and perspective on a new strategic goal framework that will govern all aspects of work in the Department.

Our strategic planning efforts dovetail nicely with President Obama's commitment to improve the performance of the Federal Government through three complementary performance management strategies. They are:

- Use performance information to lead, learn, and improve outcomes;
- Communicate performance coherently and concisely for better results and transparency; and
- Strengthen problem-solving networks.

As part of this process, the Department's FY 2011 budget articulates five ambitious – but realistic – high-priority performance goals that we will strive to achieve in the next 18 to 24 months. These goals – which I've touched on above – offer an opportunity for the Department to achieve remarkable and lasting benefits for the American people. Our high-priority performance goals will focus the agencies on the most critical needs affecting the safety, health, and economic security of workers. We are working with our colleagues in the Office of Management and Budget to establish an action plan for implementation of the Department's high-priority performance goals – including quarterly milestones that we will use to gauge the progress and success of our implementation strategy.

A Strengthened Commitment to Program Evaluation

In the 2011 Budget, the Administration encouraged Departments to volunteer for a new program evaluation initiative designed to strengthen rigorous, objective assessments of existing federal programs to help improve results and better inform funding decisions. The Department of Labor is proud to be one of a limited number of agencies selected to pilot this new approach in the FY 2011 budget. The budget includes $40.3 million to fund five rigorous evaluations and demonstrations of workplace safety enforcement and workforce development services. Most are demonstrations that would provide program services, coupled with rigorous evaluations of the strategies. While the evaluations are still in the design phase, we expect a substantial portion of this funding will go to states, workforce agencies, or for participant services. The five evaluations, which will be shaped and guided by Labor, working closely with the Office of Management and Budget and Council of Economic Advisors, will cover the following:

- WIA performance measures
- Effects of job counseling
- Using linked administrative data to evaluate workforce programs
- Incentives for dislocated workers
- Effects of OSHA inspection strategies

In addition, the budget includes $10 million in the Departmental Management account and $11.6 million in the Training and Employment Services account to continue to pursue a robust, Department-wide evaluation agenda. To effectively manage the new evaluation resources, the Department is establishing a Chief Evaluation Office in FY 2010 to directly manage the Department-wide evaluation resources, and work with the other components of the Department to ensure a high level of rigor and quality in the evaluations they support.

Workforce Data Quality Initiative

The FY 2011 budget requests $13.8 million for second-year funding for the Department's Workforce Data Quality Initiative, which we are carrying out in partnership with the

Department of Education. The initiative provides competitive grants to develop longitudinal data systems that have the capability to link workforce and education data collected as individuals progress through the education system and into the workforce. These data systems can provide valuable information to consumers, practitioners, policymakers, and researchers about the performance of education and workforce development programs. In FY 2010, up to 12 States will receive grants to implement longitudinal databases over a three-year period. The FY 2011 request will support participation of up to 12 additional States in the initiative.

OTHER PROGRAMS

Bureau of Labor Statistics

Through its 21 economic programs, the Bureau of Labor Statistics (BLS) produces some of the Nation's most sensitive and important economic data. The FY 2011 budget proposes $645.4 million and 2,465 FTE for BLS, an increase of $34 million (6 percent) from the FY 2010 level. The budget proposes several initiatives to modernize and improve the accuracy of BLS survey data. For example:

- An increase of $27.3 million is requested to improve the data quality of the Consumer Price Index (CPI) and Consumer Expenditure (CE) Survey, including work to support the Census Bureau in its development of a supplemental poverty measure.

- An increase of $4.9 million is included to expand the Occupational Employment Statistics (OES) program to annual data reporting from a subset of establishments, making possible year-to-year comparisons.

In addition, the FY 2011 budget proposes new, cost-effective data collection strategies that would not diminish the quality of the data that BLS publishes. For example:

- A restructuring of the way in which the Current Employment Statistics produces State and metropolitan area data estimates would save $5 million annually.
- An alternative, model-based methodology will allow BLS to produce Locality Pay data at a lower cost. The new approach will eliminate the Locality Pay Surveys, ensure no reduction in the data quality, and save $10 million annually.

Finally, the FY 2011 budget proposes to eliminate the International Labor Comparisons program. The savings from this elimination and the two-cost effective data collection strategies mentioned above will be used to partially finance the OES, CPI, and CE enhancements.

We look forward to working with Congress to implement the FY 2011 budget strategies to improve and modernize the critically important economic data produced by BLS.

Office of Disability Employment Policy (ODEP)

Even though the majority of workers with disabilities are prepared, willing, and able to work, they remain a largely untapped labor pool. We know that people with disabilities are out of the labor force at a much higher rate than their counterparts without disabilities, and we are launching innovative partnerships to increase their employment opportunities. For example, along with the Office of Personnel Management, in April the Department is hosting a national disability job fair with participation by numerous Federal agencies and human resources professionals. Also, along with the Departments of Defense and Veterans Affairs, we have re-launched an improved National Resource Directory website for America's wounded warriors, their caregivers, other members of the veterans community, and employers. By visiting www.nationalresourcedirectory.gov, customers can now access thousands of services and resources at the national, state and local levels to support recovery, rehabilitation and community reintegration for veterans.

The FY 2011 budget requests $39 million and 52 FTE for ODEP to combat the problem by developing policy and policy strategies that, when implemented by ODEP's Federal, state and local partners that include public and private-sector employers, will:

Increase physical and programmatic access for individuals with disabilities in Workforce Investment Act partner programs and at One-Stop Career Centers, though a partnership between ETA and the Department of Education.

- Increase the employment of people with disabilities within the Federal Government, in partnership with the Office of Personnel Management.

- Make workplaces more inclusive and welcoming to both transitioning youth and adults with disabilities.

- Expand access to employment supports – like technology and transportation. These services are crucial to the success of all workers in the job market, especially those with disabilities. ODEP will utilize ongoing partnerships with the Department of Commerce and Education; the General Services Administration; the National Science Foundation; businesses; technology designers, developers and manufacturers; and the disability community to ensure that emerging workplace information and communication technology is universally available.

- Spur new strategies for integrated employment opportunities for workers with disabilities within minority, women, and veteran-owned businesses. For example, ODEP's *"Add Us In"* initiative funds a competitive grant to encourage small businesses, particularly minority-owned businesses, to increase the number of people with disabilities hired by such employers.

The request includes $12 million for ODEP to continue its partnership with ETA on the Disability Employment Initiative, which strives to increase the capacity and accountability of

the One-Stop Career system to provide accessible programs and services to individuals with disabilities. A companion request of $12 million is contained within the ETA budget. Our goal is to ensure that *Good Jobs for Everyone* includes workers with disabilities.

Bureau of International Labor Affairs

One of my goals as Secretary of Labor is to help American workers build the foundation for a sustained recovery of the global economy, while contributing to a more balanced pattern of global trade in the future and respect for workers' rights around the world. The FY 2011 budget requests $115 million for the Bureau of International Labor Affairs (ILAB), an increase of $22 million and 10 FTE from the FY 2010 level. The additional resources will allow ILAB to expand its oversight and monitoring of labor rights in countries that have free trade agreements and trade preference programs with the United States.

Based on the funding for workers rights initiated by Congress in FY 2008, the Bureau will also expand support for innovative programs that address root causes of violations of workers' rights. Given the challenges of the global economy, we believe that these programs will create the right environment to prevent and address incidents of labor exploitation.

The FY 2011 budget will support the Department's high priority performance goal to improve worker rights and livelihoods for vulnerable populations in eight countries by the end of FY 2011. The budget will also continue the Bureau's longstanding commitment to building international relationships that improve global working conditions and strengthen labor standards around the world.

Women's Bureau

This year, the Women's Bureau will mark 90 years of work formulating standards and policies that promote the welfare of wage-earning women and advance their opportunity for fair and profitable employment. The Bureau's efforts to provide women in the workplace with the information and tools needed to obtain good jobs and economic security for themselves and their families is invaluable in this time of economic recovery.

The Bureau's FY 2011 budget includes $12.3 million and 58 FTE, which is $700,000 above the FY 2010 enacted level. This budget will allow the Women's Bureau to continue and increase its role of conducting research, outreach, and evaluations of programs and policies affecting working women. The budget will also allow the Bureau to work with the Bureau of Labor Statistics to improve data collection on work-family responsibilities, and support my vision of *Good Jobs for Everyone.*

CONCLUSION

Too many Americans are ready, willing, and able to work – but cannot find a job. The FY 2011 budget for the Department of Labor will help spur new and better job opportunities, foster safe workplaces that respect workers' rights, and ensure American workers are ready for 21st Century jobs. I am committed to achieving the goal of *Good Jobs for Everyone*, and I look forward to working with the members of this committee to make that vision a reality.

Mr. Chairman, this is an overview of the programs proposed at the Department of Labor for FY 2011.

I am happy to respond to any questions that you may have.

Mr. OBEY. Thank you very much.
Mr. Tiahrt.

GREEN JOBS

Mr. TIAHRT. Thank you, Mr. Chairman.

I want to talk just a little bit, ask you some questions about the green jobs. In the fiscal year 2011 request for increased funding for green jobs training, the request is for $45,000,000 over fiscal year 2010, for a total of $85,000,000, more than doubling its funding in one year. This would be in addition to the $500,000,000 provided in the Recovery Act.

However, your latest Recovery Act execution report states that only $520,000 of the $500,000,000 provided for green jobs has been spent. These funds were provided 13 months ago. I am aware the obligation rate is higher, but I think it is important to focus on what has actually been injected into the economy.

Money that is merely obligated does not provide the economic stimulus intended by the Recovery Act, and it certainly does not help the American worker. Furthermore, I am concerned about the push to create green jobs, whether they will actually have a counter effect. There is a Washington Post article about the smart grid, and that is considered to be one of the clean energy sector jobs growth. The author, who is the Director of GE Smart Grid Initiative, suggests that because the smart grid is premised on automation, more than 28,000 jobs of meter readers are likely to disappear.

Now, maybe that is just the normal course of technology; we should accept that. But green jobs is kind of a novel concept. In the article he says that there are really four categories, based on what has happened in Europe, for green jobs when it comes to this smart grid: it is research and development, it is manufacturing, installation, and then information technology.

Now, we are excited about the manufacturing side of it because we have to make things in this Country. If we do not make things, our economy is going to be stagnant. We cannot exist as a service economy only; we have to make things. So the manufacturing side of it is very good. In fact, we have a wind generating manufacturing facility owned by Siemens, a German company, in Hutchinson, Kansas, not far from my home. But when you look at the actual jobs that are residual or long-term for these green jobs, it is a minimal number. So I am concerned that we are overestimating the impact on our economy by green jobs.

If you take into consideration the study done by King Juan Carlos University in Spain, they decided that for every green job that was created, the resources were taken from the private sector and actually cost 2.2 jobs in the private sector. So we had a net loss of 1.2 jobs, according to their estimate, in Spain for having a single green job. So taking resources out of the private sector to create these and subsidize these jobs may not be the best plan to get the economy rolling again.

I am going to go back to this $500,000,000. So if you have not spent any of the $500,000,000 of the stimulus fund, how can we assess whether or not unemployed individuals have been able to obtain work through the so-called green jobs sector?

DECREASE IN JOB LOSSES

Secretary SOLIS. Thank you, Congressman Tiahrt, for your question. You bring up a lot of good questions here, and what I would like to begin with is, frankly, if we can all look back where we were in January and February of last year. We were losing well over 700,000 jobs a month at that time.

This last month, one of the roles that I play in the Department of Labor is to have to issue what that job report is. I am happy to say that we have seen a very, very dramatic decrease in job loss; it went down to 32,000 jobs a month. However, I do want to say that we have a high, high number of people who continue to be unemployed and have been out of work for longer than six months.

GREEN JOBS

The green job programs that we have rolled out—and much of that money was actually released through a competitive process where we had—in each case, entrepreneurs, partnerships with different providers that were a compilation of community colleges, apprenticeship programs, but, more importantly, we had business involved. These efforts are to help create job training slots, and the idea is that the results of those partnerships come about because of the design of the grants' writers from the local area.

Much of what is coming to us is by way of what the community sees as a need. So, for example, in a community that I visited in Tennessee, their interest was in looking at solar panels, looking at trying to change how work was done in the Sharp Corporation. They were doing televisions before; now they are doing solar panels. The owner of that property was telling me that they would like to see more help so that they can have a trained workforce to make that kind of transition. This is where I believe our partnerships will work in a better way to help focus in terms of what regional sectors are looking for.

I know that there has been much debate about how many jobs we created, but I know that because of the Recovery Act we have seen more than 1.5 to at least 2.5 million jobs that have been created. That also represents people in law enforcement, teachers, people who are also working in construction and hopefully now beginning to get involved in those construction projects that are going to be rolled out through the infrastructure monies that were made available by the Congress.

Mr. OBEY. The gentleman's time has expired.

Mrs. Lowey.

And let me explain. I am going to try to hold each questioner to five minutes, so if members want long answers from the witness, they need to ask short questions.

G–20 SUMMIT

Mrs. LOWEY. Well, I am delighted, Madam Secretary, to have you with us, and once again I want to congratulate you on your effective administration. We really are delighted to see you in this position.

I know that you were very enthusiastic at the last year's summit in Pittsburgh when the G–20 leaders called upon you to host a

meeting of employment and labor ministers in early 2010. The economic crisis that our Country is recovering from has been felt worldwide. So if you can tell us about this G–20 meeting, how it will help us solve the jobs crisis we face, I think it would be very helpful.

Secretary SOLIS. Thank you, Congresswoman Lowey, and it is a delight and pleasure to be here with you as well. I know how deeply concerned you are with respect to foreign relations, and have watched you in action on the floor and always with the mind-set of how can we build our relationships with our trading partners; and under that premise the G–20 summit that is going to be held here in Washington for the first time, I think, is a very historic moment. To have our Administration actually present this idea in Pittsburgh and have, then, the buy-in from the G–20 labor ministers and all those parties to say yes, we want to come together.

This is a global crisis. The economic crisis of job loss is hitting everyone, and more severely than our own Country; and I think this is an opportunity for us to be able to position ourselves once again to talk about some of the innovative things that we are doing and listen clearly to what some of the other countries are doing that may work better.

But, more importantly, making sure that the U.S. can play a significant role in this effort. And I am very, very appreciative that we are able to get the support that we did in the last year's budget to help provide the foundation for the ILAB division under the auspices of Sandra Polaski. She is doing a tremendous job to help build upon those relationships that we saw that may have been very fragile in the last few years.

And I am very excited about the opportunity, as I travel to other meetings representing our Country at the G–8 Summit, talking to other labor ministers there. They are very, very much engaged to see where our investments are; where that safety net, where those monies are going to help provide security for those dislocated workers and what kinds of new programs are being implemented to keep people on the job.

Germany and other countries have very, very different types of approaches in how they address keeping workers on the job; they help to subsidize that salary and they actually give an incentive to businesses to keep those industries in place, unlike what we have been doing here. And I say that because they have had a tremendous manufacturing industry going there for many years, but they know that that investment cannot be lost easily, so they make sure that they try to attempt to keep dollars there. Those are things that we can learn from.

So I am very excited to be able to pull together the labor ministers here, along with the Administration, to hear about some good innovative programs, but also bring together business leaders. So we are also bringing together the different chamber representatives, the manufacturing representatives, as well as labor, to talk about the kinds of ideas and what is needed most now in the world.

So I take this very seriously and I am very pleased that the Department of Labor can finally play a role here.

BUREAU OF INTERNATIONAL LABOR AFFAIRS

Mrs. LOWEY. Thank you. In the couple of minutes I have left, I know you have been proud of the work that the International Labor Affairs Bureau has done. Well, we have given you, I believe, the budget request—I do not know that the Chair has appropriated it yet—$22,000,000 and an increase which would be focusing on labor conditions in foreign countries, reducing child labor, protecting women's rights, maintaining our education, HIV/AIDS initiatives. Could you comment on the importance of that increase to accomplish these goals?

Secretary SOLIS. I think these are very, very important investments that we are making. As I said earlier in my statement, we have been working with other international partners, including the International Labor Organization, the ILO, to look at what best practices we can offer to other countries that are perhaps having some trouble, with trade enforcement or labor relation protections.

But, more importantly, how to try to bring up the quality of life for some of our trading partners. I think about the example in Cambodia, where an effort was made there to look at the garment industry and to try to bring all those industries in that part of the world together to set a better standard to protect their workers, provide better wages for them, and then allow for our markets and other international markets through the ILO to also become partners with them. This expands their economic base, which creates more jobs, and creates opportunities for the U.S. to import and export those goods from countries like Cambodia.

We are trying to use that model in other parts of Central America. In particular, we are exploring discussions with El Salvador and Nicaragua.

Mr. OBEY. Mr. Rehberg.

OSHA ERGONOMICS REGULATION

Mr. REHBERG. Thank you, Mr. Chairman. I was going to ask a meaningful question, but our staff left to have his picture taken with Herschel Walker, and I had to decide whether to go with him. He is out in the hall.

Welcome. Nice to have you back.

Secretary SOLIS. Thank you.

Mr. REHBERG. The majority put language in the bill last year to add a column in the 300 log for musculoskeletal injuries, and some of us kind of think that that is the first sign towards a movement towards doing something that we successfully stopped in 2001, and that was the creation of an ergonomics regulation. Does your Administration intend to reestablish an ergonomics regulation in the three years that you have left?

Secretary SOLIS. Congressman, I do want to tell you that there is a lot of confusion surrounding this issue, and we have decided that we want to put this back in terms of gathering information, because we think it is going to be useful. Many businesses are required to report any injury anyway, and all we are saying is that we are going back to the 2001 practice. It does not mean that we are going to roll out an ergonomics standard——

Mr. REHBERG. So there is no intent at this time for the Administration?

Secretary SOLIS. At this time that is not——

Mr. REHBERG. And you do not anticipate in the future a movement towards——

Secretary SOLIS. At this time I can tell you that that is not the direction that the Department is going in. It is more of a means and mechanism to help provide information to businesses so we can prevent injuries. We know worker's compensation premiums and what have you have gone way up. We think this is a way to help provide provision information.

WORKER PROTECTION

Mr. REHBERG. Over the course of 2001 forward, Secretary Chao was very aggressive in, one, enforcement; two, working on the things she promised to do, and that was create industry-specific guidelines; and, three, to continue ergonomic research. Could you report what the Department has done in all three of those areas? Are you still going to aggressively work on industry-specific regulations like the nursing home industry?

Secretary SOLIS. I think that we are obviously trying to put the OSHA division back where it was in 2001, so one of our efforts is to try to make sure that we staff up, that we are not having to do things that really bog down the system; and we would like to try to streamline the system and get information out to businesses, as well as workers, so that we can prevent injuries. I think we will be taking a look at different regulations in more detail, and I would be happy to provide you and your staff that information.

But at this time, we are trying to respond to what Congress has also made clear to us, that in the past, OSHA and the Wage and Hour Division have not been as aggressive in terms of going and seeking and investigating some of these problems that have been occurring. The GAO is very clear on that; the Congress, this Congress, has been very clear. So we are attempting to address those issues that have kind of landed on my lap now as the Secretary of Labor.

[The information follows:]

There are no specific plans involving ergonomics rulemaking at this time. OSHA is carefully assessing its best course for preventing work-related musculoskeletal injuries, which includes a review of the guidelines that have been published and the effectiveness of guidelines as a strategy to address work-related musculoskeletal injuries.

The agency plans to continue to use the general duty clause, when appropriate, for enforcement when work-related musculoskeletal injuries occur. OSHA has also launched a recordkeeping National Emphasis Program (NEP), which will help ensure that musculoskeletal injuries are being recorded accurately by employers filling out the OSHA recordkeeping logs.

A final rule will be issued in FY 2010 to revise the Occupational Safety and Health Administration's (OSHA) recordkeeping form to restore a separate column on musculoskeletal disorders (MSD) that was removed from the form in the last administration. Restoring this column will improve the workplace injury and illness data collected by OSHA and the Bureau of Labor Statistics (BLS). Having more complete and accurate data will further our understanding of work-related MSDs, which is certainly beneficial to any ergonomics research, and also better inform employers about ergonomic hazards in their workplaces.

OSHA STAFFING

Mr. REHBERG. Well, that is an interesting comment, putting the agency back. What was done to the agency, was the budget cut? Are there less employees?

Secretary SOLIS. I would say to you that the priorities were much different. And in terms of, again, trying to address the issues that the Congress has put before us, we thought it was well worth our efforts to focus in on looking at how we can reduce the injuries in the workplace; minimize fatalities and injuries that cost business and our economy an even greater amount of money.

Mr. REHBERG. Okay, I would like to see the research that has been done. It was promised that it was being done, and I am not sure I have ever seen that. Again, was the budget cut or are there less employees in OSHA that there were at the start of 2001?

Secretary SOLIS. Over the course of the last decade, we did not see the same—how could I put it?—equivalent number of staffing that should have been kept up to pace. So again, what I am saying is that we are trying to go back to 2001 levels. There may have been priorities placed on other divisions and did not focus in on enforcement and protection, where the Congress has been stating very clearly for the past few years that they wanted to see more enforcement occurring. And because there were a lot of complaints that were made, that is where our focus has now been directed.

Mr. REHBERG. So if we go back and compare enforcement pre-2001, we will find there was more enforcement on an individual basis than there was from 2001 forward?

Secretary SOLIS. I would say that there was more of a compliance approach to enforcement, which did not always result in changes in behavior in terms of prevention on the part of businesses and industry to make those corrections, to provide training, and to access new tools so that we could reduce the number of injuries in the workplace.

Mr. REHBERG. Thank you, Mr. Chairman.

Mr. OBEY. The Chair would simply point out that the Chart shows that there was a decrease of 252 people in OSHA between 2001 and 2008, and within Federal enforcement there was a decrease of 146 people, or 8.7 percent. The percentage reduction in the entire agency was 10.2 percent. And for safety and health standards the reduction was 22 percent.

Ms. Lee.

RACIAL DISPARITIES IN UNEMPLOYMENT

Ms. LEE. Thank you very much, Mr. Chairman.

Good morning again, Madam Secretary. Good to see you. You are doing a great job. I want to thank you and your staff for being so accessible and for really tackling the tough issues of the economy and unemployment. It is very desperate out there, as you know.

A couple of things. In the committee report in 2009, we had report language that addressed looking at what the issues were as it relates to racial disparities in unemployment as it relates to the structural issues and why this unemployment gap is so great between the national average and the African American and Latino communities. So that is one question I would just like to get an up-

date for the record. And I want to thank your Assistant Secretary for Policy for working on this and for keeping me informed on this.

EX-OFFENDER GRANTS

Also, secondly, there was report language, I believe it was $20,000,000 for ex-offender funding that should have been put out for competitive grants for communities of color, for dropout, for ex-offenders, for making sure that these young people have the requisite skills to become employed; and I do not believe any of that has been spent yet. So have you issued guidance on that or what is the status of that $20,000,000? And that, I believe, was report language in 2009 also.

Secretary SOLIS. Thank you, Congresswoman Lee. To begin with, I am also pleased that we now have my Assistant Secretary for Policy, Mr. Bill Spriggs, who is here behind me. He has been the individual that has been working on the request for that report that you issued some time ago. And I apologize that we have been so late in getting it fully together, but, upon his arrival, we found that we needed more data sets, more information so that we could have a more accurate picture of what is really taking place.

That report had now left my office and has been sent over to OMB for review. We hope that in a few weeks or perhaps next month we will be able to issue that report to you. So I am pleased. And a part of it is, as you know, a staffing issue because we just were able to get the appropriate staff onboard. But, believe me, this is an issue that I am greatly concerned about as well.

With respect to the ex-offender program, I want to go to that because I know that is of great concern to many members of this Committee as well.

Ms. LEE. I believe it was the 2009 committee report that issued the report language for the $20,000,000 that would be allocated for ex-offenders and dropouts.

Secretary SOLIS. Well, what we have done for the 2011 request is, to bring together these programs in a more meaningful way so that we can actually attack the issue of employment, because the hardest, I think, factor here is while we are trying to reintegrate folks back into society, the problem is really the barrier of employment.

Once they are able to achieve employment and get the services they appropriately need, I think then we are on our way to recovery; and that is something that really has not been focused on as heavily in the past, it was actually more of a focus for younger offenders, which was more in terms of education, which I do not want to take away from, because we are going to keep that component, but when we talk about adult ex-offenders, it is really more about providing assistance so that they can help stabilize their immediate families that they return to in many cases, and part of it is making sure that we can find them jobs or help to subsidize a portion of that.

So we are combining our efforts here and we are really trying to make it more strategic because we know dollars are limited.

Ms. LEE. But have you issued the guidance for that $20,000,000?

Secretary SOLIS. I think later this month, my staff tells me, it will be issued.

Ms. LEE. Later this month.

Secretary SOLIS. So we will work with you to give you that information, and then if there is any input that you want to——

Ms. LEE. Okay. Yes, because that is very important. I mean, we have it already and all, it is my understanding, we need is to hear from your office in terms of how to get that out, in terms of the competitive grants. Okay.

Secretary SOLIS. Thank you.

Ms. LEE. Thank you very much.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Alexander.

RATIO OF JOB SEEKERS TO JOBS

Mr. ALEXANDER. Thank you, Mr. Chairman.

Madam Secretary, in your opening statement you said something about six applicants per job opening. How can we determine that?

Secretary SOLIS. Congressman, that is the information that economists have reported, the ratio of job seekers to jobs is about six to one. I just saw a report earlier this morning on the news that said it actually went down a bit, to 5.5 to one. I cannot break that down for you, I am not an economist, but I can tell you that people out there are very much looking for jobs.

And as I go across the Country visiting some of our programs and hear about the kinds of efforts that are being made for people to try to get into training programs that can upgrade skills so that they can be ready when the full-blown economy is back to speed, that is the urgency that I hear, and from employers. Employers want to know that that gap, the education gap for training, is slowly closing, because they cannot find, enough trained personnel ready for some of these jobs that they would like to hire out for.

NUMBER OF FEDERAL EMPLOYEES

Mr. ALEXANDER. Can you tell us how many new Federal employees have been hired in the last year?

Secretary SOLIS. I cannot tell you how many Federal employees, but I can tell you that through the Recovery Act monies, through the CBO, we know that there were anywhere from 1.5 to over 2 million jobs that were created; and not all of them were Federal Government, a lot of them were also in the State with respect to teachers, police officers, and also other various industries. And we are trying to do a better job in terms of the Recovery Act money and how to actually account for those jobs that are created.

FOREIGN GOVERNMENT SUBSIDIZED EMPLOYMENT

Mr. ALEXANDER. When you were responding to Mrs. Lowey's question a while ago, you said something about the fact that you had been to some other nations and in some countries they actually subsidize employees, unlike we do here. Can you tell us what that means?

Secretary SOLIS. Well, just as an example, in Germany I am aware that they provide substantial subsidies for workers that are in areas or industries that are going through economic crisis, the automobile industry as an example.

And what they do is they make a concerted effort then to allow for that salary to be paid for by the Government. A portion of that is paid for, maybe two days as opposed to three days, so they do not lose that talented, skilled, crafted person. Those are ideas. And it is not just in Germany; there are other parts in Europe where that model has been used.

Mr. ALEXANDER. Thank you.

Mr. OBEY. Mr. Jackson.

DOL BUDGET REQUEST

Mr. JACKSON. Thank you, Mr. Chairman. Thank you for the time.

I want to thank my former Rayburn neighbor, Secretary Solis, and welcome her back to our Committee, and thank her for her testimony.

Madam Secretary, during this tough economic period, and with unemployment hovering just around and under 10 percent, you have one of the toughest jobs in the Administration: putting people back to work. I read with great interest your testimony and I understand that we are under budget constraints as we write these appropriations bills. However, I find it incomprehensible that we are quibbling over about $14,000,000,000 in your discretionary budget. We spend close to $1,000,000,000,000 bailing out banks that do not lend to us and got us into our current financial crisis.

My problem with your discretionary budget, at least from my perspective, is that it is not bold enough. I read the part of your testimony that provides and seeks to put significant resources back into employment and training to prepare workers for the 21st century. However, last week the House voted on a "jobs bill" which would provide tax incentives to businesses to hire more workers. I voted against that bill because I do not believe that tax incentives are the best way to create jobs.

ADDRESSING CHRONICALLY UNEMPLOYED

In my district—and I have been here for 15 years—I am deeply concerned about the chronically unemployed. In my district, there are three people for every one job, while in the northwest suburbs, around O'Hare Airport, there are three jobs for every one person. Just under $1,000,000,000,000 to bail out the banks, but for a fraction of that number, let us say $300,000,000,000, my math says that $300,000,000,000 could employ 7.5 million Americans at about $40,000 a year. 7.5 million Americans put to work at $40,000 a year is about $300,000,000,000, a fraction of the $1,000,000,000,000 that we spent to bail out the banks.

Are not sometimes the simplest ideas the best ideas? What does your budget do to address the chronically unemployed? And my colleague who asked the question about how many Federal employees have been hired over the last year, if I had my say, it would be 7.5 million more Federal employees, doing everything from painting bridges to cleaning up highways, to cleaning up vacant lots across this Country. And I fundamentally believe that the Federal Government has a responsibility during these tough economic times to shore up unemployment and put the American people back to work.

Madam Secretary, your budget, what does it do to address the chronically unemployed?

Secretary SOLIS. One of the things I would like to respond to, Congressman Jackson, is that through the Recovery Act money, we were able to help, set a good foundation to begin this holistic approach to really trying to assist people that were out of the workforce, the dislocated workers, the folks who lost their jobs recently in the automobile industry, the financial institutions, people who were also highly qualified. We are talking about people that had different skills sets.

Through our Workforce Investment Act monies, we made grants available just through the green job approach, the partnerships that we established, about $500,000,000 went there. And we are asking for a bump-up there because we think it works and we know that there is a big interest.

We know that there are people out there that may have lost their job because the assembly plant or manufacturer is no longer here, and we are trying to get people identified to get the appropriate type of counseling and assessment that they need. We plan to make sure that our one-stops are more accessible and that these grants that we provide through the Workforce Investment Act—and that is something that I believe you will want to be involved in by helping us with the reauthorization—to really reach down and touch those neighborhoods and communities like yours that may not have benefitted in the past from these types of efforts and targeted funding.

We also make a special attempt through our Pathways Out of Poverty program to identify high unemployment areas; of 15 percent and higher, that require people to come together, partners, business, community colleges, apprenticeship programs, CBOs, and stakeholders that have a better sense of where these individuals are that could obtain this job skill.

Keep in mind our effort is to make sure that we connect the business with the job training. I do not actually create the job. What I do is bring partners together that then say, at the end of the program, we expect to hire so many people. We fund those slots. That is really what the Workforce Investment funds and the partnerships that we have been able to put together are focused on.

But we try to make the best assessment to make sure that we are getting the people in, and it is taking a long time because we have had to change guidelines, we have had to change the way that we even bring people on to read proposals. Much of that had not changed in the past 10 years. And I do not have to tell you communities like yours and others have been left out, quite frankly, from many of these job training programs.

So our attempt is to, look at green jobs, health care jobs, as well as careers where we think there will be continual growth. We have actually seen that is the one spot where we see that there will be job growth, where we can integrate our local communities to get into those entry level health careers.

Mr. OBEY. The gentleman's time has expired.

Mr. Cole.

JOB SECTORS FACING CONTRACTION

Mr. COLE. Thank you very much.

Madam Secretary, great to see you again. You and your folks in your Department probably see more data on what is happening in the labor force than anybody else in the Government. I am very curious. We know we have lost about 8 million jobs over the course of the recession, and there are a lot of articles now beginning to appear to suggest a lot of these jobs "are not coming back." What are the areas that you think, frankly, we will not be able to recover in, the particular sectors or kinds of work that, looking forward, you suspect there will be considerably less of in the future than we had in the past?

Secretary SOLIS. Well, thank you, Congressman Cole. That is a good question. One figure that I continue to see that is not recovering as quickly is obviously in construction, and a lot of it has to do with the housing industry and the fact that we are just not building more houses. We have inventory, in fact, an overwhelming number of houses that now are in foreclosure. So that is creating a strain in terms of that workforce.

REBOUNDING JOB SECTORS

I would say also that in manufacturing overall we are just finally seeing an up-tick. The most recent report, issued in February, saw about 1,000 jobs added in manufacturing.

What I do see happening, the positive sign, is that businesses are bringing on temporary workers. But, when you talk about temporary workers, it is not the clerk; these are engineers, architects, very highly skilled individuals that are helping that business come back and hopefully, with the Recovery Act and all the funds that you all have made available, and with the credit and capital market changing its direction, that businesses will feel more confident in bringing people on.

The health care industry, as I said earlier, helped to create about, I would say, close to 500,000 or 600,000 jobs this last cycle. I also see growth in IT technology energy efficiency, and the renewable energies. That is why I think other countries are taking full advantage of that and we should also be heading in that direction.

And I know that there has been a tremendous amount of investments made by different Cabinet secretaries, Department of Energy, in our railway system, as well, high speed rail. If we can get those projects on the ground ready to go—and much of that money has already now been given to different States—that is going to create jobs not just for the two-year period of the Recovery Act, it will go on for ten years because of all the other jobs that will be created around that rail system.

JOB SECTOR CONTRACTIONS

Mr. COLE. If you could just have somebody from your Department give me a list of where you really expect the contractions. We clearly are going to have a lot of very skilled people that do not have a future that you are going to want to redirect.

[The information follows:]

EMPLOYMENT PROJECTIONS: 2008-2018

The employment structure of the U.S. economy in 2018 is expected to reflect a continuation of recent trends. In general, goods-producing sectors will lose employment while service-providing sectors will expand. Below are two tables showing those industries and those occupations with the largest employment declines projected between 2008 and 2018. These projections do not reflect changes to the labor market that have occurred since the baseline year of 2008.

Industries with the largest wage and salary employment declines, 2008 and projected 2018

Industry Description	Sector	2007 NAICS	Thousands of jobs		Change	Average annual rate of change
			2008	2018	2008-18	2008-18
Largest declines						
Semiconductor and other electronic component manufacturing	Manufacturing	3344	432.4	286.8	-145.6	-4.0
Newspaper, periodical, book, and directory publishers	Information	5111	618.9	499.2	-119.7	-2.1
Motor vehicle parts manufacturing	Manufacturing	3363	544.4	443.3	-101.1	-2.0
Postal Service	Federal government	491	747.5	650.0	-97.5	-1.4
Printing and related support activities	Manufacturing	323	594.1	499.3	-94.8	-1.7
Telecommunications	Information	517	1021.5	931.9	-89.6	-0.9
Cut and sew apparel manufacturing	Manufacturing	3152	155.2	66.7	-88.5	-8.1
Support activities for mining	Mining	213	327.7	251.7	-76.0	-2.6
Crop production	Agriculture, forestry, fishing, and hunting	111	950.6	880.7	-69.9	-0.8
Converted paper product manufacturing	Manufacturing	3222	319.7	255.6	-64.1	-2.2
Insurance carriers	Financial activities	5241	1401.8	1338.2	-63.6	-0.5
Electric power generation, transmission and distribution	Utilities	2211	404.7	345.7	-59.0	-1.6
Computer and peripheral equipment manufacturing	Manufacturing	3341	182.8	124.7	-58.1	-3.8
Basic chemical manufacturing	Manufacturing	3251	152.1	99.9	-52.2	-4.1
Pulp, paper, and paperboard mills	Manufacturing	3221	126.1	81.9	-44.2	-4.2
Machine shops; turned product; and screw, nut, and bolt manufacturing	Manufacturing	3327	360.1	319.5	-40.6	-1.2
Animal production	Agriculture, forestry, fishing, and hunting	112	860.6	823.9	-36.7	-0.4
Ventilation, heating, air-conditioning, and commercial refrigeration equipment manufacturing	Manufacturing	3334	149.5	112.8	-36.7	-2.8
Plastics product manufacturing	Manufacturing	3261	589.0	555.2	-33.8	-0.6
Textile furnishings mills	Manufacturing	3141	75.4	41.9	-33.5	-5.7

Source: Employment Projections Program, U.S. Department of Labor, U.S. Bureau of Labor Statistics

EMPLOYMENT PROJECTIONS: 2008-2018

Occupations with the largest job declines, 2008 and projected 2018 (Numbers in thousands)

2008 National Employment Matrix title and code		Major occupational group	Employment		Change, 2008-18	
			2008	2018	Numeric	Percent
Farmers and ranchers	11-9012	Management, business, and financial	985.9	906.7	-79.2	-8.03
Sewing machine operators	51-6031	Production	212.4	140.9	-71.5	-33.66
Order clerks	43-4151	Office and administrative support	245.7	181.5	-64.2	-26.12
Postal service mail sorters, processors, and processing machine operators	43-5053	Office and administrative support	179.9	125.3	-54.5	-30.32
File clerks	43-4071	Office and administrative support	212.2	162.6	-49.6	-23.36
Shipping, receiving, and traffic clerks	43-5071	Office and administrative support	750.5	701.2	-49.3	-6.57
Telemarketers	41-9041	Sales and related	341.6	303.8	-37.8	-11.07
Office and administrative support workers, all other	43-9199	Office and administrative support	306.7	271.0	-35.7	-11.64
First-line supervisors managers of production and operating workers	51-1011	Production	681.2	645.5	-35.7	-5.24
Packers and packagers, hand	53-7064	Transportation and material moving	758.8	724.8	-34.0	-4.48
Cutting, punching, and press machine setters, operators, and tenders, metal and plastic	51-4031	Production	236.8	203.5	-33.3	-14.05
Electrical and electronic equipment assemblers	51-2022	Production	213.3	182.0	-31.3	-14.66
Machine feeders and offbearers	53-7063	Transportation and material moving	140.6	109.5	-31.2	-22.15
Door-to-door sales workers, news and street vendors, and related workers	41-9091	Sales and related	181.6	154.7	-26.9	-14.79
Information and record clerks, all other	43-4199	Office and administrative support	226.9	200.1	-26.7	-11.79
Paper goods machine setters, operators, and tenders	51-9196	Production	103.3	81.0	-22.2	-21.54
Computer operators	43-9011	Office and administrative support	110.0	89.5	-20.5	-18.60
Machinists	51-4041	Production	421.5	402.2	-19.3	-4.57
Laborers and freight, stock, and material movers, hand	53-7062	Transportation and material moving	2,317.3	2,298.6	-18.7	-0.81
Miscellaneous agricultural workers	45-2090	Farming, fishing, and forestry	807.0	788.8	-18.2	-2.26
Data entry keyers	43-9021	Office and administrative support	284.3	266.9	-17.4	-6.13
Switchboard operators, including answering service	43-2011	Office and administrative support	155.2	138.3	-16.9	-10.89
Inspectors, testers, sorters, samplers, and weighers	51-9061	Production	464.7	447.8	-16.9	-3.63
Mail clerks and mail machine operators, except postal service	43-9051	Office and administrative support	141.4	124.8	-16.6	-11.76
Lathe and turning machine tool setters, operators, and tenders, metal and plastic	51-4034	Production	55.7	40.8	-14.9	-26.73
Grinding, lapping, polishing, and buffing machine tool setters, operators, and tenders, metal and plastic	51-4033	Production	92.7	77.9	-14.8	-15.92
Textile winding, twisting, and drawing out machine setters, operators, and tenders	51-6064	Production	34.9	20.7	-14.2	-40.70
Postal service clerks	43-5051	Office and administrative support	75.8	62.1	-13.7	-18.02
Multiple machine tool setters, operators, and tenders, metal and plastic	51-4081	Production	86.0	73.4	-12.6	-14.66
Photographic processing machine operators	51-9132	Production	51.3	38.8	-12.5	-24.31

Source: Employment Projections Program, U.S. Department of Labor, U.S. Bureau of Labor Statistics

Please note that the BLS employment projections are based on analysis of long-term structural changes to the economy, not short-term business cycle fluctuations. BLS does not attempt to project the peaks and troughs of business cycles, and our projections model assumes a full employment economy in the target year. Because the economy is expected to trend out of the recession and return to full employment over the 10-year projections period, the current projections indicate faster growth rates and more numerous openings than might have been expected in several industries had employment not fallen in 2008, as the economy recovers from the current downturn. Please see http://www.bls.gov/opub/mlr/2009/11/art1full.pdf for more information about the impact of the recession on the projections.

SHORTAGES IN TRADITIONAL ENERGY INDUSTRY

Let me ask you. You mentioned energy and I had a particular question about that. I am not one who is critical of the money going to training on green jobs; I see a lot of wind power sprouting up in my State. I think there is no question there is going to be a market there.

But there are also pretty critical shortages now in what I call the traditional energy industry as well. We are now doing a lot more natural gas in a lot more places; it is a much cleaner fossil fuel. I can tell you it is hard to find people that know how to drill in Western Pennsylvania or New York now, or that have a lot of knowledge of that particular business. Plus, we have some shortages in our own industry.

So while you are incentivizing the movement—and I think appropriately—of people into the so-called green sector, what are we doing to help the industries that have critical shortages that produce traditional forms of domestic energy?

Secretary SOLIS. Congressman Cole, that is an excellent question. I have actually seen many of our programs training up again in the area of hard manufacturing, and I am talking about jobs that you just mentioned, welding as an example.

I have been to some of our programs that we have funded and find very regularly that the business components out there in the industry are saying I cannot find a qualified welder. And the salary levels that they offer are anywhere from $60,000 to $100,000. If the public were made more fully aware of what the potential is, I am sure people would not mind relocating to where those jobs are, because they do pay very good salaries.

And because we are going into, say, renewable energies, I think there are going to be more opportunities. I know that the folks that we have been working with in partnership in public and private entities know that this is where we need to move our training programs, and I am acutely aware of that and know that that is an important factor in our recovery.

We have to bring back, also, some steady skill sets, but also that manufacturing base, and we have to have that workforce staying here because there are a lot of people that are retiring from those industries. Same thing in the coal mine industry; you see a lot of retirees. We are still going to need people to be trained to go into those mines.

Mr. COLE. I know my time has expired. I would just urge you to look at these traditional areas too. Green energy is the new buzz word, but there are going to be a lot of jobs in natural gas going forward and it is going to be national in scope; we are going to be way outside of traditional areas where people will have some new opportunities that have not had them in the past.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Honda.

Mr. HONDA. Thank you, Mr. Chairman.

CONTINUING EDUCATION

Again, welcome, Madam Secretary. It is good to see you. A couple of things just real quick off the top of my head. I really appreciated

the allocation of $5,000,000 to San Jose State University, where we will be able to look at health care and biotechnology training programs, and the vision I think that you are providing the Department is we are doing a lot of innovation and a lot of emphasis on green employment and green careers, but in order to have the workforce there that support that also, we need to have higher education. Some of these other institutions are prepared to do that.

One of the things that we did in Santa Clara County was have an AA program, a pilot program to have folks who were in the labor industry, laborers, who want to pursue a AA degree in contract managing. Where, before, those folks were always the ones who were managed, now they have that background experience and can take a traditional job that Congressman Cole had talked about and upgrade them and convert them into other jobs that are going to be in high demand, especially when we have more activities in the green industries.

So looking at the AA, hopefully somebody in your Department might work with the education department to look at how we can link the AA to a BA into the four-year college, where they can continue their education and their life skills into something more productive.

GREEN JOBS

In terms of the green jobs issues, I think that if people visited Santa Clara County and Silicon Valley, that although we have companies like Applied Materials that make machines that allow us to have photovoltaic gadgets or panels or flat screens, the instruments that are being sold and made by this company have a ripple need that goes upwards towards folks who do work like design and do work like creating the machine parts. There are skilled laborers and skilled artisans out there that are necessary. So those are traditional jobs that still exist that need to be continued and supported. So a green job could support more than five other jobs that are necessary for them to do that.

I just wanted to have some of our colleagues understand that there are supportive groups that are out there. Even Caterpillar. When you have heavy machinery, you just do not have one kind of worker. So I think that in the green area we are expanding our vision and making this a better place.

And the term greener and green, I think that that is probably a good term to use because we have to have every individual in this Country, and globally, understand that we all have individual impacts on our carbon footprint, and collectively we need to be constantly aware of it. So in your Department I really do appreciate that constant attention to that, because otherwise, as a Nation, we are not going to be able to effect any changes in our attitudes.

I have no questions, Madam Secretary, but I just wanted to feed back some of the things and observations I have had over the past few months.

Mr. Chairman, closing comments. Folks asked me in my internet town hall meeting I had last night one of the interesting questions was that if these things are happening and we are creating more jobs, why is unemployment looking like it is getting more.

And I think that those who understand the statistics is that people who are not in the job market are not coming back in the job market, so that is going to create a blip in that unemployment, and then it goes down as they secure jobs. So folks who would be negative, we need to just respond in kind to let people know the information, what it really means in real life and people's jobs and the situation in this Country.

Thank you very much for your work, Madam Secretary.

Mr. OBEY. Mr. Moran.

EMPLOYEE READINESS TO ENTER JOB MARKET

Mr. MORAN. Thank you very, Mr. Chairman.

Let me just say ditto for all the nice comments that have been addressed to you, Madam Secretary. We are delighted you are in this position and we appreciate all your diligent efforts.

I represent an area that has a preponderance of technology firms, a lot of jobs. We are in pretty decent shape relative to the rest of the Country. But we are trying to make the most of the employment training opportunities that are available for those who are underemployed or unemployed because we have a lot of jobs. So we want to bring them in to this knowledge-based economy.

But the employers tell me that there is a very serious deficiency in terms of employment training programs that the Federal and State government operates; that, in fact, they cannot use the skills that are taught through these training programs. At best, if they find that somebody shows up every day, is reliable, that is one of the best indicators that they can hire them, but they have to hire them at pretty low entry level skill levels and, thus, compensation levels.

And they tell me the problem in an area like computer skills, where the jobs are available, is that the trainers are really not up to speed on the computer skills that are needed; that in many cases the trainer is teaching what they knew when they last left the private sector and came in to be a trainer. And because the computer skills advance at such a rapid pace, what they know is kind of outdated, and they either do not have the inclination or do not have the time, really, to bring themselves up to speed on the latest technology.

Can you address this? Do you think this is an unfair criticism or is it something that you have observed and are addressing?

Secretary SOLIS. Thank you, Congressman Moran. You hit the nail on the head. In my travels across the Country visiting different workforces and workplaces, I often hear from the employer that it is very tough to find someone who is really prepared that they can hire right way with the set of skills that they need.

Therefore, the need to have reform with respect to some of the programs that we operate in the Department of Labor and, we are proposing in our budget to provide some new and better methods of trying to make our systemic approach more targeted so that we really do get at what the business owner needs, and make sure that those skill sets are really going to lead to a good job, and are marketable and timely.

So it is going to require, I think, a lot of support on the part of the Congress, as well, as we look at revamping the Workforce In-

vestment Act, because we do have some traditional partners who have been used to doing things for the last decade a certain way, and many times those folks are not going out as they were intended to to really talk to the business community, the entrepreneurs, the new inventors of this new technology that is coming out not just in the green industry, but just IT overall.

I think that one of the incentives that we want to use is reward those programs that can demonstrate that there are some good methods being used. We want to be able to replicate them and we want to support innovation. So I am very much interested in your ideas and would like to learn more about how we can work together to help craft these kinds of activities so we make this a more effective program.

EXTENSION OF RETIREMENT AGE

Mr. MORAN. Thank you, Madam Secretary. I was not supposed to ask questions that elicited long answers, but that was a superb response. I have one other question.

The President is putting together a group of people to address structural deficit problems and, invariably, they will look at entitlement programs, Social Security especially, and I am sure one of the recommendations is going to be that they extend the retirement age.

Now, in my district, a significant portion of the workforce is not going to be bothered by that. In fact, I think they would welcome it, to be able to keep working until 70. The problem is that we have a cookie-cutter approach in entitlement programs, and people who work with their back and their legs and their arms all their life, they cannot keep working until 70. So what are you going to do for those 15 years or so when the body wears out?

I mean, I really am serious about this. It is not fair to manual workers to extend that retirement age. But if we could come up with a more sophisticated retirement system that was more correlated to the physical, as well as the mental demands of various workforce classifications, then it would be fairer to extend the retirement age; people would be more comfortable. We would have a more productive economy and probably save substantial sums in our entitlement programs for retirees.

Is there any research, any thought that is being given to that within the Department of Labor, Madam Secretary, that might help us in this difficult decision-making arena?

Mr. OBEY. The gentleman's time has expired.

Secretary SOLIS. I would like to get back to you in more detail about what we are looking at in terms of approaches now in EBSA and also the PBGC, because we are really talking about retirement security too, so people do not have to stay longer in the workforce for those folks that work in very hard assembly line and very labor-intensive jobs. We are looking at some creative mechanisms there and I would love to work with you on that.

[The information follows:]

As we consider Social Security deficit issues, we are concerned about a range of issues including changes in the Social Security Full Retirement Age (FRA) that would disproportionately hurt workers in physically demanding jobs. These workers tend to have lower income compared to white collar workers.[1] We are aware of studies that show retirees from physically demanding jobs, especially operators/laborers, make up a disproportionate share of younger retirees.[2] For instance, it has been shown that classifications of operators/laborers constitute 19 percent of workers aged 55 to 61 and 22 percent of retirees, while in contrast, managers/professionals make up 25 percent of workers aged 55 to 61 and 19 percent of retirees.[3]

Because of changes enacted in 1983, the retirement age is already going up. For those born between 1943 and 1954 the full retirement age is 66, and for those born after 1960, the full retirement age is 67. These changes will be accompanied by cuts in benefits to those retiring at age 62, their spouses and widows. This process is, as you point out, affecting workers in all occupations.

Some researchers have characterized the principles behind social security as a balance between individual equity (you get what you put in) and social adequacy (providing for those in need).[4] It is argued that the stability of the social security system over the last 25 years is evidence of a consensus around the current balance between these principles.[5] Therefore, it makes sense that reform proposals should balance individual equity and social adequacy to be politically feasible.

There has been some research recommending social adequacy leaning policies in conjunction with raising the FRA. Suggestions have been made as to possible ways to accommodate workers in physically demanding jobs including adding a second tier disability benefit for those who cannot work, but do not meet current disability requirements.[6]

While we are aware of policy proposals, we have made no decisions about what course we will take in addressing the Social Security deficit issues.

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[1] See Tables 5-2 through 5-7 of "The RP-2000 Mortality Tables," The Society of Actuaries. http://www.soa.org/files/pdf/rp00_mortalitytables.pdf

[2] See p. 13 of Cori E. Uccello (1998), "Factors Influencing Retirement: Their Implications for Raising Retirement Age," Urban Institute #9810. http://www.urban.org/UploadedPDF/1000207_retire_factors.pdf

[3] See p.13 of Uccello (1998).

[4] See p. 11 of Eric Klieber (2009), "Strengthening Social Security for Workers in Physically Demanding Occupations," National Academy of Social Insurance Working Paper. http://www.nasi.org/research/2009/strengthening-social-security-workers-physically-demanding

[5] See p. 14 of Klieber (2009).

[6] See p. 15 of Klieber (2009).

Mr. MORAN. Thank you, Madam Secretary.
And thank you for your indulgence, Mr. Chairman.
Mr. OBEY. Ms. Roybal-Allard.

PROTECTING MIGRANT FARM WORKER CHILDREN

Ms. ROYBAL-ALLARD. As always, welcome, Madam Secretary. Let me begin by thanking you for hosting a briefing last September at the Department of Labor on the serious issues confronting migrant farm worker children.

Last year, as you know, I introduced the CARE Act to give the estimated 400,000 youth working in agriculture the same child labor workplace protections that safeguard children in all other industries; and I know that you have been a champion for a very long time of child labor rights, and I look forward to continuing to work with you and your staff on this legislation as it moves forward.

But in the meantime, children in agriculture are not equally protected by our child labor laws. They work in the fields at younger ages for longer hours and under very dangerous conditions that would not be permitted in any other industry. For example, a Human Rights Watch study found that while there are only 8 percent of children in agriculture, approximately 40 percent of all workplace deaths and nearly half of all workplace injuries suffered by children occur in agriculture.

Until the CARE Act is passed into law, these findings highlight the critical need for oversight and enforcement of our current laws, which at least provide some protections to our children. Yet, in 2005, the average civil penalty assessed by the Department of Labor was only $1,011, or just 9 percent of the maximum penalty for child labor infractions; and in 2006, of the 1,344 child labor investigations by the Department, only 28 were in agriculture. This lack of enforcement obviously gives employers little incentive to follow the laws that do exist to protect these children.

Now that the Wage and Hour Division staffing has been restored to the 2001 levels, can we look forward to increased investigations and meaningful penalties for child labor violations in agriculture?

Secretary SOLIS. Thank you, Congresswoman Roybal-Allard, and I also want to commend you for introducing your legislation, the CARE Act, and I want to applaud your work and the work of those that helped to work behind the scenes to bring this issue before the Congress. It is something that all of us deeply care about, and I certainly am putting forth as much effort as possible to see that our Wage and Hour Division, working in conjunction with the Migrant Seasonal Agricultural Worker Protection Act, or Field Sanitary Standards in OSHA, are all working together in a strong effort to focus in on combating child labor.

The Wage and Hour Division is conducting training right now with our investigators; they are out in the fields so that we can detect and get those parties involved in this egregious behavior to understand that this is not the direction that we need to be going in.

It is also working with stakeholders, with parents, and also with the community, and even religious groups and organizations that can help to provide more information. We are rolling out a campaign to provide assistance to those most vulnerable populations,

which will include, by and large some of the farm worker and farm worker children.

It is egregious that this goes on. I was very upset when I heard about the violations that were occurring in the blueberry fields up in the northeastern part of our Country, where young children of ages 5 to 8 were out picking blueberries, and parents were allowing their children not to attend school because they needed the money; and they were out there through contractors who would bring these folks in and kind of move them around different farms.

Well, when I heard that news, I ask that there would be immediate action taken by our staff, and I am happy to say that we have been able to now begin a more robust process, because we have more field investigators and the staff, and even people who speak their languages, so we can ascertain actually what is going on on the ground without intimidating people and them not being fearful of sharing information, because you know that is a big barrier that we face also with this population.

But I would tell you that civil penalties, I have a list and I can give you the details of where we have gone after some of these egregious cases just in this past year that I think would be noteworthy for you. And we know we want to work with you to continue this effort.

EXPOSURE OF CHILDREN TO HAZARDOUS MATERIALS

Ms. ROYBAL-ALLARD. Thank you. In May of 2002, the National Institute for Occupational Safety and Health issued a report recommending that more than half of the existing regulations pertaining to children working in hazardous jobs, such as those exposing them to pesticides and lead, be revised and 17 new regulations be added; and although the Department of Labor has taken some steps to amend non-agricultural hazardous odors, those pertaining to agriculture have yet to be put on the Department's regulatory agenda for updating.

Given the dangerous conditions, again, that these children face working in agriculture, what is the Department of Labor's time line for reviewing and acting on the recommendations for this specific industry?

Mr. OBEY. Very short answer, please.

Secretary SOLIS. I would love to get back to you on what our activity and our plan is, because it is something you know I care very deeply about with respect to pesticide use and hazards that find their way to our children who are forced to work in the fields.

Ms. ROYBAL-ALLARD. Thank you.

Mr. OBEY. Mr. Ryan.

Mr. RYAN. Thank you, Mr. Chairman.

Thank you, Madam Secretary. Let me first thank you and your staff. We had a visit recently from Assistant Secretary Oates and just had a tremendous visit. We had some steelworkers who were having issues with unemployment and she was just terrific, and it looks like we have fixed some of the issues; and you and your staff were ahead of the curve, as always. So thank you for being so great.

I wanted to just mention, one, what Mr. Cole talked about, natural gas. We sit in Ohio under the Marcellus Shale, which is a

huge natural gas opportunity for all of us, so talking about the Pickens plan, as far as retrofitting diesel engines and buses and trucks, I think it is an opportunity for all of us to say this is a clean fuel, and areas like Northeast Ohio and Western Pennsylvania have an opportunity to really, I think, resuscitate some long-term chronic problems that we have had.

LEVERAGING STIMULUS FUNDING

I want to make a comment about the stimulus package, too, because there has just been so much said about it. You are someone, and this Administration, I think, believes that we need to make investments into our communities, and we were able to take some stimulus money, not just stabilizing police and fire and a lot of school teachers did not get laid off in my district because of money that came, but we were able to take $20,000,000 from the State to do some site prep work, move a rail line, and it leveraged a $650,000,000 investment from a French tubing company that does a lot of natural gas tubing.

And I bring this up because I want you to bring back to the Administration and to your colleagues that you work with in the Cabinet that there are communities in our Country, as you know, that just do not have money to make deals go down. So whether it is training money or community development block grant money, we need more opportunities to make things happen when you do not have that local tax base to make deals work for businesses.

So I just wanted to put a bug in your ear to bring that back. I know you believe in it, and we need to continue to recognize that community development block grants and those kinds of things are very, very important.

I want to thank you for all that you have done for Ohio with green collar jobs and the training money that you have sent. We also are benefitting from some high speed rail lines that are going from Cleveland to Columbus to Cincinnati, and your money will come in handy to make sure that we have the workforce available to do that. So the stimulus package has been good to us. We need more, there is no question, but it has been good to us.

REEMPLOYMENT OF HIGHLY-SKILLED WORKFORCE

I have one question that hopefully you can touch upon. We have in our area a distressed auto community. We have lost a lot of very high-skilled work. A lot of high-skilled workers are unemployed now. What are we doing within the Department of Labor or in conjunction with the Department of Labor–Department of Commerce to take these very high-skilled people, engineers, people who have made companies like Delphi and General Motors a lot of money over the years? How do we take these people and help them start their own business?

And I know that may not be directly related to the Department of Labor, but they are unemployed workers. I think there is an enormous amount of opportunity for them to get creative, especially with the green economy. They have a history in manufacturing and, as we heard today, five spinoffs for every one manufacturing job. We have to get back to making things in this Country. So how do we take these brilliant engineers from General Motors or Delphi

and corporations like that and help them with business plans and opportunities to create their own businesses?

Secretary SOLIS. Well, thank you, Congressman Ryan. It was very kind of you to mention some of the things that we have done out in Ohio. I have to give you credit also for having a great leadership delegation there; everyone working together, and also your governor. I was down there when we actually issued the $400,000,000 for that high speed rail, and I can tell you there were a lot of delighted people there in the room to see that there is going to be an investment made on the part of the Federal Government to jump-start a project that will last into the next decade. Job creation is what we definitely want to see.

But to your point about how we can try to deal with the highly qualified workforce that is out there looking for jobs, you now have the privilege of also working with Dr. Ed Montgomery on our Department of Labor staff, who is addressing the whole automobile industry displacement, and what he has done is brought together the different Cabinet offices—Department of Energy, Commerce, EPA—to try to put together plans regionally so that we can start structurally looking at how we get these dollars out to those most distressed areas; and yours is one that is on target for us to bring those resources.

We know that capital still remains a big obstacle, making sure that there is more credit available. I think the President is moving in that direction to see that we can provide incentives for businesses, tax cuts, research and development, more assistance targeted in a fashion that will help to spur that innovation so that businesses will not think that they can just have maybe support for two years, but be able to make a plan for 15 years.

So I understand clearly where your thought process is and would want to work with you more to see how we can maybe learn from some of the things that are happening in your State and share with other industries. We also have some issues in California with some of our auto plants that are closing there. If we can use those best known practices and share them, I think we can all win in the long run. We have other industries, for instance aerospace is affected and we would be at a disadvantage if we do not also do something for these highly skilled individuals.

Mr. RYAN. Thank you.

TRAINING FOR HIGH-GROWTH INDUSTRIES

Mr. OBEY. The gentleman's time has expired.

Let me just ask two questions before we end the hearing.

First of all, as you know, in the Jobs for Main Street Act, which we passed in the House in October, we provided $500,000,000 for Workforce Investment Act Youth Activities; we provided $750,000,000 for job training grants; and I am happy to see that the Administration has picked up both of those items in your statement that you made today.

I do have one question about your choice of priorities, however. Can you explain the Administration's request to fund additional green jobs or green jobs training grants, when there is a more immediate need for additional health care professionals?

And in that context, in the Recovery Act, Congress provided $250,000,000 for training in high-growth industries with an emphasis on the health care sector; and my understanding is that DOL received an overwhelming number of applications for those grants. Can you tell the Subcommittee what percentage of the grant proposals you were able to fund for those items and whether there are additional high-quality applications that were denied due to a shortage of funding?

Secretary SOLIS. First of all, Chairman Obey, I do want to give you credit for your outstanding work in helping us look to where the high need areas are, and you did that for us last year in our budget. With respect to the over-subscription of grants that we received in health care, we received 800 applications, and I would say that a good portion of them, a large portion, were eligible for funding.

But we did not receive the amount of funding to be able to go beyond 8 percent of that fully-eligible population of applicants that came in. We were only able to fund 55 awards. And I know that this is a very sensitive issue for you, as it is one for me. I recently visited one of our nursing programs that we provide assistance to in Sacramento, a community college program, and to hear the testimony that I heard from some of the students there that had to wait years just to get into an entry level position was mind-boggling.

But these were the students that persisted and some, by accident, were actually able to get enrolled into the program. Many were already well above 21 years of age; one was even 50 years of age, but felt so compelled because of the need to get into these careers that pay well that we know we have a shortage of.

I know that the Department of Health and Human Services has a more robust budget than I do in nursing, and we want to collaborate with them to see how we can work on improving and expanding this effort, because there is a shortage and I think this is something you and I can talk about and figure out a way to work together.

Mr. OBEY. We are really missing an opportunity if we do not recognize that possibility.

IMPROVING JOB LOSS PICTURE

Just one other point. With respect to the stimulus package, I frankly find it quite tiresome to be in an argument about whether or not the stimulus package "worked or not." This is a pretty badly hand-drawn chart, but what it shows is that, beginning in March of 2008, this downward line represents the average monthly job loss that we were experiencing in the economy. This line represents zero job loss and, as you can see, by December of 2008 we were losing 750,000 jobs per month the last three months of that decline.

Since then, we have had a steadily improving picture in terms of job loss, so that today, over the last three months, we have averaged 35,000 job losses each month. That is a 95 percent improvement.

Now, it certainly is not good enough because we still have not reached positive growth in the economy, but before a ball can bounce, it has to stop falling, and that is pretty much what I think we were able to do with the Recovery Act. The bill was never large

enough to plug the entire $3,000,000,000,000 hole in the economy that we were facing, but what it did do is soften the blow, lessen the pain, reduce the number of people who were losing jobs. And let us hope that we have enough imagination, enough luck, and enough help and cooperation between the public and private sectors to actually turn that into a positive job growth area in the months ahead.

CONCLUSION

But I thank you for your testimony here today. Sorry we had to delay you by an hour, but it is good to see you.

Secretary SOLIS. It is good to see you. Thank you very much, Mr. Chairman and members of the Committee.

Mr. OBEY. You bet.

[The following questions were submitted to be answered for the record:]

YOUTH UNEMPLOYMENT

Mr. Obey: The unemployment rate for youth (ages 16 – 19) is 25 percent—a slight reduction from a few months ago but still, as you say, unacceptably high. This is particularly troubling because studies have shown that persistent unemployment at the beginning of a worker's career results in lower earnings throughout their lifetime. Workers simply do not catch up. What would your proposed *Workforce Innovation Fund* do to address this situation?

Ms. Solis: The proposed Youth Innovation Fund, which is part of the Workforce Innovation Partnership, will assist in addressing the issue of youth unemployment. Research suggests paid work experience may improve educational and employment outcomes for at-risk youth.

Two core components of the Youth Innovation Fund are paid work experience for youth, which will enable youth to gain world-of-work experience, and workplace skills that are necessary to succeed in the labor market. These paid work experiences are particularly critical in the current economy where the youth unemployment rate is so high.

The Youth Innovation Fund will support and evaluate innovative models for delivering summer and year-round employment opportunities and comprehensive services to at-risk youth. Thirty percent of the Youth Innovation Fund will be reserved for summer jobs programs, while the remainder will focus on comprehensive programs that include work experience as a core component Research suggests paid work experience may improve educational and employment outcomes for at-risk youth.

WIA CARRY-IN

Mr. Obey: According to data provided by the Labor Department, States came into program year 2009 with a combined $983 million in unspent WIA formula funds. Can you account for the size of the WIA carry-in balance and explain to this subcommittee the purpose of reserving WIA funds beyond a single program year?

Ms. Solis: As you know, the Workforce Investment Act authorizes States and local areas to expend their grant funds over three years, so it is to be expected that there would regularly be unspent carry-over balances in this program. There are several factors that influence the balance of unspent WIA formula funds that are carried into each program year. Before discussing these factors and other reasons why states may reserve funds, it is important to emphasize that the data reflect total expenditures, not total obligations which is a more immediate indicator of spending patterns. Since expenditures lag behind obligations, the amount of formula funds carried in that is actually available for services tends to appear larger than it actually is - in reality most funds have already been obligated by the State or local area.

The system provides training for jobseekers that spans more than a single Program Year -- at the point in time when carryover is determined (June 30 of each program year), many workers are

midway through training, which appears as "carryover" even those funds are already legally obligated. WIA provides its workforce boards with multiple years to spend formula funds, allowing for long-term planning to meet the training needs of their states and local economies.

Additional factors that may influence carry-in balances include:

- **Use of performance-based contracts:** States may provide job training using performance-based contracts. This approach requires holding back a portion of the payment until outcomes, such as graduation or job placement, are reported and performance goals are reached. This approach is a responsible practice but delays the reporting of expenditures.
- **Length of training:** States that focus on longer training courses rather than short courses would likely show slower expenditures and higher carry-in balances.
- **One-Stop payrolls:** States and local areas obligate the funding needed to meet payroll needs and keep local offices running. However, these funds are paid out on a week-by-week basis and may contribute to higher reports of carry-in balances.
- **Reserving Funds for Emergency Use:** Given the state of our recovering economy, normal fluctuations in WIA funding levels, and the difficulty with predicting where and when large-scale lay-offs will occur, states may have held back funds in anticipation of future layoffs and plant closures.
- **Prioritized use of American Recovery and Reinvestment Act of 2009 (Recovery Act) Funds**: During the past year, states may have prioritized the use of Recovery Act funding over regular formula funds which would also contribute to unusually high carry-over funds from the regular appropriation and lower expenditure rates.

The Government Accountability Office (GAO), in its own study on WIA expenditures (GAO-07-1051T, page 13), reported "states are spending their WIA funds within the authorized 3-year period." The same report also noted, "nationwide, states spend over 66 percent of their program allocation in the first year."

COMMUNITY SERVICE JOBS FOR OLDER AMERICANS

Mr. Obey: The recession has created record levels of unemployment among older Americans. In response, Congress has increased the funding for the Senior Community Service Employment Program (SCSEP)—in both the Recovery Act and the FY 2010 bill—in order to increase the number of community service jobs for low-income adults age 55 and over. Using Recovery Act funds, SCSEP grantees so far have provided nearly 20,000 unemployed older adults with jobs through December 31, 2009, in addition to employing nearly 100,000 older workers already in the program with FY 2009 funds.

The Labor Department deserves credit for awarding these additional funds in a timely manner so that unemployed individuals and communities could benefit. But can you explain why the nearly 20,000 SCSEP participants are not included in the official jobs count for the Recovery Act?

Ms. Solis: The Congress exercised considerable foresight appropriating funds to assist older Americans, a group that was heavily impacted by the recession. The SCSEP program provides

senior workers with part-time, community-service employment opportunities. These subsidized employment opportunities serve as means for SCSEP participants to give back their communities, while developing the skills and abilities needed to join or reenter the workforce and obtain unsubsidized employment outside the program. Therefore, the subsidized employment opportunities provided by SCSEP are not counted as jobs created. A more detailed description about how ETA calculates jobs created under the Recovery Act can be found in the August 14, 2009 Training and Employment Guidance Letter #01-09 which is available at http://wdr.doleta.gov/directives/attach/TEGL/TEGL01-09.pdf.

BACKLOG OF APPEAL CASES

Mr. Obey: In 2005 and 2006, there was a series of tragic mine accidents—including the horrible disaster at the Sago mine in nearby West Virginia. As a result, Congress passed the MINER Act to strengthen enforcement of safety standards and modernize our emergency response system—so that we could avoid similarly tragic mine accidents in the future. MSHA also established larger penalties for safety violations and included a process for shutting down flagrant offenders that failed to redress serious repeat violations.

Unfortunately, instead of working with MSHA to improve safety standards in their mines, mine operators have chosen to file appeals against 67 percent of all penalty dollars—up from 24 percent a few years ago. Some mines are appealing more than 90 percent of their penalty assessments in a brazen attempt to avoid severe sanctions that could result from repeat violations. This steep increase in appeals has lead to a serious backlog of appeal cases at the Federal Mine Safety and Health Review Commission (Review Commission). At its current capacity, the Review Commission is able to clear about 5,000 – 7,000 cases per year but new cases are coming in at the rate of more than 9,000 per year. The backlog has reached 16,000 cases and is continuing to grow.

Madame Secretary, what is the Labor Department doing to eliminate this growing backlog of appeals? And how can Congress help to reduce the backlog so the MINER Act fulfills its intended purpose of improving mine safety?

Ms. Solis: We will take several approaches to reduce the contested case backlog. Mine operators, with the assistance of miners, have the primary responsibility to prevent the existence of unsafe and unhealthy conditions in the nation's mines, and the best way to reduce the backlog is to have safer mines. Simply put, hazards which are identified and fixed before the inspector gets there will result in fewer citations. One of the ways MSHA could encourage mine operators to proactively find and fix safety problems would be to require health and safety management programs. Opportunities also exist at the time of a mine inspection to resolve disputes about violations, and we will encourage this approach. To further reduce the number of citations that are contested, MSHA will work with the Office of the Solicitor to implement reforms to resolve disputes about the merits of citations during the conference process prior to cases being filed with the Federal Mine Safety and Health Review Commission. Finally, some operators who appear to be developing a pattern of significant and substantial safety violations may be contesting citations to delay enforcement. We will work with the Office of the Solicitor to ask

the Review Commission to expedite appropriate cases so that problem operators cannot delay the process for establishing a pattern of violations simply by contesting cases.

FARM WORKER REGULATIONS

Mr. Kennedy: Farm workers and their families have long been forced to contend with a confusing regulatory structure and fragmented enforcement regimes because of their exclusion from the National Labor Relations Act and differing standards for workplace safety, hourly wages and family leave. In an effort to address this issue, I authored a letter to the Department of Labor and was joined by 23 of my colleagues in support of farm workers nationwide. Also, the Committee authored language in the 2010 Department of Labor appropriations bill urging the Department to pursue special coordination for farm workers and their families. Could you please provide the Committee with an update on your recent efforts to better coordinate farm worker regulations in response to this language?

Ms. Solis: The needs and welfare of U.S. farm workers and their families are a priority for the Department and this Administration. We are fully committed to improving the effectiveness and coordination of services to farm workers and their families, and the strong enforcement of statutes that provide protections to these workers. Ensuring strong and effective worker protections for this vulnerable workforce is an essential part of my vision of Good Jobs for Everyone.

We have taken a number of steps over the past year to demonstrate this commitment through increased efforts to improve conditions for farm workers and their families. Examples of these actions include:

- On February 12, 2010, the Department published in the Federal Register new final regulations that significantly strengthen worker protections and enforcement under the H-2A agricultural labor certification program. The Department's Wage and Hour Division (WHD), the Office of the Assistant Secretary for Policy (OASP), the Office of the Solicitor (SOL), and the Employment and Training Administration (ETA) worked closely on the development of the new regulation and continue to closely coordinate on its implementation. ETA and WHD are conducting extensive joint outreach to state workforce agencies, employers, workers and their advocates to ensure a smooth transition to the new regulatory framework and will continue to work closely to ensure that the regulation achieves its objectives. Other federal partners were regularly apprised of the progress and will continue to be important allies in the implementation of this regulation.
- The Department's FY 2011 budget request includes the first request for a funding increase over the prior year's appropriation in over 20 years for the Migrant and Seasonal Farm Worker program. The increase will restore funding to the levels originally envisioned by the Workforce Investment Act while supporting services for 1,027 additional migrant and seasonal farm workers bringing the total served in the program year to 18,860. The program extends training and other workforce development services to eligible migrant and seasonal farm workers and their families through the public workforce system's One-Stops, enabling them to gain access to education and career

pathways, particularly jobs that provide stable, year-round employment both within and outside agriculture.

- I am very concerned about children who work in agriculture, as they are among the most vulnerable of the country's workers. The Department is working hard to crack down on violations of the child labor provisions of the Fair Labor Standards Act (FLSA) and other important laws. WHD is focusing on youth employment in agriculture through a variety of strategies. Every agricultural enforcement initiative WHD conducts will include a child labor component. Investigators will be trained and expected to not only look for child labor violations but to identify all youth employed in the fields. While using its enforcement tools, WHD is also continuing outreach efforts to ensure important compliance and occupational safety and health information reaches farmers, farm labor contractors, parents, teachers, those who provide services to farm workers, and other federal agencies.
- Additionally, WHD enforces, under its own authority and under the 1997 transfer of the Occupational Safety and Health Administration's (OSHA) authority, temporary labor camp and field sanitation standards which are directed to the protection of migrant and seasonal farm workers. Fourteen states that operate OSHA-approved and funded state plans continue to enforce these standards as well, and in several cases have adopted more stringent occupational safety and health standards for the protection of these workers. In particular, California OSHA has an extensive program to enforce its Heat Illness Prevention standard in the fields.

These actions are a sample of the actions taken by the Department that demonstrate our commitment to providing fair wages and strong labor protections for this vulnerable group of workers and their families. At my direction, our agencies are working closely with one another to advance this goal in as comprehensive and effective manner as possible and ensure that good jobs for everyone includes farm workers and their families.

WORKER MISCLASSIFIACTION

Mr. Kennedy: I commend the Administration for taking action to combat the growing problem of worker misclassification. This abusive practice creates a significant loss of tax revenues to both federal and state governments by giving tax cheats an unfair advantage in the marketplace. Furthermore, misclassification prevents workers from getting critical workplace protections and from getting benefits they deserve. I look forward to working with you to implement these efforts and am interested in their timeframe. How soon does the Department of Labor expect to have this initiative fully functional?

Ms. Solis: Should the Congress provide the requested funds the different elements that are a part of the initiative will be implemented at various points over the next year. The Department's budget request for FY 2011 includes $25 million for the Department of Labor, including $12 million for increased enforcement of wage and overtime laws in cases where employees have been misclassified; these funds will allow us to hire more investigators and provide better training on how to determine who is an employee and who is an independent contractor. Even though these funds will not be available until FY 2011, we are already planning how best to

target enforcement to identify and remedy widespread misclassification and we are emphasizing this issue in our current, FY 2010 enforcement strategy. We have also established a working group, headed by the Wage and Hour Division Deputy Administrator, which includes members from a number of Departmental agencies, including OSHA and ETA. The working group is exploring ways for all DOL agencies to provide better guidance to both workers and employers and increase information sharing between Department agencies. Over the next few months, the working group plans to bring in a diverse array of stakeholders, including unions, worker advocates, and employer groups, to get their input on misclassification and what steps we should take. We are also planning to meet with representatives from state misclassification task forces to learn from their experiences. The working group is also working with the Vice President's Middle Class Task Force and the Department of Treasury on a similar, government-wide effort to develop strategies to address misclassification.

An additional $10,950,000 is requested for the Employment and Training Administration for two initiatives focused on increasing the capacity to address misclassification within the Federal/state administered Unemployment Insurance program. The first initiative provides states the opportunity to compete for grants to increase their capacity to participate in data sharing activities with the IRS and other Federal and state agencies; to implement targeted audit strategies; establish a cross-state agency task force to target egregious employer schemes to avoid taxation through misclassification, and to develop education and outreach programs. The second initiative would pilot a high performance award program designed to encourage states to improve misclassification efforts. States that are most successful (or most improved) at detecting and prosecuting employers that fail to pay their fair share of taxes due to misclassification and other illegal tax schemes will be rewarded.

STATE PAID LEAVE FUND

Mr. Tiahrt: The budget requests $50 million for a new "State Paid Leave Fund". The justification behind this request says that nearly 40% of private-sector workers do not have paid sick leave. But, according to the Bureau of Labor Statistics, 73% percent of full-time workers have paid sick leave, 91% have paid vacation, and 89% have paid holidays. Furthermore, 80% of part-time workers do so voluntarily. California, Washington, and New Jersey have existing paid leave programs. Why is it the Federal government's responsibility to spend $50 million for states to do something that's already being done in other states?

Ms. Solis: Data from the Department of Labor's Bureau of Labor Statistics (http://www.bls.gov/news.release/pdf/ebs2.pdf) shows that 61 percent of all private sector workers have paid sick leave. Because nearly 40 percent of private-sector workers do not earn paid sick leave to care for themselves, and even fewer have leave available to care for another family member when they are ill, millions of workers risk losing pay and or their jobs when they are sick or their children are sick. In spite of the guidance from the Centers for Disease Control and Prevention (CDC), which recommends that if individuals have a fever and are sick or their children are sick they should not go to work, many workers have no choice but to go to work. This presents a major public health concern and some studies suggest that it costs U.S. businesses billions of dollars annually. In addition, changes in family circumstances - whether

it's the birth of a new child or the serious illness of an older relative - put greater stress on the economic security of families than ever before. Today, nearly two-thirds of mothers of young children work outside the home.

Under this new initiative, grants would assist states in planning and start-up activities relating to paid leave programs. The program would be voluntary and no state would be required to participate.

WORKER TRAINING AND EMPLOYMENT PROGRAMS

Mr. Tiahrt: If this request is approved, there will have been over $19 BILLION provided for Training and Employment Services since fiscal year 2008. Can you provide enrollment numbers for FY 2008 through your estimate for FY 2011?

Ms. Solis: The attached chart "People Served by ETA Training and Employment Services Program" provides enrollment information for Training and Employment Services program for FY 2008-2011. Your estimate of over $19 Billion in available funding appears to include appropriations under the ARRA, thus ARRA participant totals are included as part of the current (FY 2009) program year totals where appropriate.

People Served by ETA Training and Employment Services Programs

	PY 2008 Results	PY 2009 Q2 (4-Qtr. Summary)	FY 2010 Projections[1]	FY 2011 Projections[1]
Career Pathways Innovation Fund[2]	N/A	N/A	60,130	60,130
Community-Based Job Training Grants[3]	113,438	141,048	N/A	N/A
Green Jobs Innovation Fund	N/A	N/A	6,640	14,110
High Growth and Emerging Industries grants--ARRA funded[4]	N/A	N/A	195,000	N/A
Job Training in High Growth Industries[3]	80,760	90,469	19,593	19,593
Indian and Native American (adult and youth programs)	16,496	33,716	25,000	26,196
National Farmworker Jobs Program	18,477	20,371	17,833	18,860
Reintegration of Ex-Offenders (adult and youth programs)	9,844	13,807	24,725	23,355
WIA Adult[5]	4,921,774	5,597,700	5,171,158	5,443,323
WIA Dislocated Workers[5]	666,313	864,237	647,106	675,640
National Emergency Grants[6]	61,355	52,611	N/A	N/A
National Emergency Grants--ARRA funded[7]	N/A	8,644	N/A	N/A
WIA Youth	275,243	307,214	282,426	266,274
WIA Youth--ARRA funded[7]	N/A	363,460	N/A	N/A
YouthBuild[8]	6,618	11,309	7,890	7,450
TOTAL	**6,017,666**	**7,499,594**	**6,457,501**	**6,554,931**

Sources: PY 2008 results are from WIA State Annual Report data; all other data is cumulative data from grantee quarterly reports for the final quarter of the program year. PY 2009 Quarterly data are summary data from most recent 4 quarters of data or program-to-date data. Projections are taken from the Congressional Justification of Appropriation Estimates for FY 2011.

[1]Projections for participants served are derived using the FY appropriation amount relative to the cost per participant specific to each program. These projections include only participants funded with regular resources.

[2]Career Pathways Innovation Fund is in budget request, as successor to Community-Based Job Training Grants.

[3]Participant counts are cumulative since inception of grants.

[4]These grants are funded with monies from the ARRA; estimates included in FY 2010 are the total number of participants to be served through the life of the grants.

[5]PY 2009 outcomes for these programs include some ARRA-funded participants; however, they are not reported separately.

[6]States report on NEG participants separately from the WIA Dislocated Worker formula program; however, projections for NEGs are included in the overall WIA Dislocated Worker Training and Employment Activities section.

[7]States report separately on participants in ARRA-funded WIA Youth, National Emergency Grants, and YouthBuild projects. Participant counts are program-to-date through 12/31/2009.

[8]YouthBuild PY 2009 participant numbers include participants served by ARRA-funded YouthBuild projects.

WIA FUNDING STREAMS

Mr. Tiahrt: What other funding streams exist on the mandatory side of the ledger that compliments the Department's Workforce Investment Act and Employment Service programs? Please itemize and list the amounts provided for each fiscal year since 2008.

Ms. Solis: There are two mandatory accounts that complement the Department's Workforce Investment Act and Employment Service Programs: (1) Federal Unemployment Benefits and Allowances (FUBA) for Trade Adjustment Assistance (TAA), which offers trade eligible dislocated workers training, weekly income, out-of-area job search and relocation allowances, and assistance with health insurance courage; and (2) High Growth Training Grants, which are competitively awarded, using H-1B visa application fee revenues, to train U.S. individuals for occupations for which visas are now used.

The funding provided is as follows:

FUBA – Trade Adjustment Assistance
FY 2008 – $929,700,000
FY 2009 – $958,800,000
FY 2010 - $1,818,400,000
FY 2011 - $1,938,200,000

High Growth Training Grants
FY 2008 - $130,597,000
FY 2009 - $111,000,000
FY 2010 - $120,000,000
FY 2011 - $125,000,000

CHANGE TO 300 LOGS

Mr. Tiahrt: OSHA is proposing to add a column to the 300 logs to track MSD injuries. What is the purpose of this rulemaking, and is it the Administration's intention to issue an ergonomics regulation as a result?

Ms. Solis: There are no broader regulatory plans involving ergonomics at this time, other than to use the general duty clause when appropriate for enforcement and to issue a final rule in FY 2010 revising the Occupational Safety and Health Administration's (OSHA) recordkeeping form to include a separate column on musculoskeletal disorders (MSD). Adding this column will improve the workplace injury and illness data published by the Bureau of Labor Statistics (BLS). Having more complete and accurate data will further our understanding of work-related MSDs. The proposed rule would require employers that are subject to the recordkeeping requirements to mark a new, separate MSD column, instead of choosing between one of the existing available columns, which are less well defined for the purpose of accurately recording MSDs.

The MSD column will provide a simple, transparent, easily accessible, and consistent reference for employers and workers to identify whether there are MSD problems in their workplaces.

The requirement to record cases in an MSD column will affect approximately 1.5 million (19%) of the nation's 8 million employers. Employers with 10 or fewer workers (more than 4.6 million employers) are exempt from requirements to record injuries and illnesses, including the proposed MSD column requirement. In addition, the proposed rule would not apply to employers in certain low hazard industries.

Currently, BLS publishes data on MSDs using the OSHA Form (301), which is only for cases that result in days away from work. Because there currently is no MSD column on the OSHA Form (300) log, OSHA and State officials must do a line-by-line analysis to tabulate cases. The proposal will allow BLS to publish statistics on all MSDs, by industry, for the Nation and for states that participate in the survey. The statistics also will be useful for conducting further analysis and evaluation of MSDs, and for safety and health research.

CREATING FEDERAL GOVERNMENT JOBS AT THE EXPENSE OF THE PRIVATE SECTOR

Mr. Tiahrt: Madame Secretary, the national average annual income in 2009 was approximately $45,000. Admittedly rough estimates suggest the average Federal government compensation (salary and benefits) to be around $100,000. How many private sector jobs would it require to raise enough tax revenue to support each new FTE?

Ms. Solis: Income and compensation have very different definitions, and to compare them would be misleading. The reference to $45,000 average income is approximately correct: According to the Bureau of Labor Statistics' (BLS) Quarterly Census of Employment and Wages (QCEW), the average annual wage earnings of non-Federal workers (private and state/local) for 2008 was $45,129. However, your comparison figure is described as "compensation (salary and benefits)" which is a broader concept. The appropriate comparison to the $45,000 figure mentioned in the question is to wage earnings of federal employees, which averaged $66,293 according to the 2008 QCEW report from BLS.

The understanding that Federal investment in facilities and jobs spurs economic growth and private investment is seen in the enthusiastic reaction of local civic and business leaders to an announcement of a new military base or other Federal facility in their community. They welcome it as a spur to job creation and economic development throughout the community.

Federal jobs can be a spur to private job creation, an effect that is particularly important in times of recession when private demand is falling. New Federal jobs result in expanded consumption demand as Federal employees spend their pay checks in their local communities. The economic multiplier effect of new Federal pay checks results in increased sales by private merchants, builders, service providers and manufacturers and translates into job growth and increased earnings in the private sector that ultimately echoes back through the economy in terms of increased Federal, State and local tax revenues.

I would disagree with the premise of this question ("Federal Government Jobs at the Expense of the Private Sector") that Federal employees' compensation represents a deadweight loss to the economy. Federal employees make valuable contributions to public safety, health, security and welfare that provide net benefits to taxpayers that exceed the taxes paid for their compensation. In some cases the productivity of Federal employees is directly measurable in terms of fees and other revenues that their work directly generates.

- An example is an Occupational Safety and Health Administration (OSHA) inspector whose work saves lives and prevents costly injuries.
- While more difficult to measure, no less real is the benefit that all Americans receive from the hard work and sacrifice of our armed forces whose efforts to protect our safety and freedom so clearly exceed the value of their compensation.

As context, it is important to note that Federal employment at 2.8 million in February, 2010, represented only 2.3 percent of the 131.3 million total payroll jobs.

The premise of the question is inaccurate in its implication that Federal workers' salaries and compensation are only derived from taxes on the earnings of private sector workers.

- Private workers are not the only payers of personal income taxes: State, local, and Federal employees also pay income taxes.
- Personal income taxes are only one of the many streams of Federal tax receipts and other revenues that support the Federal budget. In 2009, personal income taxes accounted for only 26 percent of Federal outlays. And, Federal employee compensation is paid in part from all of the sources of federal revenue, including corporate income taxes, excise taxes, estate taxes, fines, fees and rents.

THURSDAY, MARCH 18, 2010.

FY2011 BUDGET OVERVIEW: DEPARTMENT OF EDUCATION

WITNESS

HON. ARNE DUNCAN, SECRETARY OF EDUCATION

CHAIRMAN'S OPENING REMARKS

Mr. OBEY. Good morning, everybody.

Today we are pleased to have the Secretary of Education, Arne Duncan, to testify.

Mr. Secretary, don't interpret the lack of Democratic members here as a lack of interest. We are having a Democratic Caucus on a new-fangled idea that we have been rushing at breakneck speed through Congress over the past year, so people are still having some last-minute thoughts on that, and that is where they are this morning. I assume they will be by shortly.

But we are here today, of course, to discuss the fiscal 2011 budget. Let me say, Mr. Secretary, that I know you and I share the same goal of seeing every kid in this country having access to a school that can provide them with a top-notch education and produce a good strong skill set. In addition, I know that we both agree that the funds we provided for education last year in the Recovery Act were absolutely imperative and have been essential in keeping our schools from drowning.

I am not so sure we are on the same page when it comes to immediate needs and priorities about how to proceed from here. The work of the Education Department is more critical than ever. Today we face record high unemployment nationwide, while State school districts and colleges are in economic crisis. Educational opportunity, at all levels, is our most powerful tool in helping the poor and the middle-class climb up the economic ladder.

AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009

The underutilization of our human potential in the United States imposes heavy consequences on our society: lower productivity, lower earnings, poorer health, higher rates of incarceration and less civic involvement. That is why I was pleased to participate in the efforts to provide an unprecedented $98 billion investment in education in the Recovery Act which, among other things, was responsible for creating more than 300,000 education jobs. But we need to do more, in my judgment.

According to the Center on Budget and Policy Priorities, State budget gaps will total $180 billion in fiscal 2011 and $120 billion in 2012. The consequences of that for our education system are staggering, and the numbers are daunting. Twenty-nine States and

the District of Columbia have cut K–12 services, even with the Recovery Act funds. In California, though I am always reluctant to cite that State because of their wacky budget process, aid to local school districts has been reduced by billions of dollars. Cuts to early childhood funding in Illinois will leave 10,000 children ineligible for services. Mississippi cut its fiscal 2010 K–12 funding by nearly 5 percent. In New Jersey, more than 11,000 students will likely lose access to after-school programs. And the list can go on and on.

In light of all of this, in my judgment, we need to do more to help States and school districts weather this financial crisis, and I hope that the Administration will put the full weight of its efforts behind efforts to do so. We also should make sure that any emergency financial assistance is broadly distributed and available for purposes like avoiding teacher layoffs and keeping the lights on.

SCHOOL REFORM

I know you and the President are very focused on using Federal aid to promote certain types of school reform. I am certainly in favor of improving our schools. I voted for No Child Left Behind, though I had huge misgivings about the details, because I felt, as I said yesterday, that it was the President's first initiative out of the box and he deserved the benefit of the doubt and because I wanted to see reform. I get just as tired as anybody else of seeing non-performing schools and dull teachers.

But, nonetheless, we can be for improving schools, but it seems to me that right now our most immediate problem is that school districts are drowning in red ink. As I said yesterday, I like to sail, but when the sailboat is sinking, my top priority would not be to put a new coat of varnish on the deck. I would want to protect the hull first.

FY 2011 BUDGET REQUEST FOR EDUCATION

Secondly, in the interest of brevity, let me skip that and simply say, on your 2011 Budget, that request includes over $3.5 billion for new and untested initiatives, for which you will control how the funding is allocated to State school districts and other providers. In times like this, we need to worry about our core foundational programs, which go out by formula and are widely shared across the Nation. A school district's ability to attract funds should not depend upon its capacity to write a grant application.

ELEMENTARY AND SECONDARY BUDGET REQUEST

I want to support this Administration in your education priorities, but not at the expense of reliable and predictable Federal support that thousands of districts across the country rely upon.

Perhaps most troubling is the lack of any increase at all in Title I funds, which are broadly distributed by formula to all school districts in need. At the same time, the budget includes an extra $500 million to expand the Innovation Fund, which makes grants through competitions run by your Department. Similarly, it seeks to more than double the appropriation for Teacher Incentive Funds,

even though your Department has yet to complete any rigorous evaluation of this 5-year-old program.

Overall, in the Administration's budget, funding for ESEA, funding for formula grants go down by almost $700 million, while narrowly targeted competitive grant programs increase by $3 billion. It seems to me that is not the correct balance, particularly during these hard economic times when most school districts need immediate help.

HIGHER EDUCATION BUDGET

I also want to express reservations about your higher education budget. I believe that a more educated citizenry is vitally important to our economy, especially in our changing economy. But we need to make sure that a student's brain, not their bank account, is the only determinant on whether they can get a college degree.

Would you put that chart up, please?

We put this chart up earlier this week, and I want to emphasize it again. What the chart demonstrates is that a student who in the 8th grade was in the top 20 percent of performers in mathematics had a 29 percent chance of graduating from college if they come from a poor family and a 75 percent chance of graduating from college if they come from a rich one. That, in my view, is an indictment of our indifference to the needs of children who are stuck in low-income families and stuck in poverty-related schools. And it seems to me our number one priority needs to be to redress that imbalance.

PELL GRANTS

I would also say that a key tool to increasing access to higher education for students of modest means is the Pell Grant. These grants currently help over 8 million students get the college or technical education they need to qualify for a decent job. Over the past 5 years, this Congress has worked to increase the maximum Pell Grant award by $1,500. We are facing a real challenge in continuing that policy.

The cost of maintaining Pell Grants at that level is rising. You have large numbers of students going back to school because they recognize the tightness of the job market, and they are trying to upgrade their skills. Unfortunately, as we look for a solution to Pell funding, the administration's budget leaves me somewhat confused. It proposes to somehow move Pell Grants over to the entitlement side of the budget. I have no idea how well that is going to be received by the Congress. But we understand that if enacted, the Higher Education Reconciliation Act would provide a portion of the shortfall that we are facing today.

But even counting that funding, it still leaves a substantial shortfall, and we need the Administration's help in finding a solution. It is not just good enough to ask us for the money, without suggesting how it is going to be paid for. So, I hope you can explore those issues over the next couple of hours, Mr. Secretary.

RANKING MEMBERS OPENING REMARKS

Mr. Tiahrt, I would invite you to make whatever comments you think are appropriate.

Mr. TIAHRT. Thank you, Mr. Chairman.

I want to begin by thanking Secretary Duncan and Mr. Skelly for showing up today before the committee.

Welcome to the committee.

EDUCATION SPENDING AND BUDGET DEFICIT

We all know that education is critical, and I think we can all agree it is very important that we give the tools to every child to achieve their view of the American dream as well as equipping our economy for the skilled workforce needed to keep us competitive in a global economy.

To do this, we need a world-class education system that puts the needs of students, parents and teachers first, while partnering with our local schools. I know there are differences on how we intend to accomplish this, particularly when the Federal Government would continue hemorrhaging red ink under the President's budget as far as the eye can see.

The deficit this year under the President's budget will reach $1.5 trillion and never dips below $700 billion over the next decade, while our national debt would nearly double, despite an economy that is projected to have recovered and the war in Iraq ended. Beyond the next 10 years, the current path is unsustainable, as spending on the big three entitlement programs will continue to consume all of the available resources under current law.

So as we look at the Department's budget request, tough choices will have to be made. We are putting the burden of today's spending on the kids who will be working tomorrow. So we have a trade-off: a good education system with frills that the students have to pay off in the future, or a system that meets the needs to give them the tools so they can achieve their dreams without the frills.

While I have questions and concerns about many of the specifics in the Department's budget proposal, I look forward to the opportunity to continue discussing with the Secretary and the members of this subcommittee how we can responsibly invest in educational excellence, both today and going forward.

Thank you, Mr. Chairman.

Mr. OBEY. Thank you.

Mr. Secretary, please proceed. Why don't you take 5 or 10 minutes to summarize your statement. And we will put the full statement in the record.

SECRETARY ARNE DUNCAN'S OPENING STATEMENT

Secretary DUNCAN. I will be brief. Thank you so much, Chairman Obey and Ranking Member Tiahrt, for the opportunity to appear before the entire committee today.

I want to begin by thanking you for what you have done to keep America's teachers in the classroom and to keep America's children learning. The Recovery Act saved nearly 325,000 education-related jobs and another 75,000 non-education jobs at the State level, and that is just through our Department. This funding not only helped

stabilize the economy and avoid a depression, but it absolutely averted an educational catastrophe.

And, Chairman Obey, I want to personally thank you for all your leadership in making that happen.

All told, we have obligated over $70 billion from the Recovery Act. We have $25 billion left, most of which will be out the door over the next few months. That money will help States balance budgets, help young people pay for college, and help drive the change we need in our classrooms to prepare our children for the jobs of the future.

DEPARTMENT OF EDUCATION FY 2011 BUDGET REQUEST

Let me turn to our proposed 2011 education budget. As you know, while most Federal spending is frozen, President Obama is proposing an historic increase in education funding. He understands that education is the key to our economic security, and even in these challenging times, he remains deeply committed to this issue.

DISCRETIONARY FUNDING REQUEST

The President is requesting a 7.5 percent increase in discretionary spending, from $46.2 billion to $49.7 billion. It supports our cradle-to-career agenda, from preschool through college. Our K–12 budget is focused on six areas, all of them about supporting students and teachers.

COLLEGE AND CAREER READINESS

"College and Career Ready Students" is our new proposed name for the Title I formula grant program, which we continue to fund at historic levels. The Title I program will also receive substantial Recovery Act dollars next year.

We also propose more funding for School Turnarounds, from $546 million to $900 million, so we can continue to focus on the lowest-performing 5 percent of each State's schools.

PROMOTING WELL-ROUNDED EDUCATION

Second, because students need a well-rounded education, we propose a $100 million increase for learning programs beyond tested subjects like reading, writing, math and science, that is, for programs such as technology, the arts, foreign languages, history and other subjects. All told, we will request more than $1 billion next year to promote a well-rounded education.

ENSURING PROPER LEARNING ENVIRONMENTS

Third, student supports are needed to ensure a proper learning environment. Our budget proposes a $245 million increase over 2010 for a total of $1.8 billion to improve school climate, student health, student safety, parental engagement and community involvement. This includes continued support for the 21st Century Community Learning Centers program. We also want to work with the Congress to refine this program so that it lifts student outcomes and incorporates enrichment activities through community partnerships.

PROMISE NEIGHBORHOODS

We are also proposing a major investment in a new program modeled on the Harlem Children's Zone. It is called Promise Neighborhoods, and it seeks to transform whole communities with schools as neighborhood anchors. It provides wrap-around social services from birth through college for students and families at risk.

RESOURCES FOR DIVERSE LEARNERS

The fourth area of reform we are calling Diverse Learners. This includes students with disabilities who will benefit from a requested $250 million boost to the IDEA formula grant program. Like Title I, substantial IDEA Recovery Act dollars will continue to be available this year.

Other diverse learning populations include English-language learners, which will get a $50 million boost under our proposal, and we are maintaining dedicated funding for migrant students, homeless students, rural students and Native American students.

EFFECTIVE TEACHERS AND SCHOOL LEADERS

The fifth area of reform is called Teachers and Leaders. No one is more essential to educational success than the person in front of the class and the person who is running that school building. This proposed budget seeks $3.9 billion, a $350 million increase, to elevate the teaching profession and get effective teachers and leaders into the schools that need them the most.

We are also requesting a large investment in teacher and principal leadership programs so States and districts can recruit and train the very best people possible.

We further support both traditional and nontraditional pathways into teaching so people from all walks of life can bring their experience and knowledge into the classroom. And our budget invests in programs to reward educators for raising achievement and working in hard-to-staff schools and subjects.

COMPREHENSIVE CHANGE NEEDED

The final area falls under the category of innovation. We are proposing almost $2.5 billion to increase high-quality charter and magnet schools and other autonomous public schools and to continue the Race to the Top and the Investing in Innovation programs. With so many children at risk of failure, America cannot accept the status quo. We have to be bold.

The facts are both startling and disturbing. Today, 27 percent of America's young people drop out of high school. That means 1.5 million teenagers are leaving our schools for the streets. And this is a national problem, urban, suburban and rural. Our 15-year-olds rank 24th out of 29 countries in math. In science, 15-year-olds rank 17th. And just 40 percent of young people earn a 2-year or 4-year college degree, and the U.S. now ranks 10th in the world in the rate of college completion. We used to lead the world. We have flatlined. Many other countries have passed us by.

We must embrace new approaches to learning and expand upon proven models of success. We must hold everyone accountable for results, and we must aim higher.

Our States recognize the problem, and that is why 48 of them are working together to raise standards, and 40 of them, along with Washington, D.C., have developed bold reform plans in their bid for Race to the Top funding. And everyone who applied is a winner. Those good, courageous, tough conversations are happening around the country, and we are seeing huge progress.

FY 2011 BUDGET AND ESEA REAUTHORIZATION

We are also seeing considerable bipartisan interest—both in the States and here in Congress—in our reauthorization proposal.

I would like to briefly touch on some of the key elements which are organized around three main goals: first, raising standards so the students truly graduate from high school ready for college or the world of work; second, rewarding excellence and growth; and, third, increasing local control and flexibility while maintaining the focus on equity and closing those stubborn achievement gaps.

We believe that States do not need a prescription for success. States and districts need a common definition of success. And we need a better system of accountability.

As you know, No Child Left Behind greatly expanded the Federal role in holding schools accountable. It required States, districts and schools to report test scores disaggregated by student subgroups, bringing much-needed transparency around achievement gaps. NCLB was right to create a system based on results for students, not just on inputs.

But there are far too many perverse incentives, and we must fix that. NCLB's accountability system actually encouraged States to lower standards. It doesn't measure growth or reward excellence. It prescribes the same one-size-fits-all interventions for schools with very different needs.

It also led to a narrowing of the curriculum and excessive focus on test preparation. And it labels too many schools as failing, regardless of the progress they are making.

Our proposal will use student academic growth and gain as the measure of whether schools, districts and States are making progress. It is a fairer, more honest and much more useful indicator. Most educators say they want to be evaluated on growth, not proficiency.

As I said before, our proposal supports a well-rounded education, not only by requesting more than $1 billion for the arts, science, history, languages and other subjects, but by allowing, not mandating, States to use these subjects in their accountability systems.

Under our plan, we will reward schools that are making the most progress, and we will be tough-minded with our lowest performing schools and schools with large achievement gaps that aren't closing. All other schools will be given flexibility to meet performance targets working under their State and local accountability systems.

SUPPORT FOR RURAL DISTRICTS COMPETING FOR FUNDS

Now, we understand there are concerns that small rural districts cannot compete with large urban districts for grants, so here is

what we will do: First, we will continue funding the Rural Education Achievement Program, also known as REAP. In our budget, it has not been consolidated with any other programs or funding streams.

Second, we will look at competitive priorities for rural districts where it makes sense and is needed, and we welcome that discussion with you. We recently did exactly that with the Investing in Innovation Fund, the $650 million I–3 fund.

Finally, we are also identifying foundations and nonprofit organizations to partner with rural districts. I have traveled to many rural areas in the past year and seen firsthand both the challenges they face as well as their capacity to address them. And I am confident that our Department can support rural school districts as they work to improve—and compete.

So those are some of the highlights. I encourage you and your staff to review the blueprint for reauthorization which is now available online.

PROGRAM CONSOLIDATIONS AND SAVINGS

I want to make one additional point about efficiency and our obligation to taxpayers. In our proposed 2011 budget, we list $340 million in savings by cutting ineffective programs and eliminating earmarks. We also consolidated 38 programs down to 11 funding streams to reduce red tape and paperwork for local educators, and they have been very appreciative of that.

The bottom line is that, between our budget and our blueprint, we have a coherent and comprehensive vision for education in the 21st century that builds on core values shared by Congress and by the Administration: high standards and better assessments, rewarding excellence with real incentives based on student growth, and a smarter, more limited Federal role that supports rather than directs State and local educators.

STATE OF EDUCATION BUDGETS NATIONWIDE

Let me just close by voicing my concern for education budgets around the country. Even with the remaining Recovery Act dollars, States are facing teacher layoffs, cutting school days and furloughing teachers to balance their budgets. For many States, that funding cliff arrives this July.

I want to thank the House for supporting an education jobs bill. I appreciate that there is growing concern that the Federal Government cannot continue funding States indefinitely. But America cannot neglect its obligation to children now. Somehow, we must find a way to continue to support our teachers and principals, parents and students, so that we emerge from this difficult economic period stronger and better prepared for tomorrow.

Thank you so much. I am happy to take your questions.

PREPARED STATEMENT OF SECRETARY DUNCAN

[The statement follows:]

DEPARTMENT OF EDUCATION

Statement by

Arne Duncan
Secretary of Education

on the

U.S. Department of Education Fiscal Year 2011 Budget Request

Mr. Chairman and Members of the Committee:

Thank you for this opportunity to testify on behalf of the President's 2011 budget request for education. I want to begin by thanking all of you for your commitment to our children's education. This Committee has played a critical role in helping the Department to accomplish an extraordinary amount of work over the past year, both to help America's education system weather the economic recession and to launch key initiatives to improve the quality of that system.

AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009

It was just over a year ago that Congress and President Obama worked together to complete the American Recovery and Reinvestment Act of 2009 (Recovery Act). This legislation is delivering nearly $100 billion to Recovery Act recipients, including States and school districts, to help address budget shortfalls in the midst of the most severe financial crisis and economic recession since the Great Depression. To date, the Department has awarded more than $69 billion. For the quarter ending December 31, 2009, recipients reported that assistance from the Department of Education funded approximately 400,000 jobs overall, including more than 300,000 education jobs, such as principals, teachers, librarians and counselors. These numbers are consistent with the data submitted in October, during the first round of reporting, and this consistency reflects the steady and significant impact of the Recovery Act. Although State and local education budgets remain strained, schools systems throughout the country would be facing much more severe situations were it not for the Recovery Act. The Recovery Act also increased Federal postsecondary student aid to help students and families pay for college.

I believe, however, that the Recovery Act did much more than just provide short-term financial assistance to States and school districts. Indeed, I think the Recovery Act will be seen as a watershed for American education because it also laid the groundwork for needed reforms that will help improve our education system and ensure America's prosperity for decades to come. Thanks to the Recovery Act, all States now are working to strengthen their standards and assessments, improve teacher and leader effectiveness, improve data systems and increase the use of data to improve instruction, and turn around low-performing schools.

In addition, the Recovery Act helped to jumpstart a new era of innovation and reform, particularly through the $4 billion Race to the Top program and the $650 million Investing in Innovation Fund. States already have demonstrated their interest in the reforms called for by the Recovery Act and Race to the Top. Just in preparation to apply for Race to the Top grants, States have made essential changes, such as allowing data systems to link the achievement of individual students to their teachers and enabling the growth or expansion of high-quality charter schools. States also are demonstrating the progress they have made toward implementing the reforms called for in the State Fiscal Stabilization Fund in their applications for Phase II of that funding. We must continue to invest in innovation and scale up what works to make dramatic improvements in education. The President's fiscal year 2011 budget requests $1.35 billion for Race to the Top awards, both for States and for a new school district-level competition, as well as $500 million in additional funding for the Investing in Innovation (i3) program.

The House also has passed the Student Aid and Fiscal Responsibility Act (SAFRA), which would make much-needed reforms to Federal postsecondary student aid programs that would enable us to make key investments in education by redirecting the tens of billions of dollars that otherwise would be spent on unnecessary subsidies to lenders over the next decade. These investments include expanding student aid though a more generous Pell Grant program and low-cost student loans, preparing students and workers for 21st Century jobs to increase our social well-being and economic prosperity, including through President Obama's American Graduation Initiative, and helping more low-income children enter school with the skills they need to succeed through the President's Early Learning Challenge Fund. SAFRA also includes important investments in Historically Black Colleges and Universities and minority-serving institutions. Our 2011 budget request strongly supports SAFRA, and we are working to win Senate approval for it as soon as possible.

PRESIDENT OBAMA'S 2011 BUDGET REQUEST

The centerpiece of the 2011 budget request for the Department of Education is the pending reauthorization of the Elementary and Secondary Education Act (ESEA). The President is asking for a discretionary increase of $3.5 billion for fiscal year 2011, of which $3 billion is dedicated to ESEA, the largest-ever requested increase for ESEA. Moreover, if together, we complete an ESEA reauthorization that is consistent with the President's plan, the Administration will submit a budget amendment for up to an additional $1 billion for ESEA programs. But, our budget and reauthorization are not simply about more resources - they also are about using resources more effectively. We would greatly appreciate your support for this historic budget.

The Department's budget and performance plan for 2011 also includes a limited number of high-priority performance goals that will be a particular focus over the next two years. These goals, which will help measure the success of the Department's cradle-to-career education strategy, reflect the importance of teaching and learning at all levels in the education system. The Department's goals include supporting reform of struggling

schools, improvements in the quality of teaching and learning, implementation of comprehensive statewide data systems, and simplifying student aid. These goals and key initiatives and other performance information are included in the President's Fiscal Year 2011 Budget materials and are on www.ed.gov.

FISCAL YEAR 2011 BUDGET REQUEST AND ESEA REAUTHORIZATION

Our 2011 budget request incorporates an outline of our key principles and proposals for ESEA reauthorization. We have thought a great deal about the appropriate Federal role in elementary and secondary education, and want to move from a simple focus on rules, compliance, and labeling of insufficient achievement, toward a focus on flexibility for States and local educational agencies (LEAs) that demonstrate how they will use program funds to achieve results, and on positive incentives and rewards for success. That is why, for example, our 2011 budget request includes $1.85 billion in new funding for the Race to the Top and Investing in Innovation (i3) programs. In addition, our reauthorization proposal for Title I, Part A of ESEA would reward schools or LEAs that are making significant progress in improving student outcomes and closing achievement gaps. Our budget and reauthorization proposals also would increase the role of competition in awarding ESEA funds to support a greater emphasis on programs that are achieving successful results.

We believe that our goals of providing greater incentives and rewards for success, increasing the role of competition in Federal education programs, supporting college- and career-readiness, turning around low-performing schools, and putting effective teachers in every classroom and effective leaders in every school require a restructuring of ESEA program authorities. For this reason, our budget and reauthorization proposals would consolidate 38 existing authorities into 11 new programs that give States, LEAs, and communities more choices in carrying out activities that focus on local needs, support promising practices, and improve outcomes for students, while maintaining Federal support for the most disadvantaged students, including dedicated formula grant programs for students who face unique challenges, such as English learners, homeless children, migrant students, and neglected and delinquent students.

COLLEGE- AND CAREER-READINESS

Another key priority is building on the Recovery Act's emphasis on stronger standards and high quality assessments aligned with those standards. We believe that a reauthorized Title I program, which our budget request would fund at $14.5 billion, should focus on graduating every student college- and career-ready. States would adopt standards that build toward college- and career-readiness, and implement high-quality assessments that are aligned with and capable of measuring individual student growth toward these standards. To support States in this effort, our request would provide $450 million, an increase of 10 percent increase, for a reauthorized Assessing Achievement program (currently State Assessments).

States would measure school and LEA performance on the basis of progress in getting all students, including groups of students who are members of minority groups, low-income, English learners, and students with disabilities, on track to college- and career-readiness, as well as closing achievement gaps and improving graduation rates for high schools. States would use this information to differentiate schools and LEAs and provide appropriate rewards and supports, including recognition and rewards for those showing progress and required interventions in the lowest-performing schools and LEAs. To help turn around the nation's lowest-performing schools, our budget would build on the $3 billion in school improvement grants provided in the Recovery Act by including $900 million for a School Turnaround Grants program (currently School Improvement Grants). This and other parts of our budget demonstrate the principle that it is not enough to identify which schools need help – we must encourage and support State and local efforts to provide that help.

EFFECTIVE TEACHERS AND SCHOOL LEADERS

We also believe that if we want to improve student outcomes, especially in high-poverty schools, nothing is more important than ensuring that there are effective teachers in every classroom and effective leaders in every school. Longstanding achievement gaps closely track the inequities in classrooms and schools attended by poor and minority students, and fragmented ESEA programs have failed to make significant progress to close this gap. Our reauthorization proposal will ask States and LEAs to set clear standards for effective teaching and to design evaluation systems that fairly and rigorously differentiate between teachers on the basis of effectiveness and that provide them with targeted supports to enable them to improve. We also will propose to restructure the many teacher and teacher-related authorities in the current ESEA to more effectively recruit, prepare, support, reward, and retain effective teachers and school leaders. Key budget proposals in this area include $950 million for a Teacher and Leader Innovation Fund, which would support bold incentives and compensation plans designed to get our best teachers and leaders into our most challenging schools, and $405 million for a Teacher and Leader Pathways program that would encourage and help to strengthen a variety of pathways, including alternative routes, to teaching and school leadership careers.

We also are asking for $1 billion for an Effective Teaching and Learning for a Complete Education authority that would make competitive awards focused on high-need districts to improve instruction in the areas of literacy, science, technology, engineering, mathematics, the arts, foreign languages, civics and government, history, geography, economics and financial literacy, and other subjects. Our request also includes $2.5 billion for an Effective Teachers and Leaders formula grant program to help States and LEAs improve teaching and enhance the teaching profession.

In addition, throughout our budget, we have included incentives for States and LEAs to use technology to improve effectiveness, efficiency, access, supports, and engagement across the curriculum. In combination with the other reforms supported by the budget, these efforts will pave the way to the future of teaching and learning.

IMPROVING STEM OUTCOMES

One area that receives special attention in both our 2011 budget request and our reauthorization plan is improving instruction and student outcomes in science, technology, engineering, and mathematics (STEM). The world our youth will inherit increasingly will be influenced by science and technology, and it is our obligation to prepare them for that world.

The 2011 request includes several activities that support this agenda and connect with President Obama's "Educate to Innovate" campaign, which is aimed at fostering public-private partnerships in support of STEM. Our goal is to move American students from the middle of the pack to the top of the world in STEM achievement over the next decade, by focusing on (1) enhancing the ability of teachers to deliver rigorous STEM content and providing the supports they need to deliver that instruction; (2) increasing STEM literacy so that all students can master challenging content and think critically in STEM fields; and (3) expanding STEM education and career opportunities for underrepresented groups, including women and girls and individuals with disabilities.

Specifically, we are asking for $300 million to improve the teaching and learning of STEM subjects through the Effective Teaching and Learning: STEM program; $150 million for STEM projects under the $500 million request for the i3 program; and $25 million for a STEM initiative in the Fund for the Improvement of Postsecondary Education to identify and validate more effective approaches for attracting and retaining, engaging and effectively teaching undergraduates in STEM fields. And, I have directed the Department to work closely with other federal agencies, including the National Science Foundation, the Department of Defense, the National Aeronautics and Space Administration, and the National Institutes of Health to align our efforts toward our common goal of supporting students in STEM fields.

COMPREHENSIVE SOLUTIONS

We also recognize that schools, parents, and students will benefit from investments in other areas that can help to improve student outcomes. Toward that end, we are proposing to expand the new Promise Neighborhoods program by including $210 million to fund school reform and comprehensive social services for children in distressed communities from birth through college and career. A restructured Successful, Safe, and Healthy Students program would provide $410 million to – for the first time – systematically measure school climates, which we know can affect student learning. This will help direct funding to schools that show the greatest need for resources to increase students' safety and well-being by reducing violence, harassment and bullying; promote student physical and mental health; and prevent student drug, alcohol, and tobacco use.

COLLEGE ACCESS AND COMPLETION

The Administration has made college- and career-readiness for all students the goal of its ESEA reauthorization proposal, because most students will need at least some

postsecondary education to compete for jobs in the 21st Century global economy. For this reason, we are proposing a College Pathways and Accelerated Learning program that would increase high school graduation rates and preparation for college by providing students in high-poverty schools with opportunities to take advanced coursework that puts them on a path toward college. This new program would help expand access to accelerated learning opportunities such as Advanced Placement and International Baccalaureate courses, dual-enrollment programs that allow students to take college-level courses and earn college credit while in high school, and "early college high schools" that allow students to earn a high school degree and an Associate's degree or two years of college credit simultaneously.

Just as essential to preparing students for college is ensuring that students and families have the financial support they need to pay for college. As I noted earlier, the Administration supports passage of SAFRA, which would make key changes in student financial aid and higher education programs that are consistent with President Obama's goal of restoring America's status as first in the world in the percentage of college graduates by 2020. In combination with SAFRA, the 2011 request would make available more than $156 billion in new grants, loans, and work-study assistance—an increase of $58 billion or 60 percent over the amount available in 2008—to help almost 15 million students and their families pay for college. And another achievement of the Recovery Act, the new American Opportunity Tax Credit, will provide an estimated $12 billion in tax relief for 2009 filers. The budget proposes to make this refundable tax credit permanent, which will give families up to $10,000 to help pay for four years of college.

The 2011 budget request would raise the maximum Pell grant to $5,710, nearly a $1,000 increase since the President took office. In that time, the number of students receiving grants has grown from six million to nearly nine million, and the total amount of aid available has nearly doubled. In addition, we are asking Congress to make funding for the Pell Grant program mandatory rather than discretionary, to eliminate annual uncertainty about Pell Grant funding and end the practice of "backfilling" billions of dollars in Pell Grant funding shortfalls.

No one should go broke because of student loan debt. That is why our budget also would help borrowers struggling to repay student loans by reducing the minimum payment to 10 percent of their discretionary income, and providing for all of their debt to be forgiven after 20 years – 10 years if they choose a career in public service. These changes will help more than one million borrowers next year.

IMPROVING OUTCOMES FOR ADULT LEARNERS

The 2011 budget request includes funding for a variety of programs that support adult learners, including career and technical education, and adult basic and literacy education. These programs provide essential support for State and local activities that help millions of Americans develop the knowledge and skills they need to reach their potential in a global economy. For example, our request would provide $1.3 billion for Career and Technical Education State Grants, to support continued improvement and to

increase the capacity of programs to prepare high school students to meet State college and career-ready standards. One of our greatest challenges is to help the 90 million adults for whom increasing basic literacy skills is a key to enhancing their career prospects. For this reason, we are asking for $612.3 million for Adult Basic and Literacy Education State Grants, an increase of $30 million over the comparable 2010 level, to help adults without a high school diploma or the equivalent to obtain the knowledge and skills necessary for postsecondary education, employment, and self-sufficiency.

IMPROVING OUTCOMES FOR PERSONS WITH DISABILITIES

The budget also includes several requests and new initiatives to enhance opportunities for students and other persons with disabilities. For example, the budget request includes a $250 million increase for Grants to States under the Individuals with Disabilities Education Act to help ensure that students with disabilities receive the education and related services they need to prepare them to lead productive, independent lives. The $3.6 billion request for Rehabilitation Services and Disability Research would consolidate nine Rehabilitation Act programs into three to reduce duplication and improve the provision of rehabilitation and independent living services for individuals with disabilities. The request includes a $6 million increase over the 2010 level for a new Grants for Independent Living program (which consolidates Independent Living State Grants and Centers for Independent Living) and would provide additional funding for States with significant unmet needs. It also includes $25 million for a new program that would expand supported employment opportunities for youth with significant disabilities as they transition from school to the workforce, through competitive grants to States to develop innovative methods of providing extended services.

The Budget provides $112 million for the National Institute on Disability and Rehabilitation Research to support a broad portfolio of research and development, capacity-building, and knowledge translation activities. And the request includes $60 million—$30 million under Adult Education and $30 million under Vocational Rehabilitation—for the Workforce Innovation Fund, a new initiative in partnership with the Department of Labor. The proposed Partnership for Workforce Innovation, which encompasses $321 million of funding in the Departments of Education and Labor, would award competitive grants to encourage innovation and identify effective strategies for improving the delivery of services and outcomes for beneficiaries under programs authorized by the Workforce Investment Act. This investment will create strong incentives for change that, if scaled up, could improve cross-program delivery of services and outcomes for beneficiaries of programs under the Workforce Investment Act.

CONCLUSION

In conclusion, we have made extraordinary progress in meeting the needs of our schools and communities in the midst of financial crisis and recession, making long-needed reforms in our Federal postsecondary student aid programs, and reawakening the spirit of innovation in our education system from early learning through college. The next step to cement and build on this progress is to complete a fundamental restructuring

of ESEA, and we believe strongly that our 2011 budget request is essential to that effort. I look forward to working with the Committee toward that goal and have every confidence that with your continuing leadership and strong support from President Obama and the American people, we will accomplish this important task.

Thank you. I would be happy to answer any questions you may have.

Arne Duncan
U.S. Secretary of Education

Biography

Arne Duncan was nominated to be Secretary of Education by President-elect Barack Obama and was confirmed by the U.S. Senate on Inauguration Day, Jan. 20, 2009.

Prior to his appointment as secretary of education, Duncan served as the chief executive officer of the Chicago Public Schools, a position to which he was appointed by Mayor Richard M. Daley, from June 2001 through December 2008, becoming the longest-serving big-city education superintendent in the country.

Prior to joining the Chicago Public Schools, Duncan ran the non-profit education foundation Ariel Education Initiative (1992-1998), which helped fund a college education for a class of inner-city children under the I Have A Dream program. He was part of a team that later started a new public elementary school built around a financial literacy curriculum, the Ariel Community Academy, which today ranks among the top elementary schools in Chicago.

Duncan formerly served on the boards of the Ariel Education Initiative, Chicago Cares, the Children's Center, the Golden Apple Foundation, the Illinois Council Against Handgun Violence, Jobs for America's Graduates, Junior Achievement, the Dean's Advisory Board of the Kellogg School of Management, the National Association of Basketball Coaches' Foundation, Renaissance Schools Fund, Scholarship Chicago and the South Side YMCA. He also served on the Board of Overseers for Harvard College and the Visiting Committees for Harvard University's Graduate School of Education and the University of Chicago's School of Social Service Administration.

Last year, he was honored by the Civic Federation of Chicago and the Anti-Defamation League. In 2007, he received the Niagara Foundation's Education Award, the National Foundation for Teaching Entrepreneurship Enterprising Educator Award and the University High School Distinguished Alumni Award. He also received honorary degrees from the Illinois Institute of Technology, Lake Forest College and National-Lewis University. In 2006, the City Club of Chicago named him Citizen of the Year. He was a member of the Aspen Institute's Henry Crown Fellowship Program, class of 2002, and a fellow in the Leadership Greater Chicago's class of 1995.

From 1987 to 1991, Duncan played professional basketball in Australia, where he also worked with children who were wards of the state.

Duncan graduated magna cum laude from Harvard University in 1987, majoring in sociology. He was co-captain of Harvard's basketball team and was named a first team Academic All-American. He credits basketball with his team-oriented and highly disciplined work ethic. Duncan is married to Karen Duncan and has two children, daughter Clare, 7, and son Ryan, 4.

Mr. OBEY. Thank you.
Mr. Tiahrt.
Mr. TIAHRT. Thank you, Mr. Chairman.

PELL GRANT PROGRAM COSTS

Mr. Secretary, there is a huge rise in cost in Pell Grants since fiscal year 2007. The maximum Pell Grant award under the House-reported Labor-HHS bill was $4,150 per student at a total cost to taxpayers of about $13 billion. That represented an increase of $100 in the maximum award over the previous year. Since then, Congress has increased the maximum award to $5,550, the bulk of which is this committee's responsibility. Your request for that amount is an increase to $5,710, for a total cost of $36 billion. When you consider the increase for the amount coupled with the number of students, which in the last 4 years has gone up by about 50 percent, it is a lot of money that we are setting aside.

How has the cost of this important program skyrocketed so much in just 4 years?

Secretary DUNCAN. What we are trying to do is make sure—and I think Chairman Obey's slide is very compelling. There are so many students around this country who want to go to college who, due to difficult financial circumstances, simply can't afford it. And we want to make sure that those dreams don't die young.

I don't worry just about our seniors and juniors. I worry about those 9- and 10-year-olds around the country whose mom or dad loses their job or takes a huge pay cut, and they start to think that college isn't for them. We have to continue to invest. We have to educate our way to a better economy.

If we simply stop subsidizing banks and put those savings behind Pell Grants, we can close that shortfall in the Higher Education Act. And the bill, I appreciate Chairman Obey and Chairman Miller for their leadership on that. If we choose to invest in education and stop subsidizing banks, we can do the right thing by the country.

Mr. TIAHRT. And we are very proud of our institutions in Kansas, and especially around March Madness, I have seen some brackets where the finals is KU versus K-State.

Secretary DUNCAN. I am picking Kansas.

Mr. OBEY. What are they playing, badminton?

RISING TUITIONS AND COST TO STUDENTS

Mr. TIAHRT. My concern is that, as we put more money and dollars in the system, it seems like the universities just bump up their tuition costs, and we end up with the kids in the same problem. By putting more money in the system, doesn't necessarily open the doors for them; as a matter of fact, it may be more difficult for them, because they don't get enough, they start borrowing money, and by the time they get through their 4-year program, they owe $100,000.

Secretary DUNCAN. It is a great question. I share that concern. And it is really interesting. If you look across a couple thousand higher education institutions, you see folks doing different things. You see some with absolutely runaway costs, way above the rate

of inflation. You see other universities going to 3-year programs, going to no-frills campuses, doing some very creative things.

And I think our students and families are very, very smart, and they are going to vote with their feet. They are going to do their homework, and where the costs are out of control and the value is not there, folks are going to stop going. You have seen a number of universities start to go in the other direction, reducing costs even in tough times, going to 3-year programs, no-frills campuses.

So I think our students and parents through the marketplace are going to help drive more universities to go where they need to. But where schools have runaway costs, I think you are going to see students and parents choose to go in a different direction.

FINANCING PELL GRANTS AND DIRECT LENDING PROPOSAL

Mr. TIAHRT. Well, we are going from $13 billion in fiscal year 2007 to now a total cost of more than $36 billion. That is almost three times the increase. My concern is, these kids are going to end up paying for this because it is borrowed money. It is money we don't have.

Secretary DUNCAN. Again, this is money we can invest in students without going back to taxpayers for another dime. We simply stop subsidizing banks. So this is a real chance for America, I think, to get its priorities right. I think we have to stop subsidizing banks. If we can do that, we can invest unprecedented resources to make college more accessible and affordable for our Nation's young people.

DIRECT LENDING PROPOSAL—TERMINATING LENDER SUBSIDIES

The President has drawn a line in the sand. He says, by 2020, we want to again lead the world in college graduation rates. We have to educate our way to a better economy. Again, we used to lead the world. We have flatlined. Many other countries have passed us by. And making college more accessible and affordable is very important.

There is a piece of that legislation that is something else called income-based repayment, IBR. Again, simply by stopping those subsidies to banks, we could reduce those loans and repay them at the back end.

Mr. TIAHRT. Mr. Secretary, we just had Secretary Geithner here a couple days ago, and he is very proud of subsidizing the banks. And I don't think he is going to stop.

It doesn't prevent our kids from having to pay back this borrowed money. I think you are absolutely right; we have to quit bailing out the buddies on Wall Street.

It is tragic that our kids that are in school today, the kids that are going to qualify for these Pell Grants, are saddled with the burden of paying back not only the money that is being allocated for education now, higher education Pell Grants, but also what we paid to bail out the banks.

We are overdrawn by $655 billion this year alone. We are going to have to start making some tough choices, and it seems like this is a dramatic increase.

Secretary DUNCAN. Again, I think we are trying to make some tough choices. I agree with you. We are trying to make a tough

choice to stop subsidizing banks and put that money behind young people.

Mr. OBEY. The gentleman's time has expired.

Ms. Lowey.

Mrs. LOWEY. Thank you, Mr. Chairman.

21ST CENTURY COMMUNITY LEARNING CENTERS

And thank you, Mr. Secretary, for your leadership and creativity. However, I want to ask you a couple of questions about the after-school programs. This has been very important to me and to many of our communities.

The budget request includes $1.6 billion for the 21st Century Community Learning Centers program. So this appears to be the same as fiscal year 2010, but after I look closely, I realize that $10 million of the request would fund full-service community schools, and $3 million would stay at the Department to run a national competition. So it is actually a $13 million cut.

Now, we know that after-school programs serve more children than 5 years ago. There are more children, however, unsupervised each afternoon. The demand for programs is higher than ever. In fact, parents of 18.5 million children not currently participating in after-school programs say they would enroll their children if one were available.

Now, my constituents say that reducing funds for after-school programs is like pulling the rug out from under working families who are struggling right now. So I am not opposed to extending the school day, but it is important to delineate between extended day and after-school programs.

The vast majority of after-school programs last until 5 to 7 p.m., whereas extended-day programs often run only until 4 p.m. After-school programs just keep children safe longer, giving them enrichment and education activities until their working parents get home.

IMPACT OF ECONOMY ON AFTER-SCHOOL PROGRAMS

There was a survey conducted by the Afterschool Alliance that looked at how the economy is affecting after-school programs. It found that 95 percent of after-school programs report that the recession is affecting their community. Approximately 6 in 10 programs report a loss in funding due to the recession; 86 percent say more kids in their community need after-school programs; and 83 percent report that funding for their program is less than secure for the next 3 to 5 years.

So the gap between the proposed funding level and the authorized level of $2.5 billion leaves as many as 1.5 million children behind and many States unable to make new grants, and that prevents new programs from getting off the ground and turning away established programs looking to renew grants.

AFTER-SCHOOL PROGRAMS

So I would like to ask you three questions: One, why is the Department proposing to effectively reduce after-school funding by

using these funds for other purposes, as good as they may be, besides funding 21st Century Community Learning Centers?

How does extending the school day fill the gap between what would otherwise be accomplished through after-school programs?

And given the obvious need for more after-school programs, did the Department consider increasing funding for the program? You have asked for an overall increase in the budget. So I would say, why didn't you increase these programs when the need is so obvious?

I want to make it clear, I am not against extended-day, but I don't think it takes the place of the after-school programs.

Could you respond?

Secretary DUNCAN. Sure. Those are really powerful questions. Let me just say I got my start in education in my mother's after-school program. I was raised as part of that and ran my own after-school program for 6 years before I went to join the Chicago public schools. So, throughout my life, I have seen the extraordinary benefits.

Our streets often aren't as safe as we want them to be. As you know, we have more and more children on their own after school, and whether it is two-parent working families or a single-mom working two or three jobs, those hours, I would say, not just 3 o'clock to 5 o'clock, but 3 o'clock to 7 o'clock, 8 o'clock, are times of high anxiety for parents. And we have to find ways to address that. Let me start talking in bold strokes and then answer your question specifically.

We talk about what our priorities are. One of the six buckets is student supports, and the total pot there is $1.8 billion. That is a 16 percent increase. That is for after-school and extended-day. It is trying to create safe and healthy students, and it is this idea of creating more—replicating the ideas behind Jeffrey Canada's Harlem Children's Zone to make sure we have entire communities that are supporting students, enabling them to——

Mrs. LOWEY. Kid's Day does a great job, too. We have that in New York as well.

Secretary DUNCAN. It does a great job. I will also tell you the President has requested an additional $1 billion if the reauthorization passes, and we want to put a large chunk of that money into after-school programs. So if that passes with Congress's support this year, there is another huge funding source.

We are not looking to cut funding. We are challenging grantees to tackle both of those two things.

Mrs. LOWEY. Wait. You are not looking to cut it, but you are, for something else that is good.

Secretary DUNCAN. Again, we are going to challenge grantees to do these things. I don't see these two ideas as in conflict. I think folks can work on these things together.

Mrs. LOWEY. How?

Secretary DUNCAN. Community schools can integrate after-school programs.

Mrs. LOWEY. Where are they going to get the money?

Secretary DUNCAN. Again, these are through the grants we are going to put out. So there is a chance here for folks who are being

creative to add time. We couldn't agree with you more; we want to add more time after school.

Mrs. LOWEY. Okay, let me just say this: I think your extended-day, your other programs are all great and all wonderful, but in the meantime, there are over 1 million kids who will not be able to get services of after school.

So what I would just say, and I am hoping we can work together on the budget, is, I might adjust those figures, because I think it is important to address the after-school program. And we are certainly willing to support your creativity and extended-day, and I am familiar with CIPS and all the others. So I hope we can work together on that.

Secretary DUNCAN. Thank you so much for your thoughtfulness.

Mr. OBEY. Mr. Rehberg.

Mr. REHBERG. Thank you.

I want to thank minority staff for sticking around for my questioning this time.

COMPETITIVE GRANT PROGRAMS AND RURAL DISTRICTS

Welcome. Nice to have you. And if you haven't checked my biography, I am from Montana. I represent 147,000 square miles. And we wish we would be rural education, but we are not; 85 percent of my kids are either rural or frontier.

I had lots of problems with the No Child Left Behind as well, but I always found the Administration and the Secretary of Education to be fairly amenable to changes, flexibility.

So if I could make some suggestions: Moving to the grant program does not necessarily work for a State like Montana, because we just don't have the economy of scale. There aren't grant writers in these schools. They are so small, that we especially see it in other areas like fire grants. There are other grant programs within the Federal Government, and we have struggled. We have tried to do education programs to help them learn how to write grants. We even offered in my office to help them write grants.

And to expect us to try to make up $12 million for our schools in Montana through grant writing is practically impossible. And I plead with you, don't move so quickly in that direction.

TURNING AROUND LOW-PERFORMANCE SCHOOLS

The second area is the Race to the Top. Once again, the four model categories you have created are nice, but the difficulty is they don't really reflect our kind of schools. It is not that easy for us to get rid of a principal, fire half our teachers, restructure the way you have done it.

I guess if you could give me some assurances of your desire or willingness to be flexible, and can you work with the Rural Education Caucus that we have here in Congress to address some of the lack of flexibility in the creation of the models in the first place?

Secretary DUNCAN. Absolutely. I had a wonderful visit to Montana and learned a tremendous amount.

Mr. REHBERG. Did you fly, or drive around?

Secretary DUNCAN. We flew in, and we drove around. So we got a good sense of the issues. We traveled with the Governor and

spent some time with the State school superintendent. I went to Northern Cheyenne country as well. It was a fascinating day, and I got a lot from it.

Mr. REHBERG. As you know, we did not, our Office of the Public Instruction did not compete for the grants.

Secretary DUNCAN. They can come in, in the second round. To be clear, we are not looking for fancy grant proposals. We want to go where the need is, and we have been very, very clear about that. We are looking for folks who have a heart, who want to get dramatically better, who want to raise the bar for all children, close achievement gaps. Again, we are not interested in fancy grant proposals or consultants or anything like that. We just encourage everyone to put their best ideas forward. And please rest assured, we want to go where the greatest need is.

SCHOOL IMPROVEMENT INTERVENTION MODELS

In our proposals, I think you are talking about the school Turnaround model, the Transformational Model doesn't require you to move staff out. We can continue to have the conversation and be flexible with that model put in place. We thought about it to make sure in those rural communities where you——

Mr. REHBERG. Can those other models be added? You are not dead set on those four?

Secretary DUNCAN. We can have that conversation. We had lots of conversations with rural superintendents about that model. We didn't just sort of come up with these models—which also include the Restart and School Closure Models—in a vacuum. There were a number of conversations there. Frankly, there was pretty good support. But if we missed something, we are happy to continue those conversations.

Mr. REHBERG. That is probably the thing I hear most from the school administrators: It is not practical or does not work. Maybe you are hearing from other areas of the country that it does, but my rural administrators——

Secretary DUNCAN. Okay. We will continue to vet it. I will absolutely commit to you to continue those conversations. I have tried to travel throughout the country, so whether it is Montana, whether it is West Virginia, whether it is Wyoming——

HELPING STRUGGLING POPULATIONS

Mr. REHBERG. Let me switch gears rather quickly because the one thing I liked about No Child Left Behind was the testing, but the problem was we didn't do anything once we had the test done. We know it is our Native American schools in Montana. Clearly, we knew it before we went in that is what it was going to show. But the money didn't follow the tribes, didn't go into the reservations. Now we are seeing the consolidation of those accounts within your budget proposal as well.

How do you hope to address them specifically when you slip them in with the African American districts and all the other districts that are identified as some of the trouble spots?

Secretary DUNCAN. Again, our budget proposes the largest increase in spending for education ever. And so we want to put resources everywhere. At the time when the President is level-fund-

ing most other domestic spending, this is a major investment. And that is how we see it, as an investment. There is huge unmet need around the country in every community, urban, rural, suburban, frontier, and we want to work as hard as we can to meet that need.

Mr. REHBERG. Thank you, Mr. Chairman.

Mr. OBEY. Mr. Kennedy.

Mr. KENNEDY. Thank you, Mr. Chairman.

Welcome, Mr. Secretary.

CHARTER SCHOOLS IN RHODE ISLAND

I wanted to just reiterate, my State being a small State, we have about the same size school district, if you will, as a major city like Dallas, about 160,000 kids. We have full implementation of charter school laws in our State. It has really been a partnership with the Speaker, leadership, and our superintendent, both in our biggest city and also our smallest community. All of the partners are signed on.

We have an approach where we fully fund and hold accountable both our public schools and our charter schools, and we are prepared to defund both charters and public if they don't perform. We actually have criteria-based hiring for teachers, and we are putting teacher quality and evaluation into the system already.

For that reason, we get a "green" just among the National Council for Teacher Quality, green for those that should be proceeding forward with the Race to the Top measurement. I just wanted to highlight that, just in case you are deciding who to give the money to.

ADULT LITERACY

I want to bring to your attention the notion that the collaboration, if you can just elaborate for us, the collaboration with the Department of Labor on literacy.

We have in this country a growing challenge in terms of adult literacy. And you can't divorce a parent's literacy and the fact that that impacts their child's challenges in terms of learning. So I would like to ask you, in terms of your Innovation Fund whether you couldn't explain—I mean, a lot of these families, the parent can't get into college if they don't first have the basic skills.

PELL GRANTS AND COLLEGE TUITION

I want to echo what Mr. Tiahrt said in terms of the increase in Pell Grants. Frankly, I know this is politically not even good politics, but we ought to be spending this money on public universities and community colleges to make it go the furthest. The notion that we are spending it on Ivy League colleges that have no cap on expenditures and do not make the most of their dollars in terms of access to the average middle-class family to me is another challenge I think for the Administration to make the most of those educational dollars. If they really want to take on the status quo, that would be the way to do it. Because I have kids waiting for classes to get into the Community College of Rhode Island, and they can't do it because there is not enough money. And yet we are spending Pell Grants to go to the Ivy Leagues like Brown and other places,

albeit they are great universities. But frankly, I want to see more kids go to higher education, get access to basic skills and higher education than spend this money on a bunch of Ivy League universities that don't need it.

ADULT LITERACY AND TRAINING

So if you could talk about the adult literacy challenges that we have and how you are going to work with the Department of Labor and Secretary Solis on literacy issues.

Secretary DUNCAN. Thank you. It is a huge issue for us as a nation, and we think we have about 90 million American adults who need to go back to school to get basic training, to be able to take that next step. So we have had a very, very good collaboration so far with the Department of Labor. Secretary Solis has been a wonderful partner.

I have as my Under Secretary a former community college president, a visionary, Martha Kanter, the first time in the history of the Department that a community college president has been in that position. We want to make a significant increase in community colleges.

We think they are this unrecognized gem along the education continuum. And whether it is 18-year-olds or 38-year-olds or 58-year-olds going back to school to retrain and retool, in green jobs, community jobs, tech jobs, health care jobs, we think as families get back on their feet, the country is going to get back on its feet, and we think community colleges can drive a lot of that.

We also recruited, who happens to be from your State, just an absolute superstar who works with Martha, Brenda Dann-Messier, who is a phenomenal leader, passionate, has devoted her life to this issue of getting adults the skills they need and the basic skills to be retrained.

So a lot of hard work is ahead of us. But I want you to know we are absolutely committed. We have a laser-like focus on community colleges, and Brenda is just an absolute champion for adult literacy.

Mr. KENNEDY. Well, what are you doing to partner with the technology sector to provide these technology boards, if you will, so there is no stigma to people who may have literacy issues, they can learn both literacy for their job, but also basic literacy skills without people having a sense of maybe what the challenges are?

Secretary DUNCAN. We have had great relationships with the community. Then we have conversations. Folks want to be part of the solution, so we are not seeing resistance. We are not seeing silos. We are not seeing egos, and I think we have a chance to get dramatically better.

Mr. KENNEDY. If I could suggest, if we could bring all of the technology CEOs to the White House, tell them let's get a cut rate and just get a bunch of these technology boards access to people so they can learn at their own pace and be able to get both the skills and literacy without people having a sense as to where they are, because there is huge stigma to literacy, I just encourage that. I also encourage Rhode Island in the Race to the Top.

Thank you very much.

Mr. OBEY. Mr. Alexander.

Mr. ALEXANDER. Thank you, Mr. Chairman.
Good morning, Mr. Secretary.

STUDENT LOAN INTEREST RATES

So it doesn't look like we just hate banks more than we love children, let's talk about the student loan program a little bit. What is the average interest rate today that banks would charge?

Secretary DUNCAN. That banks can charge?

Mr. ALEXANDER. Yes.

Mr. SKELLY. For students, for subsidized loans, this year the interest rate students will get charged is 6 percent this year. It will be 5.4 percent as of July. It goes down for a couple more years. For unsubsidized loans, the rate is 6.8 percent.

Mr. ALEXANDER. So if we take it away from the banks and handle it in your Department, what will the interest rates be?

Mr. SKELLY. Under current law, the rates would be the same. The interest rates are the same for the Direct Loan Program and for the Guaranteed Student Loan Program.

Mr. ALEXANDER. So the students will be paying the same thing. So what we are doing is just taking it away from the banks because we dislike banks and we are going to put it in you, is that right?

Secretary DUNCAN. It is a little more complicated than that. We have basically been subsidizing banks, and we bear all the risk. And the banks have had a very, very good deal for a long time. And they have, because they have had a good deal, right now, and this is a matter of public record, they are spending millions of dollars on lobbyists who are running around town. They are running ads in a variety of places. And we think, again, when there is so much unmet need out there, when middle-class, working-class families are struggling to go to college, for us to continue to put money into banks when we can put money into students——

Mr. ALEXANDER. But if we are not going to let them have the loan at a cheaper rate, how are we benefiting the student?

Secretary DUNCAN. Because of those savings by not subsidizing banks, we can put billions of dollars in increased——

Mr. ALEXANDER. Is that what we are going to do?

Secretary DUNCAN. Yes, sir.

Mr. SKELLY. In the SAFRA legislation, the legislation will be incorporated into the Reconciliation Act . . .

Mr. ALEXANDER. And we know that that money won't be spent in other places?

Mr. SKELLY. I was just going to say that the rates will revert to a variable rate under a lot of the proposals under consideration. There would be a drop in the student loan interest rate under current laws.

EVEN START PROGRAM—FAMILY AND ADULT LITERACY

Mr. ALEXANDER. Okay. Let's go back and talk about something Mr. Kennedy was talking about. I, too, am concerned about adult literacy.

I have been a proponent of Even Start, Head Start, those programs, and it is very moving to go into a setting and see an adult learn to read and write along with their children. I am afraid if you

mix all of those programs in and put them under competitive bidding, that that program, Even Start, is going to get lost in the mix.

Can you ease my concerns?

Secretary DUNCAN. I will try to. I appreciate your leadership there so much. I am a huge fan of family literacy. Again, if we are trying to change children's lives, you have to change parents' lives. Again, this is something I learned growing up as part of my mother's program, that she makes parents come in and read with their kids, and helps them if they don't know how to read to their kids. And if you are really trying to change that child's life trajectory, you have to change what is going on inside that home.

So I am a huge, huge proponent of family literacy. We increased the funding for literacy by about 9 percent, so we are putting more money there. Even Start programs, family literacy programs generally can absolutely have a chance not to just maintain funding, but potentially increase their funding.

Mr. ALEXANDER. Good. Thank you.

Mr. OBEY. Ms. Lee.

Ms. LEE. Thank you, Mr. Chairman.

Good morning, Mr. Secretary.

TEACHER SUPPORT AND CHRONIC LOW-ACHIEVING SCHOOLS

Let me first say I recognize change is hard, and this is an entirely new approach to our educational system, which is sorely needed, but I have a lot of questions about this new direction.

First, I may as well say, probably one of the votes that I regret most is voting for No Child Left Behind, and I don't say that about many of my votes. Of course, I wanted to see it repealed, but it looks like you all are trying to fix it. But let me ask you a couple of things, because I am not so sure that the issue of teacher support—and I cite the example in Rhode Island where all teachers were fired. Historically, teachers have not had the resources. They have not had the support. And I look at your budget for counselors, you know; I look at all of the supports that need to be in the school, especially in low-achieving schools, schools in urban and rural areas where you have low-income students, the supports have not been there historically for teachers.

So for schools now to have to race to try to help teachers teach and then have the punitive measures that you all have decided upon, such as what happened in Rhode Island, if they hadn't been able to teach the way we want them to teach, to me just seems wrong.

Teachers should be the highest-paid profession in the world. Really. They are securing our future. We have historically had a problem with low teacher salaries, and that is an issue that needs addressing.

We haven't had the type of counseling at our public schools that teachers need, nor the curriculum, nor the supplies, nor the computers, the technology.

In my area, in Oakland, an entry level teacher is paid $37,000, but yet in a higher-income area, a teacher gets $45,000. Both salaries are much, much too low. It doesn't make any sense to put the onus on teachers, I don't believe. Teachers have families. They have children.

So to say we are going to lay off or fire teachers if they don't perform is a bit shortsighted, rather than do what we need to do to support teachers in terms of classes. You know what all we need to do.

Had your budget been in place before the firing of teachers in Rhode Island, what do you think would have happened?

Secretary DUNCAN. Let us be just very clear on that situation. We have actually worked very hard, and the union and the district are going through mediation and working together. So this story isn't finished yet, and we have been very encouraged by that.

You never want teachers to get fired. That is not what anyone wants. And these guys are going to continue to talk and work through this. It is a tough situation. It is a tough conversation. But we are very happy they are back bargaining, and we are hopeful for a good resolution there. These conversations are never easy at a school like that.

Reading rates have gone up, but in math I think 7 percent of students are at math proficiency levels. So 93 of students aren't. A dropout rate of 52 percent——

Ms. LEE. Sure. In my district, we have schools that are very similar.

HOLDING SCHOOLS, DISTRICTS AND STATES ACCOUNTABLE

Secretary DUNCAN. So we need to work together.

I think your point is very well taken. The partnership with teachers is hugely important. One of the many things I thought was broken about NCLB is to put all the onus onto teachers, and we are trying to say this is a shared responsibility. So for the first time we are going to hold not just schools but districts and States accountable. We are going to have a laser-like focus on equity.

To your point, often—and Congressman Jackson knows this—often, the poorest communities get the least resources. There are huge funding inequities——

Ms. LEE. That is all the time.

FUNDING FOR LOW-ACHIEVING SCHOOLS

Secretary DUNCAN. I lived on the poor side of the tracks for a long time. In Chicago public schools that were 90 percent minority, 85 percent living below the poverty line, we received less than half the money of wealthier districts, less than half of districts 5 miles north of us. And think about the compounded difference that makes over 12, 13 years of education. It makes no sense whatsoever.

What we want to do is we want to be very, very creative. The School Improvement Grants, which haven't gotten much discussion, you know, Race to the Top is $4 billion and, School Improvement Grants is $3.5 billion. We have put all that funding on the table just for that bottom 5 percent of schools.

SUPPORT FOR TEACHERS

So teachers need more time to collaborate. They need more support. We want to fund that. I think we should be paying—this is controversial—math and science teachers more. We have got a

shortage of math and science teachers; and I think we need to reward them to work in disadvantaged communities, rural or inner-city, urban.

INCREASED RESOURCES, SHARED RESPONSIBILITY

So we are going to put unprecedented resources out there, and what we are going to do is say, with these resources, we have to challenge the status quo. Where we have dropout factories where 50, 60, 70 percent of students aren't graduating, we have to collectively do something better.

So we are trying to make a huge investment there, but it has to be a shared responsibility. I absolutely agree. Teachers can't begin to do this alone. I always say, if children aren't fed, they can't learn. If children aren't safe, they can't learn. If children can't see the blackboard, they can't learn.

So this idea of the student supports emphasis, trying to create the climate in school and in the communities, the Geoffrey Canada work around schools to give students a chance to concentrate and think about algebra, trig, and biology. We have to do all those things, and I promise you we are committed to doing that.

Mr. OBEY. Mr. Cole.

Mr. COLE. Thank you, Mr. Chairman.

PROGRAMS FLAT-LINED IN FY 2011 BUDGET

Mr. Secretary, thank you for being here; and thank you for what you are trying to do. I think you have got really one of the toughest jobs in government, and you do it well.

But, like everybody else, I have concerns; and I think I share the chairman's concern about not funding programs that we think work or flat-lining them and moving toward the competitive grant system. Because I think it is very difficult. You need certainty in education, and you need to have some sort of timeframe, and if every year you are sort of up for a grant you have got a lot of problems and a lot of concerns.

But I want to ask you about some specific areas where you flat-lined programs that, frankly, are of great interest to me.

There is no increase in TRIO funding, and one of the major aims appropriately is to try to help disadvantaged kids get through school. There is no increase in GEAR UP funding, which helps kids get to college in the first place, again, usually disadvantaged. These are programs I see in my district and in my State and I think work exceptionally well.

I am concerned frankly—I remember your testimony vividly last year, and you talked about going to reservation schools and seeing the real needs and the real challenges there. But we are flat-funding tribally controlled, postsecondary career and tech institutions, and we are flat-funding Indian student education programs again. So if these are areas of real need—and they are, and I know you recognize that—why are we flat-funding in all these areas and moving toward grants—which again I share some of the concerns voiced by several of the members on the panel. Quite often, these are institutions or student groups that are going to find it very difficult in competing at that sort of thing.

Secretary DUNCAN. Again, just to be very, very clear, in the big picture, almost three-fourths of our budget is continuing to be formula based. So the overwhelming majority of our money will be formula based. We are moving some money in the competitive direction, and we want that money to go where the greatest need is. So part of what we wanted in the higher education bill was a college Access and Completion Fund so GEAR UP and TRIO and other programs like that would have a chance to grow and expand where they are doing a good job.

We think we want to continue to go where the need is. Again, we are not looking at fancy presentations, not looking at fancy Powerpoints but where there is significant need and a real desire to get better. Those are the kinds of places where we want to invest. And we think we have to get dramatically better and address those dropout rates. If we just keep doing the same thing, I don't know if we are going to get the better results we need. That is the balance we are trying to strike.

Mr. COLE. That is a fair point, Mr. Secretary. Although you could make an argument—particularly in the four cases I have mentioned—we are not doing better because those programs aren't anywhere near completely funded. It is not like every kid eligible for TRIO is in TRIO or every Indian kid who could be educated is getting that.

So maybe we actually—sometimes we do need to do more of the same thing. We just haven't done enough. And it is very difficult, I think, when you show up and everybody wants to do something new and exciting and everybody wants to do something innovative and there are lots of good ideas, but there tends—particularly in tough economic times——

And you are better off than most. As you say, the President has clearly made a decision here to try to give additional resources. I would have thought maybe in some areas at least this was an opportunity to catch up and to fund places that haven't been funded. These programs really do work extremely well, and they didn't get any increases last year. I guess $20 million for TRIO, which the chairman made available, that wouldn't happen. That wasn't in the President's Budget.

INDIAN EDUCATION

And, again, there is nothing here to reward or build on a program that is pretty good; and there is nothing directed again toward Indian kids, which are the most disadvantaged, lowest completion rate in high school, fewest—lowest percentage in college, lowest number of college grads of any ethnic group or racial group.

I think those programs really need a whole lot more in them before we sort of start trying something new.

INCREASED FUNDING IN CONSOLIDATIONS

Secretary DUNCAN. And those programs that, you know, have a demonstrated track record of effectiveness, that are doing a great job, will absolutely have an opportunity to receive more funding. So that chance is still there.

And in all of these areas often, you know, when agencies consolidate budgets, they use it as an excuse to cut. We actually increased

funding in every single one of our buckets. So that opportunity is there for them.

Mr. COLE. Well, I am somewhat skeptical, but we will talk about this more.

Thank you, Mr. Chairman.

Secretary DUNCAN. I appreciate your thoughts.

Mr. OBEY. Mr. Moran.

Mr. MORAN. Thank you, Mr. Chairman.

GRADUATION RATES OF NCAA ATHLETES

I am just reading an article here relevant to March Madness, which starts today. And I want to applaud the Secretary for pushing a proposal that if the NCAA teams are going to participate in post-season play, they ought to graduate at least 40 percent of their athletes. It doesn't seem to be a particularly high bar, and I am disappointed to see that Kentucky would fail, the number one seed, but it is disgraceful to only graduate less than a third of their players. And, likewise, Maryland at 8 percent; California at 20 percent; Washington, 29; Tennessee, 30.

And the most disturbing thing is that only 20 teams graduated at least 70 percent of their African American players.

I appreciate the fact that you are addressing this. We turn our back on these issues because we enjoy the entertainment of competitive basketball, but we are not doing any favors to these athletes.

I don't know that you need to comment on it. You can if you want.

REAL ESTATE MARKET IMPACT ON SCHOOL FUNDING

The other thing, though, that I am very much concerned about, Mr. Secretary, is that we have a disfunctionality in the way in which we fund elementary and secondary education in this country. It really relegates the Federal Government to little more than gap filling or capacity building, as you know. It is going to be particularly exacerbated, given the real estate market.

We were told by our three principal economists this week real estate values are going to continue to decline. The principal way we fund elementary and secondary education is through property values, and the people who pay the most in property taxes are the least likely to send their children to public schools. They are the least likely to have school-age children, and if they do, they send them to private schools.

Here you are with all of these initiatives, but you are bringing them out at a time when real estate values are not going to recover, where, despite what you are tying to do, the likelihood is that schools are going to have to continue to eliminate teacher positions, administrators, and the like because we don't fund public education in a manner that would give us a national workforce that is capable of competing globally. And you may want to discuss that.

Unfortunately, the decline in real estate values is going to be particularly exacerbated next year because the stimulus bill runs out. So do you want to comment on that, Mr. Secretary?

EDUCATION FUNDING AS INVESTMENT IN NATION

Secretary DUNCAN. I will comment on both of your points, and I couldn't agree more and just appreciate your moral leadership on this.

As a country, we dramatically underinvest in education; and we do it at our own peril. And, again, I don't see this as an expense, I see this as an investment. You could take the poorest child from the toughest community with the toughest home situation and you put that child in a great early childhood program and send him to a great elementary school and put him in a serious high school, and that child is going to be very, very successful.

There is a school that we started in the heart of the toughest community in Southside. Inglewood High School used to have a 60 percent dropout rate. It just made the national news. Started a new school, all young men, 141 graduates—I think 107 graduates all going to 4-year universities.

You give students from tough communities great opportunity, and they can do well. Other countries simply invest more than we do, and we are paying the price for that.

So what we want to do is continue to push as hard as we can to make sure that scarce resources are going to education; and the more we can demonstrate success and that we are getting better, the more I hope people will see this is the right investment to make. But we have to educate our way to a better economy.

DISPARITIES IN NCAA GRADUATION RATES

Quickly, on the NCAA, it is not just the graduation rates but, to your point, the huge disparities between white ball players and African American ballplayers. I grew up with too many players who got used by the universities, made millions of dollars off of them. No one cared about their education; and when the ball stopped bouncing for them, they had very, very tough lives. So that is something that scarred me from the time I was a little guy, and to be in a position now to try to speak out against that——

What is interesting is so many universities do the right thing. There was an article in the New York Times on Xavier University that has a phenomenal 77-year-old nun who is in charge of academic affairs, and they graduate 100 percent of their players and have for decades.

This is all about effort. It is all about culture. And you have other places that simply want players to entertain and to make them money, and they care nothing about their lives beyond that. And that is what we have to challenge.

Mr. MORAN. Good for you. Good point.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Bonner.

Mr. BONNER. Thank you, Mr. Chairman.

Mr. Secretary, I agree with really all of my colleagues and especially Mr. Cole. You have got one of the toughest jobs in government, and we wish you success.

NATIONAL EDUCATION POLICY DISCUSSIONS

This is not the right place to make this request, but, Mr. Chairman, I would really like for us to think about one day if we could impose on the Secretary's demanding schedule allowing us to have a conversation where we could talk about local issues. Because we are all mentioning—or most of us are mentioning—things that we know from our congressional district that are important to us, and I am going to do that in just a second, but also where we could talk about national policy. Because it would make for an interesting debate if we could just focus on national policy versus things that are near and dear to our hearts.

But, again, I won't make that request at this point. I would just throw it out for your consideration.

But let me bring a local matter to my State to your attention and just ask for your input.

I did not vote for the stimulus bill, although I have admitted multiple times that one of the good things that it did was it helped save thousands of jobs, tens of thousands of teachers' jobs throughout the country, including in my district; and I have told teachers in my district that that was one of the things—I don't know that it has created any new jobs in any district, but it certainly has saved some jobs.

FORMULA-DRIVEN STIMULUS BILL FUNDS

But one of the areas of concern in Alabama is we have three schools, a school for deaf and blind citizens, we have a school for math and science, and we have a school for the fine arts. The fine arts school is in Birmingham. The deaf and blind school is in Taladega. Those are not in my district. The school for math and science is in my district.

Unfortunately, because they are not subject to the annual formula of our State legislature but through direct appropriations of the legislature, they did not receive any assistance from the stimulus bill. And knowing firsthand about the school for deaf and blind and also the school for math and science, these are good schools, residential campuses that serve the entire State of Alabama. Is there anything that we can do to try to make sure that they are included and not excluded from these formulas?

HELPING SCHOOLS NOT IN FORMULA CALCULATIONS

Secretary DUNCAN. I think there is. Your State of Alabama received $1.16 billion, and I have had a great working relationship with your Governor, and I think we have saved a very significant number of education jobs in a State that has been critically important.

I was in Selma, Alabama, 2 weeks ago.

Mr. BONNER. That is where I was born.

Secretary DUNCAN. It was a very moving experience and one of those amazing days.

Tom Skelly can walk you through—I think we can help.

Tom, why don't you walk him through what is possible here?

STATE FISCAL STABILIZATION FUND

Mr. SKELLY. Mr. Bonner, I know there were some questions about the schools there in Alabama, and we looked into it for your office earlier in the week. It turns out that you can use the government services portion of the State Fiscal Stabilization Fund. It is just the education portion that is restricted to programs that Alabama funds at the local level that are elementary and secondary education programs. The school for the deaf, the school for the blind, the fine arts school, those still could be funded through the government services portion.

Mr. BONNER. And, unfortunately, my State is like 46 or 47 other States. I think Oklahoma and North Dakota are the only two States that I know of that actually aren't facing severe economic crises. So I am afraid that our State has already tapped into the fund, Mr. Skelly, that was available. But that is our problem, not yours. And I certainly acknowledge that, and I appreciate that.

TAX CREDIT FOR PRIVATELY SCHOOLED STUDENTS

Let me throw a crazy idea out from left field just for your opinion.

The chairman said in his opening comments—and he is right—our schools are drowning in red ink, but our Federal Government is drowning in red ink as well. And would it be totally off the wall to consider—and I know this would be a tax issue, which doesn't come before our committee. But just your personal thoughts, Mr. Secretary, as a leader in education reform—for us to consider putting on the table a tax credit for families who send their kids to private schools or parochial schools or who home school? Because these kids are getting an education through a different means, but their families continue to support public education with their taxes. How crazy an idea is that?

Secretary DUNCAN. I guess my primary concern is the vast majority of students in our country go to traditional public schools and I worry about how desperately underfunded our current public schools are. So my honest answer is my first priority is we need to do a much better job of supporting and investing—holding accountable for results, but investing in those public schools that serve the overwhelming majority of our country.

Mr. BONNER. Thank you.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Jackson.

Mr. JACKSON. Thank you, Mr. Chairman.

FISCAL CONSTRAINTS ON NATION'S SCHOOL DISTRICTS

Mr. Secretary, welcome back to our committee. It is good to see you. I have a couple of global questions, and then I want to ask a couple of specific questions in the time that has been allotted me.

We really have two processes here in the Congress. Today, you are here before our committee presenting your fiscal year 2011 budget, which represents substantial increases in education. You have correctly stated that it is the most aggressive investment in education in recent memory. But the context for which you seek to change public schools and our Nation's education system is obvi-

ously in the context of the worst economic recession since the Great Depression.

Detroit public schools are in near collapse. They are expecting to close almost 40 schools this summer.

The Chicago public school system, Ron Huberman said in yesterday's paper, I believe it was, that 37 students per class will not be an unusual size if these budget negotiations don't go well. But the expectations are that they will not go well, that the pension obligations, the local property tax issues, the inability of local taxpayers to shoulder the burden suggest major changes in the Chicago public school system.

There are two processes. There is one process that shows your very aggressive budget that seeks to change the Nation's education system in the current economic context, but the other process is the supplemental process that ushers truly the Nation's priorities, whether they be for Afghanistan and Pakistan.

FEDERAL VS. LOCAL SHARE IN EDUCATION FUNDING

The supplemental process bailed out our Nation's financial institutions, as carefully articulated by the President. I am wondering, in light of the fact that the Nation's top 50 school systems are experiencing shortfalls in revenue and, as the chairman indicated, drowning in red ink, why there is no emergency supplemental request by the Department of Education to provide relief for the major school systems that are near collapse by summertime. There will be no other process between now and the election, now and next year, to avoid many of these local disasters, and I am wondering why no supplemental request.

Secretary DUNCAN. Obviously, Congressman, as you know, education in our country is primarily a local issue; and we are trying to help in every way we can. We provide usually 8, 9, 10 percent of funding. Most of the money comes from the State and the local level.

It breaks my heart to see some of the decisions that folks are having to make out there; and, as you know, those are my colleagues and peers. Those are folks I work closely with.

Situations are different in different places. A place like Detroit has seen declining enrollment for a long time, hasn't had strong leadership, has put off tough decisions. I am actually very hopeful about where Detroit is going. They have a phenomenal leader there I think now who is doing a great job, who is getting their fiscal house in order. You had tremendous mismanagement there, adults using the system for their own benefit, not for students. And I have said repeatedly, Detroit, you know, may be ground zero; and we are going to do everything we can to support what they are doing and where they are going financially. Robert Bobb is financially——

Mr. JACKSON. I understand Mr. Secretary. No disagreement there.

I don't meant to cut you off. My time is obviously limited.

But why no supplemental request from the Administration, which is now prioritizing education, to address the red-ink issues in the top 50 school systems just as we are looking at the red-ink issues for the banking sector?

Secretary DUNCAN. I hear the thought. I hear the concern. And it gives me something to think about.

Mr. JACKSON. It is hard to imagine that it is a priority if we are not looking at the only vehicle that is leaving the station from the Administration. I have been watching the news the last couple of days that, while Congress is bogged down in a health care debate, which hopefully will end soon, the Administration seems to have already moved to education; and yet the vehicles that are leaving the station to address these areas are very, very serious; and they have enormous ramifications at the local level. And I am sure that and I hope that you will take my concerns seriously.

ADDRESSING LOW GRADUATION RATES OF NCAA ATHLETES

I also want to ask a law, rules, and regulations question that followed what Mr. Moran indicated about the number of athletes that are graduating from NCAA schools. I am seriously hoping that you would use your good offices to seek a meeting with the NCAA and demand from them rules and regulations that provide the necessary tutoring and the necessary academic support for athletes not as a goodwill gesture or some hope that they will, but with some teeth.

We have been discussing this too long, and the millions of dollars that basketball players make for many of these March Madness schools and the fact that they have shameful graduation rates, you would think that some of that money would go towards providing them with tutors, with mentors, with people to help them graduate and understand the significance of graduation. But it just seems to me the Secretary of Education's office should be honcho'ing with the NCAA such rules and regulations.

Your thoughts on that, Mr. Secretary.

Secretary DUNCAN. I spoke before the entire NCAA commission 2 months ago—I mean, the entire NCAA delegation, a couple thousand people, 2 months ago and said exactly the same things. We do plan to meet with the President, and Ben Jealous has joined me in this. When so many schools do it in the right way, it is inexcusable to me why we allow a few renegades to continue to operate the way they do. The vast majority of schools do this very well, but we have a couple bad apples and the fact that we tolerate that is mind boggling.

Mr. OBEY. Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chairman.

NATIVE AMERICAN AND ALASKA NATIVE STUDENT EDUCATION

Mr. Secretary, I want to thank you for being here today. I do want to thank you for your efforts to make sure that all children, including Native American children and Alaska Native children, have an opportunity to——

Mr. OBEY. Is your mike on?

Ms. MCCOLLUM. I guess I need to go to the school of technology. Thank you, Mr. Chair.

But when we talk about Native American children and Alaska Native American children and the work that you have done, we have to be mindful that they are included in two different budgets, the budget of the Bureau of Indian Affairs and the budget that you

have before you today that you are discussing with the committee. So, Mr. Chair, I really think in order to talk about doing what is in the best interest of our Native American children and Alaska Native children at some point if we could maybe figure out a way to have both the Bureau of Indian Affairs and the Department of Education in here at the same time, that would be very helpful for us to move forward.

COMMON COURSE STANDARDS

Last week, 48 States announced their proposal for common course standards and I applaud their efforts, and I strongly support moving forward on the national standards reform. But I am concerned that two States, Alaska and, importantly, Texas, have not participated.

TEXAS PROPOSED TEXTBOOK CHANGES

I am even more alarmed about decisions made on social studies education by the Texas Board of Education last Friday. Ten out of 15 elected people in one State have effectively manipulated academic materials based on their personal ideology.

I have here an article from the Washington Post, and it says, "Historians criticize proposed textbooks changes as partisan." In the article, the Post goes on to say that the Texas Board of Education is imposing a partisan, factually incorrect version of history on Texas students, in effect, students across America because of the way textbooks are purchased.

It is outrageous and unacceptable, that a group of 15 people should be allowed to influence the education of all of America's school children. And I don't want this decision in any way to influence textbooks in Minnesota. So I want to be clear. I don't want the Federal Government to write curriculum, but I don't want the Texas Board of Education to be writing curriculum for an entire country either.

So, Mr. Secretary, one of my questions to you at the end will be are you concerned and should our Nation's school districts be concerned about this blatant manipulation of history?

48 STATES WORKING TOWARD COMMON STANDARDS

Secretary DUNCAN. Obviously, as you said, the Federal Government does not and should not write curriculum. That is best done on the local level. But I share your hope in the way that 48 States are going together. And this is happening at the local level. If these are Federal standards, our national standard system dies. Because you have 48 governors, 48 school chiefs working together, you have the heads of both national unions working together on this, avidly supporting it, the business community has been crying out for this. This is a game changer. This is a game changer. We are still early. There is, you know, still a lot of hard work to go, but they have done phenomenal work. The leadership is exactly where it should be at the local level, and I think that is where we should focus our energy, and we should continue to move the country in the right direction.

Ms. MCCOLLUM. Thank you for alleviating some of my concerns. So we have it in front of us, and we know what we are doing. I am going to remain guardedly optimistic.

ESEA REAUTHORIZATION

Your blueprint for the reauthorization of the Elementary and Secondary Education Act puts, in my opinion, primarily all the responsibility for success with teachers. But, as you pointed out and as was mentioned in an earlier question, it is a shared responsibility.

In full disclosure, people should know I have been a classroom teacher. I know that the success of my student depended upon many factors, the ability of myself to teach but many outside classroom factors. Are the students having a bad test because they went to bed hungry the night before, because they don't have proper vision, because their parents have not been involved in making sure that homework was done, because a family is losing their house to foreclosure? All of these factors, including violence in the home, affects a student's ability to perform.

Now, sometimes a student's lack of performance will be a teacher, but it is not always. So if you could reiterate for me in a second a little bit more about that.

SHEPHERD PROGRAM—POVERTY AND HUMAN CAPABILITY

And then we have focused primarily on K–12, but I want to talk to you more at some point about the Shepherd Program that provides a great interdisciplinary study focus on poverty and human capacity through the Shepherd Consortium in colleges and universities that I think will go to the heart of addressing disadvantaged youth and moving America forward.

So, with that Mr. Chair, I will remain silent so you can answer.

EFFECTIVE TEACHERS AND LEADERS FUNDING

Secretary DUNCAN. I am just thrilled that we have a former teacher on this committee. We need more educators in the rooms, and you have lived this. You have lived the challenges that students face every single day, and I appreciate your commitment so much.

Again, a couple fundamental changes we are making from No Child Left Behind is all the accountability was on teachers before and, for the first time, we are saying this is a shared responsibility among schools, districts, and States. That is a fundamental change that I think folks haven't quite appreciated yet.

Secondly, we are trying to do everything we can to support teachers. A huge increase in funding to almost $4 billion, $3.86 billion, to create better mentoring programs, more time for collaboration, better pipelines, master teachers, giving teachers the time they need to work together and be successful.

And to your point about students, you know, not arriving to school in a vacuum, this idea of student support. A 16 percent increase to create communities whose schools give students a chance to be academically successful—schools with safe climates where

students' physical and emotional needs, and psychological needs are being met.

There is so much we can do there, and we are trying to make an unprecedented investment to give teachers an opportunity to actually teach and give students a chance to actually concentrate on their academic study and think about their long-term futures.

Ms. MCCOLLUM. Thank you, Mr. Chairman.

Mr. OBEY. Mr. Honda.

Mr. HONDA. Thank you, Mr. Chairman; and welcome, Secretary.

EDUCATIONAL OPPORTUNITY EQUITY COMMISSION

These past few weeks I have enjoyed our past discussions about establishing equity among our schools. This subcommittee included language in the fiscal year 2010 Consolidated Appropriation Act directing the Department to establish an Educational Opportunity Equity Commission to conduct hearings and community engagement meetings about how the Federal Government could improve education and eliminate disparities. I am glad to hear from my staff that your Department has been to work on this effort, and I look forward to working with you on this moving forward.

I notice that your Blueprint for Reform released the other day prominently features the words "equity" and "opportunity" on the cover and includes equity and opportunity for all students as a key goal. Can you outline for me the approaches you are proposing both in the Blueprint for Reform proposal for the Elementary and Secondary Education Act reauthorization and your fiscal year 2011 budget proposal that will help to meet the educational needs for each student, foster the maximum development potential for each student, and to ensure that each student has the knowledge and skills needed to participate effectively in community life?

And in particular can you discuss a few items like what role do your proposals envision for the Federal Government in ensuring that States maintain levels of educational service to provide each student an equitable and sound basic education during times of declining State and local revenues? How you propose to assess the needs of each student, the effectiveness of schools in meeting the standards of an equitable and sound education for each student? How does the Administration propose to address and rectify the deep, abiding inequality that exists in public education in this country?

And you will notice that instead of saying "all" students, I really emphasize "each" student, because I think that terminology will drive policy and the expression of policy. What are your thoughts on these questions?

ENSURING EDUCATIONAL EQUITY

Secretary DUNCAN. First of all, Congressman, I just want to thank you for your leadership on this issue. This is one that I think is hugely important for the country. What I have said repeatedly is if we are serious about trying to close the achievement gap, we have to close what I call the opportunity gap. And I am convinced that children from, again, poor neighborhoods, poor communities, tough families, if they have the opportunities they can do very, very well.

As you know, I have brought in Russlynn Ali to lead the Office for Civil Rights. She is an absolute superstar. She has an absolute passion for this.

We want to reinvigorate that office. We want to step up our enforcement of civil rights on behalf of students, and we will be working hard to make sure the rights of all students are protected.

We are going to specifically focus on schools with large achievement gaps and ask them to implement data-driven decisions to close that gap, and we are going to hold districts accountable for closing the gap within districts.

TEACHER AND PRINCIPAL EQUITY

We want to have a reinvigorated focus on teacher and principal equity. We have to do a much better job of supporting States and districts to ensure that the highest need schools have effective teachers and principals, and we are going to ask districts to show that the resources that they provide to high poverty schools are truly comparable to those they provide to low poverty schools.

And, finally, we have in our proposed budget approximately $900 million in school improvement grants to make sure those students who have been historically underserved have an opportunity to get a dramatically better education, and we do this with a sense of urgency.

So, a lot of hard work ahead of us. I look forward to the collaboration with you, and I think we have a chance to do some very important work as we move forward.

SCHOOLS AS A REFLECTION OF COMMUNITY

Mr. HONDA. The civil rights of youngsters—as you have said before, education is a civil right, and I agree with you. This country has attempted to correct that in terms of our efforts in desegregation. We are seeing resegregation in different ways now.

Looking at the bigger picture of how schools are created, I think what we have learned from the desegregation effort is that a school reflects the community that it is in. Will there be a role in this effort where we will work with local entities in the zoning efforts? Because the zoning determines the community, and the community is from which the students are coming from.

Looking at redevelopment projects where entire neighborhoods are gone and new ones are brought up without any consideration to its impact on schools, if we have environmental impact reports, should not the social impact of a neighborhood on children also be part of the consideration? If you have any thoughts on that.

Secretary DUNCAN. Again, schools don't exist as islands; and how we create communities to support those schools, how we fund schools equitably, all those things help to give students a chance to be successful. I think we can be much more creative and much more thoughtful on how we do that. And it troubles me that far too often the children who need the most help, the most resources, the best teachers, the best principals, the best facilities don't receive them.

Mr. HONDA. So it seems to me that we have to be looking at our cities and counties and our States in how they develop land use

rules and regulations and know that schools are part of the infrastructure of a new community.

Thank you, Mr. Chairman.

PROMISE NEIGHBORHOODS

Secretary DUNCAN. Critically, one of the big investments we want to make is in this Promise Neighborhoods initiative, again to create communities around schools to give those schools a chance to really help students learn.

Mr. OBEY. Ms. Roybal-Allard.

SHIFT TOWARD COMPETITIVE PROGRAMS AND CONSOLIDATIONS

Ms. ROYBAL-ALLARD. Welcome, Secretary Duncan.

First, let me associate myself with Chairman Obey's comments about funding new and untested competitive grant programs while districts struggle to provide children the education they need and deserve in the wake of devastating budget cuts.

The Los Angeles Unified School District is a perfect example. With a $620 million deficit, it has been forced to issue 5,200 pink slips and shorten the school year by 5 days. LAUSD and districts like that desperately need funding from reliable tested programs like Title I to retain teachers and to keep classrooms open, and I want to thank the chairman for raising the issue, and I hope you will be giving it very serious consideration.

EDUCATIONAL TECHNOLOGY STATE GRANT PROGRAMS

Mr. Secretary, the Administration has proposed the consolidation of many education programs that provide badly needed services. I find this to be very troubling because, from my experience, consolidation can and often results in the elimination of a program regardless of how great the need.

EDUCATIONAL TECHNOLOGY STATE GRANT PROGRAMS

I am particularly concerned about consolidating the educational technology State grant programs which complements our $30 billion investment in broadband Internet access and other technology for our Nation's classrooms. These grants have been essential to our State and local school districts' efforts to coordinate the purchase of technology and the training of educators on how to use it.

For example, the State grant funding received by the Los Angeles Unified School District is used to hire technology coaches who train teachers at its 680 campuses on the use of technology. Without a dedicated funding for this purpose, how will the district coordinate their technology programs and ensure that educators can effectively use the technology made available to them?

Secretary DUNCAN. I appreciate your concerns. Obviously, we think technology is a hugely valuable tool going forward to accelerate learning and to help students who haven't had those opportunities before; and we will work with Congress on reauthorization of technology activities. There has been no decision yet on whether nationally it will be formally competitive, so we look forward to working with you on these issues.

Ms. ROYBAL-ALLARD. So this is not going to become a competitive——

Secretary DUNCAN. No decision yet has been made. But we look forward to working with you on this issue.

Ms. ROYBAL-ALLARD. That is great to hear.

Secretary DUNCAN. And note, just big picture, we think that technology is a huge piece of the answer going forward; and we want to find ways to integrate it into everything we do.

Ms. ROYBAL-ALLARD. Right. Because it makes no sense that we have spent already $30 billion if teachers don't know how to use that technology.

INCOME-BASED REPAYMENT OF STUDENT LOANS

When the Higher Education Opportunity Act was signed into law in August of 2008, a loan forgiveness program was authorized for service in areas of national need, including health care professions. In light of the critical and the growing demand for nurses, I find it surprising that this program has yet to be funded. Why did the Department not include the loan forgiveness for service in areas of the national need program in your budget proposal?

Secretary DUNCAN. That is actually part of the higher education bill that is before Congress and before the Senate. So the IBR, Income-Based Repayment, we are a huge fan of. It significantly reduces loan repayments on the back end and brings folks into the public sector, great talent, and we will forgive that debt after 10 years.

So that is something that we think is very, very important; and we continue to advocate for right now, we have already reduced it to 15 percent of income in terms of loan repayments; and we want to take that down to be 10 percent and after 10 years of public service have all those loans forgiven. So whether it is nurses, whether it is folks working in medical clinics, or legal clinics, or teachers, folks going into the public sector, we want to create much better avenues so they are not handicapped by staggering debt that prohibits them from following their heart and helping out in the community.

TRIO, GEAR-UP, HEP AND CAMP PROGRAM REQUESTS

Ms. ROYBAL-ALLARD. In the few seconds that I have left, I also want to express my concern about the flat-funding for the TRIO, GEAR UP, and the High School Equivalency and College Assistance Migrant Programs, especially when the President has this goal of, by 2020, having the United States to be first in the world in the percentage of citizens with college degrees. These are, again, proven college preparation and support programs that have successfully helped low-income students achieve; and particularly when we are having experts telling us that the education of poor and minority children is absolutely key to our Nation's future economic success, I just find it incredibly surprising that the Department again is only level-funding these programs which could truly help us to reach the President's goal of 2020.

COLLEGE ACCESS AND COMPLETION FUND

Secretary DUNCAN. I appreciate that; and, again, I am a big fan of those programs. They have done a great job, and we have proposed a College Access and Completion Fund that would enable those and other programs to actually significantly increase their funding based upon their ability to demonstrate exactly your point, that they are making a difference in student's lives.

Mr. OBEY. Mr. Ryan.

Mr. RYAN. Thank you, Mr. Chairman.

Thank you, Mr. Secretary. You are doing a great job. I really appreciate everything you are doing and using your bully pulpit to reach out to different areas like the NCAA issue. I really appreciate that.

SOCIAL AND EMOTIONAL LEARNING PROGRAMS

Last year, in our report language we put some—this committee put some language in regarding social and emotional learning, and I have talked to you about this a few times. The committee believes that addressing the social and emotional development of students through evidence-based social and emotional learning programs is a highly effective way to promote safe and drug-free schools and to promote higher student achievement and attainment. The committee urges Federal support for the implementation of evidence-based social and emotional learning standards and programming. Can you just kind of comment on what you guys have done recently?

Secretary DUNCAN. And what we will continue to do.

In this budget, we are proposing $1.8 billion for a range of student supports, including social and emotional learning. That would be a $245 million increase, a 16 percent increase. So we are trying to put our money where our mouth is and say that we have to create climates again where students have a chance to be academically successful. And if we are not addressing those social and emotional needs, quite frankly, we are kidding ourselves.

Mr. RYAN. I agree.

SOCIAL, EMOTIONAL DEVELOPMENT AND DECISION MAKING ABILITY

I want to bring to your attention—Representative Kildee and I are sponsoring the Academic Social and Emotional Learning Act to provide technical assistance to schools to try to implement these social and emotional learning programs and hope we could get your support and hopefully get that passed and get some money into that as well.

One of the recent studies I wanted to share with you, a casel meta-analysis of more than 700 positive youth development, SEL character education, and prevention interventions has shown that SEL programs improved students' achievement test scores from 11 to 17 percentile points. And, as we see, the brain science, you know, more and more backs up that we have got to teach these kids how to regulate their emotions. We now know that the part of their brain that has to handle the emotional situations that these kids are dealing with also deals with their short-term memory, their decision-making ability. So all of these issues that we

have talked about these kids making bad decisions, whether it is teen pregnancy, whether it is alcohol abuse, regardless, I think teaching these kids these skills is unbelievably effective.

I have been to schools in Cleveland. We are starting a pilot program in three of the schools in my district. So I would just encourage you to stay focused on SEL. We are throwing a lot of money around, and I think this—which in many instances is needed—but I think this is a very, very effective, cost-effective way of doing business.

Secretary DUNCAN. I appreciate your leadership so much, and you hit the nail on the head that these are learned skills. So children can have huge challenges, but if you help them learn how to handle those and deal with them, then you have a chance. When you don't, they can't get past those challenges and can't begin to think about what is going on in class. But these are absolutely teachable, learned skills; and the more we can do that—and I think children today have probably never had more challenges—huge pressures, huge temptations, stresses at home—and if we are not addressing this, we are not in the game.

So thanks so much for your leadership——

TEACHING STUDENTS TO UNDERSTAND EMOTIONS

Mr. RYAN. You have got it. There are a lot of good programs out there that really break it down in the curriculum, where they are teaching about the brain, they are teaching about the amygdala and the prefrontal cortex to first and second graders so that they understand what is happening to them when they get pushed on the playground or when they have a domestic issue at home. They know what is going on.

And I think that level of awareness that the student has about what is happening to them is critically important for them to be able to then figure out how to not respond in a bad way.

EARLY COLLEGE ENROLLMENT AND DUAL ENROLLMENT PROGRAMS

One other question. We have a great early college enrollment program in Youngstown, Youngstown city schools. We also have one in Akron as well in my district. One of the issues I wanted to bring up, because of budget constraints, Youngstown State University, they have cancelled the program. So what I wanted to ask you about is making Pell grants eligible for kids who are going into early college.

I don't think it is going to cost us any more money. I think in the end it will actually save us money, because we are front-loading the money. So paying for these kids to go to college with Pell grants their last 2 years of high school and so we are going to avoid the latter years of the cost of living or the increase in education costs had they waited 2 more years.

So can you help us with that and comment on it, about creating that pipeline?

Secretary DUNCAN. Our Administration is hugely supportive of early college and dual enrollment. What is interesting to me is so often historically this is seen as a thing for the advanced juniors and seniors to do. What I often see in different contexts, it is actually a dropout prevention program.

For students who may not be the highest performing but are in the middle of the pack, when they start to take a college class and get college credit and start to think, man, I can really function and be successful in this environment, it changes their whole perspective on life. So it is a very interesting range of students who can benefit from this.

COLLEGE PATHWAYS

We have proposed in our budget $100 million for College Pathways, an accelerated learning program that would expand access to college, dual-enrollment, AP classes, the international baccalaureate program as well. So $100 million there.

PELL GRANTS AND EARLY COLLEGE PROGRAMS

On the Pell grant issue specifically we have talked about, it is an intriguing idea. I think it has been considered in the past, and there are some challenges associated with expanding Pell grant eligibility to students during high school, but it is an idea worth kicking around, and I would be happy to look into this and other options. At the end of the day, your goal of significantly expanding access to early college programs, I don't think we can do enough of this, and we have to be very creative in how we think about this.

Mr. RYAN. I mean, we are going to spend this money on the Pell grant one way or the other—I mean, if they go to college, you know—and let's spend it early and make sure they get into college, like you said, even the people in the middle of the pack.

Thank you, Mr. Chairman.

Mr. OBEY. Thank you.

Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman.

DISPROPORTIONALITY IN SPECIAL EDUCATION

Good morning, Mr. Secretary. It is great to see you.

Just very quickly a point, I am going to send a letter to you about an important issue in my district regarding significant disproportionality in IDEA. I don't want to take your time this morning.

Secretary DUNCAN. Give it to me when we are done.

Ms. DELAURO. I will get it to you, and hopefully we can take a look at this.

Secretary DUNCAN. I will have Alexa Posny take a very close look at it for you.

Ms. DELAURO. Great. Thank you.

EARLY LEARNING CHALLENGE FUND

Mr. Secretary, I have been a long-time and a strong supporter of early childhood education and the resources for critical programs like Head Start, Childcare Development Grant, others. I was excited to see the Administration's focus on early childhood through the initiative in the Early Learning Challenge Fund. I was proud to vote for this in the education bill that now will be part of reconciliation.

But, let me ask you, if we are not successful in including the Challenge Fund in reconciliation, what is the administration's backup plan to make this important
initiative a reality?

Secretary DUNCAN. It is hugely important. And, Congresswoman, I would agree with you that probably the best investment we could make, the best return is in early childhood education. And what we all talk about is we are constantly playing catch-up. I keep saying we have to get out of the catch-up business, and the best way to get out of the catch-up business is to make sure that our 5-year-olds hit kindergarten ready to learn and ready to read.

We have far too many children who—it is not just 3- and 4-year-olds, but what are we doing zero to 5 to make sure that we are leveling the playing field? I am convinced that if we did that well, so many of these challenges we face long-term, dropout rates and other things, would be dramatically lower.

So, you know, we desperately want that Early Learning Challenge Fund to be in there. If it is not, we need to work through a different vehicle or do something.

But this President, this Administration, is absolutely committed here. You know, we are asking for almost $10 billion over the next 10 years. We have had some questions about collaboration. We have had a wonderful, wonderful partnership with HHS and Secretary Sebelius; and we all are working together. This is a huge opportunity for the country to break through, and we hope it goes through. If it doesn't, we need to work together——

Ms. DELAURO. I, for one, will push to be a part of that effort. I think if it is not, we must really work together and collaborate to make sure that that happens.

EVEN START

Let me ask a question about Even Start. That is something that I have talked about before.

Last year's House report reflects the priorities of this subcommittee and the members and, I might add, certainly of the chairman. And just very briefly, the committee strongly recommends $66 million for Even Start, which is the same amount as the fiscal year 2009 funding level. It provides grants to States, family literacy, integrating early childhood education, adult education, parenting education for low-income families and their children from birth to 7 years old.

The committee goes on and says it does not agree with the Administration's program to eliminate Even Start, and the view on that was that—the elimination, which our view is that it was based on results of flawed evaluation studies, studies that were not representative of Even Start participants and programs based on small samples, et cetera.

I have to ask you this: Why have you come back again with a proposal to eliminate this program? This is a program that serves 50,000 families nationwide. It is the only Federal education program that focuses specifically on parents and their children and the literacy learning skills that they can work on together. So I am having trouble understanding why you—why the Administration insists on ending this program.

Secretary DUNCAN. We talked about it earlier, and I am a huge fan and supporter of family literacy. Growing up, as part of my mother's after-school program, she spent a lot of time not just working with children but working with parents and trying to make sure that she was changing what was going on inside the household and really making sure parents had the skills to function and to support their own children.

So this is one that we are passionate about. Family literacy is something that is part of the literacy program in the proposed ESEA authority on a well-rounded education. We actually propose a 10 percent increase in funding. Even Start projects can absolutely apply—compete to do that. Brenda Dann-Messier, who is leading our adult ed work, is a passionate advocate and did phenomenal work in adult literacy.

So this is something we are going to work very, very hard on, going forward. So it is part of an overall literacy package. We don't have a line just for Even Start.

Ms. DELAURO. Well, you know, I can't be a predictor of where this committee will come out, but I can say for myself that I would be one and I suspect that there are others that are going to want to see that this program continues.

Secretary DUNCAN. We are happy to have that conversation.

Ms. DELAURO. Thank you very much, Mr. Secretary.

Thank you, Mr. Chairman.

Mr. OBEY. Thank you.

EDUCATION JOBS SAVED BY RECOVERY ACT

Mr. Secretary, you indicated and witnesses did yesterday that about 325,000 teachers' jobs were saved by the Recovery Act. We roughly filled about 40 percent of the hole in State budgets last year. This year that is going to drop about 20 percent. This program is meant to be temporary. Some people object to it; and they say, well, this is going to wind down. What good did you do?

EDUCATION JOBS BILL

And the whole point of the program was to simply get us through the next 2, 2½ years until the private sector could recover and pick up the slack again. To do that, last December the House passed a second jobs bill, which contained $23 billion in additional assistance to education because we don't want to see 50 percent of the teachers whose jobs were saved last year lose those jobs in the coming year.

So let me ask what will happen at the local school district level to their ability to retain those teachers if we do not pass that bill or something similar to it that provides at least a similar amount of assistance to States and local school districts.

Secretary DUNCAN. Chairman, I appreciate your huge leadership on this. I share your concern. I am very, very concerned.

As I travel around the country, everywhere I go, everywhere, no one is immune from this. Folks are hurting. And we are not just cutting through fat. We are beneath bone now. And to hear about skyrocketing class sizes, to hear about—I keep arguing for more time, Mr. Chairman. We see students going to 4-day work weeks.

Those are huge challenges, and we need to do something. We need to do something.

Mr. OBEY. What will happen if we do nothing?

Secretary DUNCAN. You will see some devastating cuts around this country. And folks that are making these cuts, fiscally responsible superintendents, school boards for the fall are planning budgets now, March and April. So this is not something that is going to play out in August. These things are happening in real time.

Mr. OBEY. And won't it also put additional upward pressure on local property taxes?

Secretary DUNCAN. Sure. Sure. Absolutely.

TITLE I, ESEA FUNDS FOR HIGH-POVERTY SCHOOLS

Mr. OBEY. I referred to this chart earlier, and what it shows is that, among students who scored in the top quarter—I said 20 percent earlier. I should have said top quarter—on eighth grade math tests, the child of a wealthy family graduated from college 74 percent of the time, while a child that came from a poor family graduated only 29 percent of the time, even though they demonstrated the same ability.

I would point out a similar relationship exists between that eighth grade performance and the decision to even enter college. What is the one program for elementary and secondary education which we have relied upon for years to try to equalize that poverty situation?

Secretary DUNCAN. Title I.

Mr. OBEY. Right. How do we correct that if we don't provide significant increases in Title I?

SCHOOL IMPROVEMENT GRANTS

Secretary DUNCAN. A couple ways. One is, as you know, the school improvement grants are going to be directed to those low-performing, high-poverty schools. So we are trying to make a very, very significant investment there. We have $3.5 billion that we want to put out to those schools now.

We have to focus—and there aren't simple answers here. You have to focus on getting great talent into those historically underperforming schools, and we want to work hard on that as well.

And I would argue that Pell grants, making sure students have access to resources to go—we have so many families—you probably saw the same survey I saw a couple weeks ago. A lot of American families just don't think college is for them.

TITLE I FUNDING

Mr. OBEY. I understand about Pell grants, and I will get to that. But the fact is that if you want to provide assistance to all poor kids around the country, you don't need to go through a targeted program that gets to a few school districts. Because there are many, many poverty districts around the country who will never get the grants that you are talking about.

ADDRESSING INEQUALITY IN EDUCATION

Which leads me to the same question that I was asking before and several others have been asking. Why if we want to close that gap would we not concentrate on Title I? I mean, I was elected in 1969. That was at a time when the Federal Government had just started programs like Title I, and I sponsored Wisconsin's first State version of Title I. I still remember the bill number, 51–A. That was a tiny little initiative at that time, $5 million for the entire State. That went a lot further in those days than it does now.

But I mean I have been trying and so have most people on this panel been trying ever since to meet the needs of Title I by providing for more full funding. We have never come anywhere near close to where we should be in funding Title I.

So, I don't understand why I should be all that interested in focusing what meager additional resources there are in the education budget this year on a new program when we know that the basic program is there to deal with poverty stricken kids all over the country.

Secretary DUNCAN. I think obviously what you and I absolutely share in common is a passionate desire to help disadvantaged children be successful, and Title I is a huge piece of that.

But I would argue that everything we are trying to do is trying to address those inequalities. So trying to put money to attract great teachers into poor communities we think is hugely important. Trying to make sure that students have a well-rounded education, where so often it is narrowed, is very, very important.

Chairman OBEY. I think that is important, too, but, to me, there are lots of ways we can provide incentives to put better teachers in some of those schools. But I question such a heavy focus on teachers. Yes, I want quality teachers, but let me give you an example: Me.

When I was in 7th grade, I skipped school 2 days a week, and that is how I learned to play the harmonica. I was hiding out in the woods.

Secretary DUNCAN. We need more music in school.

Chairman OBEY. But I finally got turned around essentially by two teachers. Now, if I hadn't gotten turned around, should those teachers have been blamed for my failure?

Secretary DUNCAN. No. No, of course not. Nobody is suggesting that. No, of course not. Of course not.

But great teachers turn around children, you and many others included. We all remember those teachers that changed our lives. And all we want to do is we want to shine a spotlight on excellence. What I will tell you is there have been very few incentives for those great teachers to go to historically underserved communities, very few rewards to do that, and we want to make sure the children who need the most help are getting it.

Mr. OBEY. I understand, and you are focusing on heavily underserved communities.

RACE TO THE TOP APPLICATION PROCESS

But let me make a point. In your Race to the Top package, I am told by my State education people and by my Governor that when

your Department considered their application, that all of the points that they would have earned in your evaluation system were roughly related only to six counties in the State—Milwaukee, Kenosha, Racine, Madison, Green Bay, and I have forgotten the other one.

Secretary DUNCAN. I don't know the specifics of your proposal, but I will say what we were trying to reward is States that had comprehensive plans—urban, rural, suburban, every child.

Mr. OBEY. All I can tell you is that my State people think that the focus of your attention was almost exclusively on those six urban counties.

FOCUSING INCREASED RESOURCES ON INEQUALITY

The point I would make is simply that we have got 72 counties in the State, and there are a lot of them outside of that area that are low income and have lots of poverty kids. I just do not understand why we do not—very frankly, I am a Democrat, as you know, and so are you. I do not understand why, when we finally have a shot at it, we are not greatly emphasizing Title I before we do others.

I am all interested in reform, but, as Richard Nixon said, timing is everything in politics. And as I see it, I will be a whole lot more interested in putting additional money in reform efforts 2 years from now when the economy is through this recession than I am right now when everybody is sucking for air. I don't understand why we do not have a greater emphasis on trying to help those school districts.

Secretary DUNCAN. Obviously, I think we would agree we need to do both. We need to help stabilize schools under huge stress, and we need to get dramatically better, and we are trying to find that balance.

HISTORY AND CIVICS EDUCATION

Mr. OBEY. Let me ask an additional question. I asked this yesterday of the panel, too.

We seem to be fixated on improving performance for math and science, but I, frankly, am concerned that we are going to be producing a generation of societal and political illiterates. Because I think you see as the testing focuses on math and science, for instance, or math and reading, it isn't just the arts that get squeezed aside, it is history, it is civics.

As I said yesterday, I was in one class a few months ago where the kids couldn't tell the difference between a State legislator and a third baseman for the Chicago Cubs. They were absolutely illiterate in terms of the things they would need to know to function as citizens in a democracy.

How do you feel about this emphasis on math and science and how do we produce a much more well-rounded approach to education? Because, otherwise, we can set utilitarian goals, but it is not going to meet our other societal needs.

BUDGET INCREASE TO PROMOTE WELL-ROUNDED EDUCATION

Secretary DUNCAN. I will tell you, I was in 37 States last year—rural, urban, suburban. Everyone—teachers, parents, students—all expressed their huge concern about what we are seeing in this country, which is a narrowing of the curriculum. I couldn't agree with you more.

So yes, reading and math are important, but, again, one of our six big buckets is a well-rounded education for history, for arts, for financial literacy, which we haven't talked about, which is a big one, for foreign languages——

Mr. OBEY. Financial literacy, we could start with Wall Street bankers.

Secretary DUNCAN. And we ought to produce a next generation of students who do better than what we have seen today. I mean that very seriously.

For all those things, civics education, history, social studies, we propose a 17 percent increase, $265 million.

So the need for a well-rounded education—let me just say one more thing about it, Mr. Chairman. It is hugely important. It is not just important at the high school level, which is often what people think. I think that for first graders, second graders, and third graders, we have to give students a chance to find their passion—music for you, art for someone else, drama for someone else. We have to provide those opportunities; and if we don't do that, we really put a ceiling, a limit on what students can accomplish.

So math, reading, science, are very important. So is foreign language, literature, arts, PE. We need to get back to those things, and we are trying to do everything we can to encourage that. A well-rounded education is critically, critically important.

Mr. OBEY. Mr. Tiahrt, why don't we give everybody a shot at one last question or so before we shut down the hearing. Take a couple minutes yourself, if you want.

CIVIL RIGHTS

Mr. TIAHRT. Thank you, Mr. Chairman.

I have been hearing several times that education is a civil right. So I don't recall it being in the 14th amendment or the Civil Rights Act of 1964. I checked the White House Web site. It is not included there under civil rights. It is not in Wikipedia. I don't think it is a civil right. I think it is very important, but I don't think it has the status of a civil right, and I think it diminishes those who are protected by our laws for civil rights by trying to broaden it.

PROPOSAL FOR DIRECT LENDING FOR STUDENT LOANS

I have a question more directly about student loans and the government taking over the process of administering student loans. As I see it, we have these two avenues: One is where the government takes over student loans and takes money that we don't have, so we have to go borrow money to loan to students. So the students end up going through school and then have to pay back not only the student loans but then the money that the Federal Government borrowed to provide the student loan. When you compare that to banks, banks already have money to lend. We don't have to go bor-

row from the Chinese. So the student just has to get his education and pay back the student loan.

One can make the argument that the Federal Government is subsidizing the money and will have to borrow money to subsidize the interest. And I would say it is much cheaper to borrow just for the interest, rather than for the loan and interest, and I think you would agree that math is correct.

So why are we doing this? Is it for control? Is it to limit what institutions can receive money or limit some curriculums? What is the purpose for borrowing money for student loans when we don't have it?

PROPOSAL TO INCREASE PELL GRANT FUNDING

Secretary DUNCAN. It is very, very simple. Taxpayers are already spending this money. Taxpayers are subsidizing banks today. This is not a new expense.

Mr. TIAHRT. This program will continue, but we are not going to continue to subsidize banks.

Secretary DUNCAN. Let me just finish. So we think we should stop subsidizing those banks; and we think we should invest scarce resources, taxpayer resources, yours and mine, into students.

To be clear, what we want to dramatically increase is access to Pell grants. That chart that Chairman Obey put up there haunts me, and the lack of financial resources for poor families to go to college is a huge impediment and a huge killer of dreams.

Mr. TIAHRT. Since my time is limited——

Secretary DUNCAN. Let me finish. These are Pell grants. Students don't have to pay these back. These are grants.

Mr. TIAHRT. I am talking about student loans, the student loan program that the government is trying to take over.

Secretary DUNCAN. This is Pell grants that we are trying to increase.

STUDENT LOAN REFORM

Mr. TIAHRT. I am talking about student loans. The government is trying to take over student loans, correct?

Secretary DUNCAN. We are trying to stop subsidizing. We are trying, rather than have the private sector initiate those, we would initiate those.

Mr. TIAHRT. The bank I received my student loan from is still in business today, and it did not receive any subsidized funds, even in the latest go-around.

Secretary DUNCAN. I would beg to differ on that one, and I am happy to look at that specific situation.

But we can dramatically increase Pell grants to students, we can invest in community colleges, we can lower loan repayments at the back end, the income-based repayment, simply by stopping subsidizing banks.

Mr. TIAHRT. Well, there are students that will get access to college through student loans, do you agree?

Secretary DUNCAN. Sure.

Mr. TIAHRT. Okay. So why is the government taking over student loans? Why don't we continue to pursue that through the private lending institutions, like I did when I got my college student loans?

Secretary DUNCAN. Because we can save tens of billions of dollars by initiating the loans ourselves. The servicing of the loans will all be done by the private sector.

Mr. TIAHRT. How can we save money when we have to borrow money for the student loans and for the interest?

Secretary DUNCAN. We are going around in circles here. We can save money because of subsidizing banks, and the——

Mr. TIAHRT. The bank that I got my student loan from is not subsidized. Which bank is subsidized that is providing student loans today?

Secretary DUNCAN. This is across the country. The servicing of these loans would all be done by the private sector. It is not our sweet spot. We would do none of that. Good actors would get a lot more business. We have more and more people going back to college in this country, which is a good thing. Bad actors would lose business. The free market would play.

Mr. TIAHRT. I think it is out of line for us to get into the student loan business, because we don't have the money to start with. And it doesn't save us money. It costs us money to do this. Private banks have the money available. So I think it goes beyond just the financial side. I think there is some control issue here, and I want to know what it is.

Secretary DUNCAN. There is zero control issue.

Mr. TIAHRT. What requirements would we put on student loans? Mr. Kennedy advocates cutting them out for Ivy colleges, and I think he makes a good argument for that.

Secretary DUNCAN. Let me finish. The private market, before we have done anything, as you know, has been collapsing. This thing has been on life support. And before we got here, we have seen a huge migration of universities to direct lending, from about 1,000 universities to 2,300 before we got to town. So this is something that has happened without us doing anything because the private market wasn't working.

Mr. TIAHRT. I would say if private institutions want to pursue that path, they should be open to doing it. I just think there is something beyond this, and it is in the element of control, and I think it is a bad path.

The other thing I want to mention before my time runs out——

Secretary DUNCAN. I just want—for the record, I want to say we have zero interest in that. We simply want to stop subsidizing banks and put scarce resources behind students.

INDIVIDUALS WITH DISABILITIES—GRANTS TO STATES

Mr. TIAHRT. I want to join with Congresswoman DeLauro about my concerns on IDEA as well. I want that for the record, that we need to get to our proportionate share, and it needs to be equitable.

Secretary DUNCAN. We have a $250 million increase for IDEA grants to States. I hear that concern.

Mr. OBEY. Ms. DeLauro.

TEACHER RECRUITMENT AND RETENTION

Ms. DELAURO. Let me just echo something that the chairman said, and I guess many of my colleagues, because I arrived late, and that is it was Randi Weingarten who said a child's education

should not be based upon how well adults write grant applications. I couldn't agree more.

When States start to lay off teachers—I just want to make this statement because it has been discussed here—they undermine our economy further, not to mention increasing class sizes.

I know you believe that we have to have reform in a good and a bad economy, but I think what is key to all of us at the moment or at our core here is the timing and making this shift in education funding and the effect that it is going to have in terms of worsening the economy; and instead of providing that opportunity, a better education opportunity, we will be curtailing that. So I just want to add my voice to that.

But let me ask about the Teacher Incentive Fund, if I can. Teachers, you know, we have said are the most critical factors in improving student achievement. We are doing everything that we can to make sure we can recruit and retain the best teachers. But we know from the research that the financial incentives are of limited value to attracting teachers to low-performing schools.

A survey by Scholastic, Inc., and the Bill and Melinda Gates Foundation show that non-monetary rewards are the most important things in obtaining good teachers. I believe only 8 percent responded that pay-for-performance plans are key.

What initiatives do you propose in your budget to attract the best and the brightest to serve the neediest kids, especially once the schools are labeled as the State's worst schools?

TEACHER INCENTIVE FUND

In a related question, how can we justify an increase of $800 million in the Teacher Incentive Fund, a program that 2 years ago was only $97 million and also a program that received $200 million in the Recovery Act and I believe that the funding has not gone out yet?

Secretary DUNCAN. Many, many factors go into attracting great talent to underserved communities. I absolutely agree. Increased financial rewards is a small piece of that.

A couple of things have to happen. You have to have a great principal. Teachers will follow a great principal to the end of the Earth. Great principals make a huge difference. Bad principals run off good teachers. That is part of the problem. Principal leadership is hugely important, and we have to invest there, and we are looking for a five-fold increase there.

PROMISE NEIGHBORHOODS

You need a community to rally behind a school. So all the work we are trying to do around Promise Neighborhoods tries to create that community of support behind those troubled schools.

Ms. DELAURO. That is the Comer Model, and I am very familiar with the Comer Model in schools, Jim Comer.

Secretary DUNCAN. And when you put it in place, great teachers want to go to those tough communities. They want to have a chance to succeed. And if we can put in place the structure, more time for them, more time to collaborate, better resources, better data, we put those in place, I promise you great teachers will want to go to underserved communities.

Mr. OBEY. Mr. Cole.

Mr. COLE. Thank you, Mr. Chairman.

MOVE TOWARD MORE CONSOLIDATION AND COMPETITIVE PROGRAMS

Just an observation and a couple questions.

I think what you are running into, Mr. Secretary, is there is a lot of confidence in you, quite frankly, but I don't know who the next Secretary is going to be. And I worry about just the centralization of power and the grant approach that brings, the pickers of winners and losers, who is going to do it, how it is going to work, and how you are going to have any certainty at the receiving end of this process. I think you do need certainty over a period of time if you are going to make the kind of investments that are necessary.

ASSESSMENT OF NO CHILD LEFT BEHIND

But let me ask a historical question, because I am struggling with trying to understand what we have done right and where we need to change, get better, and what you want to do.

Under No Child Left Behind, which is now, of course, much maligned but actually had a couple of great virtues, one of which was actually bipartisan, which I think to move ahead here you need to be bipartisan; and, second, that it really did put a lot of focus on the consumer here, i.e., the kids, as opposed to anyplace else in the bureaucracy and how are we doing with them and are we really particularly looking, by breaking students out, at kids that are the most disadvantaged, the most challenged, and trying to target resources there.

I am happy we are going through reauthorization, because that is why we have it. So what have we learned? What do we need to do different?

Looking first at No Child Left Behind, could you tell me, did scores for kids broadly—and I mean very broadly—go up? Did we narrow differences, which is what we all wanted to do on both sides of the aisle?

Secondly, going forward, could you just explain for me the differences in where you propose to go? And I actually look on this as building on. I don't see this as antithetical efforts necessarily. But where are the differences, the course corrections you are making, in contrast to where we would have been had we just simply stayed on line, which never is a very good idea?

Secretary DUNCAN. I appreciate that, and I want to assure you that we will only do this and want to do this in a bipartisan way. I consider that education has to be the one thing that rises above politics and ideology. We all have common interests. I have been so impressed here. The leadership of the House, the Senate, Republicans, Democrats, everybody is working hard on this together.

DROPOUT RATE AND COLLEGE COMPLETION

My sense of urgency is—I go back—we have a 27 percent dropout rate. That hasn't moved. We used to lead the world in the percentage of college graduates 2½ decades ago. We have flat-lined. Everybody else has passed us by. You want to know why we are in

a tough economic position now? I think that explains a lot of it. So we need to get dramatically better, and we need to get better as fast as we can.

FOCUS ON ACHIEVEMENT GAPS

What I will always give the previous Administration credit for was focusing on achievement gaps. We used to like to sweep that under a rug as a country, and it forced us to have those tough conversations. We need to continue to have them and the idea of disaggregating data, really looking at what is going on there. That is something we will never, never walk away from. And we have to have focus on achievement gaps.

ASSESSMENT OF NO CHILD LEFT BEHIND

Having said that, I wasn't here. I don't know the history. There were a number of consequences intended, unintended I don't know about, challenges that I have heard repeatedly around the country as I have traveled. The law was far too punitive. The law was very prescriptive. And this is well-documented. It actually lowered the bar. Due to political pressure, States lowered standards, which is absolutely the wrong thing to do, wrong thing educationally, wrong thing economically. But due to political pressure, the standards got lowered in many cases; and, to Chairman Obey's point, we saw a narrowing of the curriculum.

FOCUS ON GROWTH, GAIN; REWARD SUCCESS, EXCELLENCE

So what do we need to fix? We need to raise the bar, have meaningful standards, a high bar for every child. We need to reward excellence and success.

Again, I want to look at growth and gain, how much are students improving each year.

Let me give you one example I use. Let's say you are a sixth-grade teacher, and I come to you, and I am three grade levels behind. I am reading at a third-grade level. I leave your class, I am one grade level behind. Under No Child Left Behind, you are a failure. You are a failure. Your school is a failure. Your State is a failure.

I think not only are you not a failure, you are not just a good teacher, you are a great teacher. I had 2 years' growth for a year's instruction, and we should be recognizing that excellence. We should be learning from it. We should be encouraging it. We should get more of those teachers into underserved communities.

So that is a huge problem we have to fix. I think by focusing on growth and gain, that is the right way to do it. So reward excellence and success, more local flexibility, essentially how you want to manage.

FLEXIBILITY AND ACCOUNTABILITY

No Child Left Behind was very loose on goals: 50 different goalposts, 50 different standards, many got dummied down, very prescriptive, very tight on how you get there. We want to flip it on its head: tight on its goals, high bar for the country, college- and career-ready standards. But give much more local flexibility, hold

folks accountable for the results, let them move to get there. And then, finally, and we are trying to invest heavily here, our students need a well-rounded education.

Mr. COLE. Thank you, Mr. Chairman.

Mr. OBEY. Ms. McCollum.

Ms. MCCOLLUM. Mr. Secretary, you talked about holding, and so I want to give you an example of why I think you need to do that.

The State of Minnesota, for balancing its budget a couple decades ago, decided it would delay payments to school districts, not make them on time. School districts had to go out on the market and borrow money and pay interest. That money wasn't going to children.

That was one of the last actions I took. We corrected that before I ran for Congress. And now Governor Pawlenty is right back. That was the demand that he had in balancing the budget, that the school districts have to go borrow money in order to make their day-to-day payroll obligations so the State of Minnesota didn't have to. That is wrong, and I hope you hold States accountable.

PROPOSAL TO MOVE TO STUDENT LOANS DIRECT LENDING

I would like to give you an opportunity to walk through what we are doing with the Direct Student Loan program. It used to be, if I understand, the U.S. had the money, we gave it to the banks that then distributed it to the schools, and everybody took their cut on it, and we took the full risk. But now we are lending directly to the schools where the financial counselors and the students are sitting together.

Would you walk through that for me?

Secretary DUNCAN. You summarized it perfectly. We have subsidized banks where we have all the risk, and if we can just cut out the middleman there and do direct loans across the country—again, we are seeing a huge migration towards this anyway before we did anything because the private market was drying up. We saved tens of billions of dollars.

I understand banks' resistance to this. They have had a very good deal; and because of those subsidies—and this is all a matter of public record—they have been able to hire and spend millions of dollars on lobbyists to oppose this. They are running ads in States opposing this. And I understand it, from their perspective, it is a hard thing to give up.

But if we can take tens of billions of dollars at a time of tremendous economic crisis and make college much more accessible and affordable for hard-working Americans, middle-class, working-class Americans, I don't see how in good conscience we can stay on the sidelines.

Ms. MCCOLLUM. Mr. Chair, I don't see how we are taking over anything except an opportunity for more children to have a chance at college. Thank you.

Mr. OBEY. Mr. Ryan.

Mr. RYAN. I appreciate you doing that, too, Mr. Secretary. I mean, subsidizing the banks where they had no risk at all and, if someone bailed, we picked up the tab. I appreciate how you are doing that.

ROBOTICS COMPETITIONS

Two things. One, the issue of math and science. We have some programs in Ohio, robotics programs, they had the first competition and whatnot, just unbelievable, where you see kids get so excited and passionate about using their hands and conceptualizing what they are going to create. And the first competition is probably the most prominent competition around the country.

When I think about robotics, I think about the old shop classes and how this is kind of like 2.0 in the shop classes.

Secretary DUNCAN. The new shop.

Mr. RYAN. Yes, exactly. Is there anything in this budget that would help local schools? Now a lot of schools can't even afford the start-up to get the kit and to pay the supplemental for the teacher.

Secretary DUNCAN. Yes, I am a big fan. We talk about well-rounded education. I am actually going to go to the national championships, the national finals of the first competition. I am a big fan. And we talk about a well-rounded education. It is those kinds of opportunities again, whether it is robotics, debate, academic decathlon, music. So I worry in tough times that those extra curricula are often the first things to get cut. Those are things that keep students engaged and keep them motivated. So we want to continue to encourage a well-rounded education. I love those robotics competitions.

INCENTIVES AND PUBLIC-PRIVATE PARTNERSHIPS

Mr. RYAN. How can we create incentives? In Warren, Ohio, we have a great program at Warren Harding High School, and it is with non-traditional kids. They are not playing hoops, they are not on the football team, whatever. The reason they have been so successful is Delphi was a local corporation who was very involved in the start-up of the robotics program at the high school.

So how do we create incentives for local manufacturers or local corporations to help contribute to these programs?

Secretary DUNCAN. That is the thing. I think the start-up costs for the robotics competition are actually minimal, and it is easy. Again, that is where we can think about it at the Federal level. But I think that that is, at the local level, just going out to those businesses and saying, for a small amount of money, you create this huge life-changing, life-transforming opportunity for students.

Those kinds of sponsoring partnerships are out there. Obviously, business is struggling now, and there are maybe fewer available dollars. But this is a low-cost, high-impact, high-visibility activity, where students from very non-traditional backgrounds are getting interested in science and engineering and thinking about a whole set of careers that they never would have thought about without this competition. So there is a huge amount of space for folks to be creative and innovative and build those public-private partnerships.

Mr. RYAN. Most of these programs, you see these kids, they have like a 98 percent graduation rate, a placement rate in college, the military, something when they get out.

PARTNERING OF SCHOOL DISTRICTS TO SHARE SERVICES

One last question before we have to run, I am not for consolidating school districts or schools. I believe in the neighborhood school. I think that is very important. But there are a lot of services that I think school districts can share—buying the food, buying computers.

Secretary DUNCAN. Textbooks.

Mr. RYAN. Textbooks, those kinds of things. Is there anything in here to create an incentive for school districts to partner with each other on those services?

Secretary DUNCAN. When times are tough, what would you rather do, increase your purchasing power or lay off a bunch of teachers? I would much rather increase my purchasing power and keep those desperately needed adults in the building. So where folks are doing all these things—HR, buses, food, textbooks—where they are doing it on an individual basis, that to me is just an absolute waste of money at a time of desperate need.

Mr. RYAN. Are there any incentives in here?

Secretary DUNCAN. We can think about it. I think this is one that is common sense.

Mr. RYAN. Well, if we are relying on common sense—thank you, Mr. Chairman.

Mr. OBEY. Thank you.

Mr. Secretary, let me simply summarize by asking two questions and then making a point.

PELL GRANTS

With respect to Pell grants, lest anybody think that we are being overly generous with them, when they were first instituted, the maximum Pell grant covered over 70 percent of the cost of going to a 4-year university. Today, despite the increases that we have had that has taken it from 32 percent upwards somewhat, we are still riding at about 37 percent. So we have hardly been overly generous.

SAVINGS FROM DIRECT LENDING

Secondly, with respect to student loans, I just want to read something that appeared in Roll Call last week. I want to quote two sentences.

"The legislation deserves GOP backing first and foremost because it eliminates government waste and saves billions. The choice is simple. Do we help Citibank make millions of dollars in profits from zero-risk student loans or find other ways to use the up to $87,000,000,000 in savings?"

That savings number comes from the nonpartisan Congressional Budget Office.

The article was written by Dr. Susan B. Neuman, former Assistant Secretary of Elementary and Secondary Education under former President George W. Bush.

IG AUDIT OF READING FIRST

Let me also ask this question: I am sure that you are familiar with the Inspector General's alarming audit of the Reading First

Initiative under the previous administration. The investigation concluded that Federal officials violated conflict of interest rules when awarding grants to States under the reading program and steered contracts to favored textbook publishers. The IG's report found that the program was awash with conflict of interest and woeful mismanagement.

It also suggested that the Department of Education violated the law by attempting to dictate which curriculum schools must use. The report states that program review panels were stacked with people who shared the Reading First director's views and that only favored publishers or reading curricula could obtain program funding.

ELIMINATING CONFLICT OF INTEREST IN COMPETITIVE AWARDS

What is your Department doing to ensure that conflict of interest does not exist in competitive grant programs under your leadership? What kinds of measures have been put in place to prevent an outcome along the lines of the Reading First initiative?

Secretary DUNCAN. First and foremost, we don't think we should be involved in curricula decisions. This has always been down at the local level and should not be driven at the national level. So we have no opinion, no stance, no interest, no investment, and are absolutely dispassionate on it. So in that spot you can't have a conflict of interest.

We have tried to recruit people with the highest integrity and to do things the right way. We absolutely hope to be and should be and will be held accountable for that. All we want to do is invest in great ideas that are coming from the local level.

But we have no agenda here, no interest in textbook publishers, and we don't think we should be playing in the curricula field whatsoever.

ACTIONS TO PREVENT CONFLICTS OF INTEREST

Mr. OBEY. I am concerned not just about that narrow approach but across the board in the agency. If you can get us some more information for the record, that would be helpful.

Secretary DUNCAN. I will.

[The information follows:]

ACTIONS TO PREVENT CONFLICTS OF INTEREST

The Department has taken significant actions to prevent conflicts of interest in the implementation of our programs. On December 4, 2007, after the release of the Office of Inspector General reports on the Reading First program, the Department issued an internal directive, "Improving Administration and Management of Department Programs." The directive provided all employees with program implementation guidance on a number of topics, including identifying a conflict of interest, prohibitions against controlling and directing curriculum and instruction, controls for the proper use of peer-review processes, and early and ongoing consultation with the Office of the General Counsel. The Department requires all employees to participate in annual training to ensure that they follow the policies described in the directive.

The policies and procedures used in the Race to the Top competition provide a recent example of the emphasis that the Department places on ensuring that grant competitions meet the highest standard of integrity. The Department has taken several actions to ensure that the Race to the Top competition peer review process is conducted in an objective manner free from conflicts of interest. A document that describes the steps the Department took to identify potential, direct, and indirect conflicts of interest, as well as the appearance of a conflict of interest, is available

on the Department's Web site at *http://www2.ed.gov/programs/racetothetop/application-review.html*.

ORIGINS OF U.S. DEFICIT

Mr. OBEY. Let me say, lastly, with respect to the education budget, I hope that you will give no ground—I would ask you to put chart number one up.

I would ask that you give no ground when people are suggesting that somehow the deficit is impacted in a major way by what we are doing in education.

As that chart shows, if you take a look at the deficit which was inherited this year by the Obama Administration, $5.1 billion of that—I mean $5.1—I can't read my own writing——

Secretary DUNCAN. I think it is trillion.

Mr. OBEY. Yes, it is $5.1 trillion. I read better with my glasses off. These are new glasses, and they are not worth you know what.

But $5.1 trillion of the 2009–2019 deficits were caused by tax cuts which were paid for with borrowed money and $1.8 trillion paid for by our entry into two wars, as I said yesterday, one I believe justified and one not. Then the economic collapse contributed $3 trillion to that deficit over that same period. Meanwhile, the Recovery Act—the entire American Recovery and Reinvestment Act, not just the education piece—the entire Recovery Act accounts for $1.1 trillion.

I would simply suggest I don't offer that chart to critique Administration performances, because you are not done yet. But what I do do is to offer it to simply suggest that, in judging whether debt is useful or not and whether deficits are useful or not, we have to differentiate between what the money was used for.

If the money was invested in items that simply add to economic consumption and immediate gratification, we have done ourselves no favor by borrowing that money. But if that money is used to invest in the long-term efforts to make this country independent from foreign oil, so we aren't shipping $400 billion a year to the Middle East to pay for our lack of foresight in energy; if we are investing in infrastructure that makes it cheaper to deliver products to market; if we are investing in education, which increases the competitiveness of our workforce and the quality of our individual lives, then those are investments worth making, provided that over time when the economy resumes its full level of performance, that we begin to pay that money back.

To me, that is the way to look at it; and I would urge the Administration to give no quarter in setting the record straight on that.

CHAIRMAN'S CLOSING REMARKS

With that, thank you for coming.

Secretary DUNCAN. Thank you for the opportunity. Thank you so much for your leadership and hard work.

[The following questions were submitted to be answered for the record of the hearing:]

QUESTIONS FROM THE SUBCOMMITTEE

MANAGEMENT

Mr. Obey: According to The Partnership for Public Service's *Best Places to Work* 2009 rankings, the Department ranked 27 out of 30 in overall job satisfaction. Are there any activities planned in FY 2010 or requested in FY 2011 that are targeted to improve the workforce environment and job satisfaction at the Department? If so, please list and explain these activities.

Secretary Duncan: In response to the relatively low levels of overall job satisfaction, the Department has implemented various strategies targeted at improving job satisfaction this fiscal year that will also continue during FY 2011. These include increased communication with employees, providing our supervisors with tools to improve the competencies needed to become more engaged and to lead better, and in October 2010 the Department will implement a new performance management system for our employees.

Some examples of the specific FY 2010 activities include:

Leadership Training and Development

- Human Capital Reviews – Established a senior-level organizational culture team that conducts quarterly reviews with senior leadership in each of the organizational components to focus on their workforce, survey results, and strategies on how to address any improvement opportunities.

- Leadership Development – Established a requirement for each of the organizational components to have a measure in their Organizational Assessment (OA) that emphasizes the importance of training and development for our leaders. Mandated that each supervisor, manager, and executive had a development plan in place by January 31, 2010 that focuses on closing Department-level competency gaps in the areas of building a performance culture and conflict management and specific organizational competency gaps.

- Education First Class Initiative – This initiative is being championed by Federal Student Aid on the key themes we identified for improvements (leadership, trust, transparency, communication and employee engagement, and improving our partnership with labor).

Communication

- Employee All Staff Meetings – Scheduled quarterly meetings with the Secretary to share with employees updates about programmatic and workforce issues.

- Colleague Acknowledgement Emails – Established an email box for colleagues to acknowledge each other's hard work in support of the mission by sending an e-mail to ThankYou@ed.gov. These are read by me and my Chief of Staff and periodically will be featured during my quarterly all staff meetings.

- OpenED Collaborative On-line Forum – Launched an online forum that allows employees the opportunity to collaboratively and transparently discuss and identify the best topics to engage in ongoing, productive discussion about ideas that enhance the work of the Department by drawing upon the institutional knowledge of all our employees. A peer OpenED Reading Committee reviews and recommends ideas to be further reviewed by the specific program office for implementation.

Performance Culture

- New Employee Performance Management System – Collaborating with the union to design a new employee performance management system for the FY 2011 performance cycle.

Employee Development

- Training Needs Assessment - Conducted a Department-wide training needs assessment of 10 organizational components to identify common and unique requirements to help focus training and development needs that can be addressed through instructor-led or available through online training. Training of supervisors was the primary need identified across the components, along with building trust, maintaining integrity, and building cohesive partnerships across the organization.

- Competency Assessment - Conducted assessments for the Department's mission critical occupations to identify strategic competency gaps and provide targeted training to address them.

- Tuition Reimbursement Program – Continue to support higher education learning through the reimbursement of tuition for courses strategically linked to an employee's current job to help attain organizational performance goals. For FY 2010, the Department has reimbursed 83 employees for training totaling $150,000.

- Mentoring Program - Announced 2010-2011Mentoring@ED program to give employees an opportunity to enhance their careers through the development of a dynamic mentoring partnership experienced through a formal, structured program.

During FY 2011 the Department will continue implementing the strategies previously mentioned to create an environment of trust throughout the Department and to continue developing supervisors and managers. As demonstrated by the results from our 2009 Annual Employee Survey, several of our 10 lowest scoring questions increased from our 2008 results, as a result of efforts.

FTE ALLOCATED TO RACE TO THE TOP

Mr. Obey: The FY 2011 budget request includes large FTE increases in many principal offices. Please provide further detail on how the additional 50 FTE will provide technical assistance to States regarding the Race to the Top program. Please provide the number of FTE that is currently allocated to the Race to the Top program and its first award cycle.

Secretary Duncan: The 50 FTE requested for the Race to the Top program will support a new approach to grants management, transitioning the Department from an organization focused on compliance monitoring to an organization adept at both supporting States in achieving their educational goals and holding States accountable for meeting educational goals, financial requirements, and legal obligations. The Race to the Top initiative will serve as the pilot for this new approach. Most of the FTE will serve on State teams to provide dedicated technical assistance. Dedicated technical assistance will mean staff having knowledge of each State's capacity, assets, and deficits, using all available tools to provide support and incentives to improve performance. Eventually, the role of these State teams may be expanded to include other Department programs.

The State team is envisioned as the first level of support for a State. Each State would have a dedicated team empowered to provide support, deploy ED resources to help solve problems, withhold funds, and grant waivers -- all within appropriate and well-specified guidelines. State teams would be supported by two types of experts. First, there would be program specialists, who would be brought in to consult/advise when there were questions related to a particular program (e.g., Title I). Second, there would be small support teams expert at evaluation, database design and mining, codifying promising practices, building and supporting active communities of practice (across States and within States), providing technology platforms to support dissemination and replication activities, and so on. Thus, these State teams would be responsible, not only for the success of the States they served, but also for the fast and effective dissemination and sharing of promising practices across States.

To implement this plan will require the resources outlined below. The majority of these people are new hires because the Department does not currently have the capacity or the skills needed to undertake this new work with current staff alone.

The new staffing resources it would take to implement this plan are estimated as follows:

- Executive and regional management/support (~5-7)

- State teams (~30-35 -- approximately 1-2 people per State team, approximately 20 State teams)

- Program specialists (no new hires; we would use existing staff for this work)

- Support specialists:
  - Technical/Data (~2-3)
  - Evaluation (~1-2)
  - Knowledge Management (~2-3)
  - Community Building (~2-3)

There are currently 20 FTE allocated to the Race to the Top program during its first award cycle.

FY 2011 BUDGET REQUEST FOR OFFICE OF THE SECRETARY

Mr. Obey: Please provide a more detailed explanation for the increase in the Office of the Secretary.

Secretary Duncan: The increase of 7 FTE in the office of the Secretary will be for continuing to administer programs in the State Fiscal Stabilization Fund ARRA account, as well as providing support for newly authorized funding of Race to the Top and Investing in Innovation. These FTE are necessary to perform key activities such as planning, monitoring, technical assistance, reporting, and risk mitigation (i.e., helping ensure that the programs achieve their intended outcomes).

FY 2009 DEPARTMENT OF EDUCATION EXPENDITURES FOR OVERTIME

Mr. Obey: Please provide for the record a table that shows all funds expended by ED for overtime in 2009. Include office, the number of employees receiving overtime in that office, and overtime amount.

Secretary Duncan: The table below displays all funds expended by ED for Overtime in 2009 by office and the number of employees receiving overtime in that office.

Office	Overtime Amount	Number of Employees
Advisory Committee on Student Financial Assistance	0	0
Chief Financial Officer	$29	17
Chief Information Officer	44	14
Civil Rights	0	0
Communications and Outreach	6	1
Deputy Secretary	0	0
Elementary and Secondary Education	1	3
English Language Acquisition, Language Enhancement, and Academic Achievement for Limited English Proficient Students	0	0
Federal Student Aid	57	36
General Counsel	7	1
Innovation and Improvement	2	1
Inspector General	3	9
Institute of Education Sciences	0	0
Legislation and Congressional Affairs	1	1
Management	7	11
Planning, Evaluation, and Policy Development	5	3
Postsecondary Education	2	2
National Assessment Governing Board	0	0
National Board for Education Sciences	0	0
National Institute for Literacy	0	0
Safe and Drug-Free Schools	3	3
Secretary	130	28
Special Education and Rehabilitiative Services	7	1
Under Secretary	0	0
Vocational and Adult Education	1	1
Total	305	132

Notes:
Amounts are in thousands of dollars.
Office of the Inspector General data excludes special law enforcement availability pay recorded as overtime.

FY 2009 DEPARTMENTOF EDUCATION COMPENSATION EXPENDITURES

Mr. Obey: Please also provide a similar table with compensation time levels.

Secretary Duncan: The table below displays the Compensation time levels in hours by office, the number of employees receiving compensation time in that office, and the equivalent dollar level of the compensation time in that office.

Office	Hours	Number of Employees	Equivalent Dollar Level
Advisory Committee on Student Financial Assistance	0	0	0
Chief Financial Officer	1,560	97	$80
Chief Information Officer	1,969	63	93
Civil Rights	4,067	253	178
Communications and Outreach	2,011	50	84
Deputy Secretary	25	1	1
Elementary and Secondary Education	2,213	99	93
English Language Acquisition, Language Enhancement, and Academic Achievement for Limited English Proficient Students	71	6	3
Federal Student Aid	5,026	229	224
General Counsel	4	1	1
Innovation and Improvement	434	31	15
Inspector General	1,015	78	45
Institute of Education Sciences	143	19	7
Legislation and Congressional Affairs	70	9	3
Management	914	38	41
Planning, Evaluation, and Policy Development	1,289	49	54
Postsecondary Education	133	16	5
National Assessment Governing Board	65	2	2
National Board for Education Sciences	0	0	0
National Institute for Literacy	197	8	6
Safe and Drug-Free Schools	1,301	38	60
Secretary	990	36	41
Special Education and Rehabilitiative Services	2,765	107	128
Under Secretary	0	0	0
Vocational and Adult Education	567	42	27
Total	26,827	1,272	1,192

Note: Equivalent dollar levels are in thousands of dollars.

STUDENT AID ADMINISTRATION – OVERSIGHT AND ECASLA

Mr. Obey: Mr. Secretary, in a February 25, 2009 NY Times article, you stated that there would be a complete report on the implementation of the Ensuring Continued Access to Student Loans (ECASLA) programs by June 30, 2009. Was such a report prepared; and if so, please summarize its findings.

Secretary Duncan: The Department has prepared weekly reports on the ECASLA (Ensuring Continued Access to Student Loans Act of 2008) Implementation. These reports are provided and discussed with congressional staff and provided to the Congressional Budget Office, the General Accountability Office and other agencies. The reports include information, by lender and in summary, of all participations interests sold, loan purchases, and conduit balances and purchases for both 2008-2009 and 2009-2010. Additional information was also provided in the 2010 and 2011 President's Budgets. The Administration is currently preparing an additional report on the ECASLA programs through FY 2010. We will deliver this to Congress upon its release.

Below is the executive summary on ECASLA implementation and summary by participant as of April 14, 2010.

Executive Summary			
	Total Through 4/13/10	**Total Through 4/6/2010**	**Net Change**
2007 - 2008 Short Term Purchase Program: - FINAL			
Total # Funded	8	8	-
Total $ Value of Loans	$ 1,028,809,368	$ 1,028,809,368	$ -
Total $ Amount of Purchase (97%) Funded	$ 997,945,088	$ 997,945,088	$ -
Total $ Principal of Loans	$ 1,007,856,408	$ 1,007,856,408	
# of Loans Funded	280,506	280,506	-
2008 - 2009 Participation Program: - FINAL			
# of Approved Sponsors	27	27	-
Total $ Requested	$ 33,375,751,248	$ 33,375,751,248	$ -
Total # of Purchase Requests	528	528	-
$ Balance in Participation	$ -	$ -	$ -
Total $ Participated	$ 33,359,225,064	$ 33,359,225,064	$ -
Total # of Purchase Requests Participated	528	528	-
$ Participated PUT to Purchase Program	$ 31,272,236,021	31,272,236,021	-
% Participated PUT to Purchase Program	93.74%	93.74%	0.00%
2008 - 2009 Purchase Program: - FINAL			
# of Approved Lenders	107	107	-
# of 45 Day Notices	428	428	-
$ of 45 Day Notices	$ 53,440,406,604	$ 53,440,406,604	$ -
# of Loans	11,883,530	11,883,530	-
# of 45 Day Notices Rescinded	2	2	-
$ of 45 Day Notices Rescinded	$ 300,861,403	$ 300,861,403	$ -
# of Loans	78,846	78,846	-
Total # of PUTs Funded	426	426	-
Total $ of PUTs Funded	$ 48,528,839,688	$ 48,528,839,688	$ -
Total # of Loans	11,591,639	11,591,639	-
$ of PUTs from Participation	$ 31,272,236,021	$ 31,272,236,021	$ -
% of PUTs from Participation	64.44%	64.44%	0.00%
$ of Straight PUTs	$ 17,256,603,666	$ 17,256,603,666	$ -
% of Straight PUTs	35.56%	35.56%	0.00%

	Total Through 4/13/10	Total Through 4/6/2010	Net Change
2008 - 2009 FFEL Put Summary - (09 AY disbursement $ continues to update)			
$ of 2009 AY FFEL Disbursements	$ 63,409,896,840	$ 63,409,896,840	$ -
$ of Disbursed 2009 AY FFEL Loans Put via the Purchase Program (Principal Balances only)	$ 46,118,709,954	$ 46,118,709,954	$ -
% of Disbursed 2009 AY FFEL Loans Put via the Purchase Program	72.73%	72.73%	0.00%
2009 - 2010 FFEL Participation Summary			
$ of 2010 AY FFEL Disbursements	$ 46,997,366,653	$ 46,997,366,653	$ -
$ of 2010 AY Participations	$ 31,181,768,741	$ 30,755,825,064	$ 425,943,677
% of AY FFEL Disbursements funded via Participation Interests	66.35%	65.44%	0.91%
2009 - 2010 FFEL Put Summary			
$ of 2010 AY FFEL Disbursements	$ 46,997,366,653	$ 46,997,366,653	$ -
$ of Disbursed 2010 AY FFEL Loans Put via the Purchase Program (includes all fees / interest)	$ 6,821,701,304	$ 6,804,221,090	$ 17,480,214
% of Disbursed 2010 AY FFEL Loans Put via the Purchase Program	14.52%	14.48%	0.04%

2003 - 2009 ABCP (Conduit):			
# of Conduit LIDs Activated	17	17	-
$ CP Expected Funding Notices	$ 52,485,000,000	$ 52,485,000,000	$ -
$ CP Advances Released	$ 33,907,334,785	$ 33,333,168,839	$ 574,165,946
	$ 31,969,914,097	$ 31,969,914,097	$ -
# PUT Notices Received	391	391	-
$ PUT Notices Received	$ 1,083,079,782	$ 1,083,079,782	$ -
# PUT Notices Canceled by SPV	146	141	5
$ PUT Notices Canceled by SPV	$ 375,139,343	$ 358,056,110	$ 17,083,233
# PUT Notices Funded	187	176	11
$ PUT Notices Funded	$ 272,098,960	$ 260,754,369	$ 11,344,591
# PUT Notices Pending	58	74	(16)
$ PUT Notices Pending	$ 116,603,796	$ 157,414,475	$ (40,810,679)

	Total Through 4/13/10	Total Through 4/6/2010	Net Change
2009 - 2010 Participation Program:			
# of Approved Sponsors	30	30	-
# of Sponsors in Review	-	-	-
# of Sponsors with no MLSA	5	5	-
Forecasted Total $ Disbursements	$ 36,276,635,500	36,752,119,532	(475,484,032)
Total $ Requested	$ 31,441,064,273	$ 31,154,344,109	$ 286,720,164
Total # of Purchase Requests	588	578	10
$ Balance in Participation (3/31/10)	$ 26,198,715,534	$ 26,198,715,534	$ -
Total $ Participated	$ 31,181,768,741	$ 30,755,825,064	$ 425,943,677
Total # of Purchase Requests Participated	586	573	13
$ Participated PUT to Purchase Program	$ 1,573,330,975	$ 1,573,330,975	$ -
% Participated PUT to Purchase Program	5.05%	5.12%	-0.07%
2009 - 2010 Purchase Program:			
# of Approved Lenders	62	58	4
# of Lenders In Review	10	6	4
Forecasted $ PUT from Participation	$ 34,167,300,533	$ 33,060,188,236	$1,107,112,297
Forecasted # of Loans PUT from Participation	7,653,432	6,381,247	1,272,185
# of 45 Day Notices	79	72	7
$ of 45 Day Notices	$ 12,506,517,932	$ 10,581,919,508	$1,924,598,424
# of Loans	2,487,008	2,125,280	361,728
# of 45 Day Notices Rescinded	-	-	-
$ of 45 Day Notices Rescinded	$ -	$ -	$ -
# of Loans	-	-	-
Total # of PUTs Funded	50	49	1
Total $ of PUTs Funded	$ 6,821,701,304	$ 6,804,221,090	$ 17,480,214
Total # of Loans	1,404,226	1,400,627	3,599
$ of PUTs from Participation	$ 1,573,330,975	$ 1,573,330,975	$ -
% of PUTs from Participation	23.06%	23.12%	-0.06%
$ of Straight PUTs	$ 5,248,370,329	$ 5,230,890,116	$ 17,480,214
% of Straight PUTs	76.94%	76.88%	0.06%
Total # of PUTs Pending	29	23	6
Total $ of PUTs Pending	$ 4,469,763,219	$ 2,562,969,506	$1,906,793,713
Total # of Loans of PUTs Pending	932,593	574,486	358,107
$ of PUTs Pending from Participation	$ 580,520,803	$ 580,520,803	$ -
% of PUTs Pending from Participation	12.99%	22.65%	-9.66%
$ of Straight PUTs Pending	$ 3,889,242,416	$ 1,982,448,703	$ 1,906,793,713
% of Straight PUTs Pending	87.01%	77.35%	9.66%

Summary by Participant

Lender	2008 - 2009 Participation Interests Sold	2008 - 2009 Loan Purchases	2007 - 2008 Loan Short Term Purchases*	2003 - 2009 Conduit (ABCP) Funding Note Balances	2003 - 2009 Conduit (ABCP) Purchases	2009 - 2010 Participation Interests Sold	2009 - 2010 Loan Purchases
1st Community Federal Credit Union	$ -	$ 6,473,208	$ -	$ -	$ -	$ -	$ -
Access Group	907,335,360	469,444,899	-	770,224,504	1,278,014	944,294,736	-
ALL Student Loan Corp	308,287,226	310,624,547	-	-	-	213,787,949	98,515,204
Alva State Bank	-	1,439,947	-	-	-	-	-
Arkansas Student Loan Authority	-	59,112,361	-	-	-	-	-
Anchor Bank, FSB	-	34,539,359	-	-	-	-	50,274,508
Androscoggin Bank	-	9,509,340	-	-	-	-	-
Austin Bank	-	27,981,969	-	-	-	-	-
Arvest Bank	-	211,602,395	-	-	-	-	-
Baptist Credit Union	-	1,893,200	-	-	-	-	-
BancFirst	-	122,887,058	-	-	-	-	-
Bank of America Corp	-	1,531,352,011	-	-	-	-	-
BCM Federal Credit Union	-	261,748	-	-	-	-	-
Black Hills Federal Credit Union	-	4,728,022	-	-	-	-	-
BONY MELLON ELT LELA	-	-	-	-	-	104,498,094	-
Bremer Bank	-	58,390,921	-	-	-	-	-
Cadence Bank N.A.	-	9,336,355	-	-	-	-	-
Citizens Bank of Pennsylvania	-	363,174,907	-	-	-	-	-
College Foundation, Inc. (SEAA)	-	-	-	741,684,886	-	826,820,056	-
CollegeInvest	130,119,860	264,735,264	-	-	-	190,916,964	-
Colonial Savings, F.A	-	1,186,564	-	-	-	-	-
Commerce Bank	-	4,830,110	-	-	-	-	-
Compass Bank	-	191,506,019	-	-	-	-	-
Coppermark Bank	-	3,785,822	-	-	-	-	-
EdAmerica	1,612,978,923	1,576,638,619	7,273,889	-	-	1,314,174,241	1,027,121,165

Lender	2008 - 2009 Participation Interests Sold	2008 - 2009 Loan Purchases	2007 - 2008 Loan Short Term Purchases*	2003 - 2009 Conduit (ABCP) Funding Note Balances	2003 - 2009 Conduit (ABCP) Purchases	2009 - 2010 Participation Interests Sold	2009 - 2010 Loan Purchases
Education Services Foundation	$ -	$ -	$ -	$ -	$ -	$ 91,977,184	$ 1,287,359
Finance Authority of Maine	-	-	-	-	-	-	-
First Bank and Trust	-	5,736,939	-	-	-	-	-
First Community Credit Union	-	1,722,584	-	-	-	-	-
First Dakota National Bank	-	3,427,460	-	-	-	-	-
First National Bank of Central Texas	-	11,947,846	-	-	-	-	-
First National Bank and Trust Co. of McAlester	-	1,289,640	-	-	-	-	-
First Financial Bank, NA	-	89,011,363	-	-	-	-	-
First National Bank of Oklahoma	-	5,929,631	-	-	-	-	-
First National Bank of Texas (includes First Convenience Bank)	-	57,014,134	-	-	-	-	85,385,047
First National Bank and Trust Co. of Weatherford	-	4,342,776	-	-	-	-	-
First National Bank of Wichita Falls	-	6,643,430	-	-	-	-	-
First National of Huntsville	-	16,096,585	-	-	-	-	-
First Premier Bank	-	3,283,899	-	-	-	-	-
First Security Bank	-	22,829,799	-	-	-	-	-
First Tennessee Bank National Association	-	124,204,905	-	-	-	-	-
First Texoma National Bank	-	4,485,885	-	-	-	-	-
Fort Hood National Bank	-	1,376,843	-	-	-	-	-
Fort Worth Community Credit Union	-	867,789	-	-	-	-	-
Georgia Student Finance Authority	-	35,582,488	12,795,419	-	-	47,619,613	53,291,267
Graduate Leverage	30,797,626	30,642,195	-	-	-	25,022,983	-

Lender	2008 - 2009 Participation Interests Sold	2008 - 2009 Loan Purchases	2007 - 2008 Loan Short Term Purchases*	2003 - 2009 Conduit (ABCP) Funding Note Balances	2003 - 2009 Conduit (ABCP) Purchases	2009 - 2010 Participation Interests Sold	2009 - 2010 Loan Purchases
Herring Bank	$ -	$ 34,550,972	$ -	$ -	$ -	$ -	$ 5,965,168
Higher ED Ln Auth of the State	682,471,418	727,285,576	-	291,494,991	-	360,022,327	-
Home Federal Bank	-	5,080,532	-	-	-	-	-
Illinois Student Assistance	-	83,280,910	-	-	-	-	-
Iowa Student Loan Liquidity Corp	144,846,241	137,521,680	-	575,723,466	8,872,576	142,687,887	-
JPMorgan Chase Bank	-	2,457,098,372	-	-	-	-	671,947,255
KeyBank National Association	167,593,042	495,174,332	-	-	-	-	346,190,043
KYHESLC	481,796,375	427,937,268	-	-	-	518,060,757	-
Legend Bank, NA	-	1,009,337	-	-	-	-	-
Maine Education Services	-	32,024,384	-	-	-	-	-
Midwestern University	-	-	-	-	-	55,619,480	-
Mississippi Higher Education Asst. Corp (MHEAC)	244,195,136	248,571,012	-	-	-	47,248,725	852,160
Mobil Oil Federal Credit Union	-	1,417,722	-	-	-	-	-
National Education Financing II	13,859,358	13,334,647	-	-	-	116,691,357	67,429,514
National Education Loan Network (NELNET)	2,185,689,719	2,265,464,257	996,155	1,384,819,289	-	1,442,185,281	-
New Hampshire Higher Education (NHHELCO)	184,108,621	185,815,280	-	-	-	54,852,676	-
New Mexico Educational Assistance Foundation	-	-	-	-	-	153,260,331	-
Northstar Bank of Texas	-	2,785,204	-	-	-	-	-
Northstar Education Finance	217,233,641	207,899,910	-	-	-	-	-
Northwest Savings Bank	-	21,325,300	-	-	-	-	-
North Texas Higher Education Authority, Inc.	-	-	13,076,173	-	-	-	-
Norway Savings Bank	-	13,172,983	-	-	-	-	-

Lender	2008 - 2009 Participation Interests Sold	2008 - 2009 Loan Purchases	2007 - 2008 Loan Short Term Purchases*	2003 - 2009 Conduit (ABCP) Funding Note Balances	2003 - 2009 Conduit (ABCP) Purchases	2009 - 2010 Participation Interests Sold	2009 - 2010 Loan Purchases
Oklahoma City University	$ -	$ 3,314,370	$ -	$ -	$ -	$ -	$ -
Oklahoma Student Loan Authority	18,973,819	19,921,556	-	309,766,352	8,708,660	19,340,237	-
Panhandle-Plains Student Finance Corp	50,577,047	61,177,983	-	-	-	-	-
PHEAA	-	-	-	751,560,165	12,299,237	-	-
PHEAA II	-	-	-	426,642,214	1,847,152	-	-
PHEAA III	-	-	-	181,038,216	834,864	-	-
Petit Jean State Bank	-	529,925	-	-	-	-	-
Pinnacle Bank	-	940,164	-	-	-	-	-
RBS Citizens, NA	-	633,795,254	-	-	-	-	-
Rhode Island Student Loan Authority	177,402,254	96,643,438	-	68,754,265	-	228,708,326	-
SC Student Loan Corporation	245,117,834	-	-	369,843,820	-	662,185,086	-
Simmons First National Bank	-	77,790,870	-	-	-	-	-
Smart Financial Credit Union	-	17,988,734	-	-	-	-	17,480,213
SLM Education Credit Finance Corp.	20,212,971,803	19,548,055,850	951,648,033	14,682,374,009	230,085,076	18,127,454,308	-
Southern Methodist University	-	7,261,183	-	-	-	-	-
Stillwater National Bank & Trust	-	6,767,660	-	-	-	-	-
Student Funding Group	-	129,892,342	12,155,418	9,444,452	-	-	-
Student Lending Works	26,431,075	26,637,435	-	-	-	34,974,992	-
SunTrust Bank	-	275,471,939	-	-	-	-	-
Surety Loan Funding Company	-	19,711,394	-	-	-	-	-
Texas Bank	-	10,190,351	-	-	-	-	-
Texas Christian University	-	5,709,846	-	-	-	-	-
Texas First State Bank	-	837,158	-	-	-	-	-

Lender	2008 - 2009 Participation Interests Sold	2008 - 2009 Loan Purchases	2007 - 2008 Loan Short Term Purchases*	2003 - 2009 Conduit (ABCP) Funding Note Balances	2003 - 2009 Conduit (ABCP) Purchases	2009 - 2010 Participation Interests Sold	2009 - 2010 Loan Purchases
Texas Tech Federal Credit Union	$ -	$ 23,255,531	$ -	$ -	$ -	$ -	$ 22,691,792
Texas Trust Credit Union	-	542,864	-	-	-	-	-
Three Rivers Federal Credit Union	-	6,078,048	-	-	-	-	5,537,163
The Student Loan Corporation (CITI)	2,898,053,391	2,782,180,469	-	10,426,856,345	-	4,593,818,418	322,862,630
University Federal Credit Union	-	105,469,938	-	-	-	-	-
University of Oklahoma Lew Wentz Foundation	-	13,103,989	-	-	-	-	-
The University of Tulsa	-	5,861,734	-	-	-	-	-
US Bank	-	1,637,072,267	-	-	-	-	278,105,761
USC Credit Union	100,617,560	128,522,721	-	-	-	108,404,652	-
Utah Higher Education Assistance Authority	423,235,777	442,272,896	-	-	-	397,889,405	-
Vermont Student Assistance Corporation (VSAC)	-	-	-	215,348,479	-	322,860,985	-
Wachovia Education Finance	1,894,531,960	5,015,054,769	-	-	-	-	1,717,892,824
Wakefield Co-operative Bank	-	2,098,834	-	-	-	-	1,830,560
Wells Fargo ELT NTHEA/HESC	-	-	-	-	-	36,391,693	25,100,083
Wells Fargo ED Services of America	-	-	-	764,338,645	8,173,380	-	-
Wells Fargo Education Financial Services	-	4,372,067,657	-	-	-	-	2,021,941,589
Totals	**33,359,225,064**	**48,528,839,688**	**997,945,088**	**31,969,914,097**	**272,098,960**	**31,181,768,741**	**6,821,701,304**
* Price is 97 percent of the total of the outstanding principal balance plus accrued but unpaid interest as of the purchase date.						**GRAND TOTAL**	**153,131,492,941**
				$ ED capital in market from ALL Puts			**$56,620,585,039**
				$ ED capital in market in 9/10 Part. balance			**$26,198,715,534**
					Total $ ED capital in Market		**$82,819,300,573**

ADMINISTRATIVE COSTS OF ECASLA PROGRAM

Mr. Obey: Please provide the actual administrative funds spent to date related to the ECASLA programs. In addition, please provide the corresponding assumptions that were originally made regarding the cost of these functions.

Secretary Duncan: From August 2008 to February 2010 $89 million has been spent towards administrative costs associated with servicing FFEL loans under the ECASLA programs (2007-2008 Short-Term Purchase Program; 2008-2009 Loan Participation Program, 2008-2009 Loan Purchase Program; 2009-2010 Loan Participation Program, 2009-2010 Loan Purchase Program).

Administrative Cost of ECASLA Programs—August 2008 to February 2010

	Costs
CSB FFEL Loans Operating Cost	$ 51,153,950
CSB FFEL Loans Transfer Cost	$ 10,935,685
TIVAS FFEL Loans Operating Cost (All 4 Servicers)	$ 27,122,527
Total	**$ 89,212,162**

Note: The above costs are associated with servicing FFEL loans solely. An additional $2,084,845 was spent on non-operational costs for system improvements.

ASSUMPTIONS UNDERLYING ORIGINAL ADMINISTRATIVE COST ESTIMATES FOR ECASLA PROGRAMS

When originally estimating the cost of the ECASLA programs, several assumptions were made in order to estimate the administrative cost. The key assumptions were:

- Borrower accounts: Number of borrower accounts was calculated by using $8,740 as the average dollar account size per borrower divided into projected dollar volume for all ECASLA programs. The projected dollar value was reported by lenders to the Department.

- Average unit price per borrower account: The average monthly unit price depends on contract terms and distribution of accounts by status (e.g., In-school, In-Grace/Repayment, Deferment/Forbearance, Delinquency). Originally, it was assumed that 92% of accounts would be In-School and 8% of accounts would be in In-Grace/Repayment. This resulted in an average unit price of $1.57 in 2009 and $1.21 in 2010.

- Average number of months that accounts would be serviced: This assumption, which tied closely to the timing of ECASLA loan purchases, was important in estimating the first year's cost of ECASLA programs. It was originally assumed that, during 2009, the Department would, on average, service 2007-2008 Short-Term Purchase Program loans for 11.5 months, 2008-2009 Loan Participation Program loans for 4 months, and 2008-2009 Loan Purchase Program loans for 7.5 months. For 2010, it was originally assumed that the Department would, on average, service the incumbent programs for 12 months, the 2009-2010 Loan Participation Program for 4 months and the 2009-2010 Loan Purchase Program loans for 7.5 months.

STUDENT AID ADMINISTRATION – PERFORMANCE PLAN

Mr. Obey: With the passage of Higher Education reconciliation, Federal Student Aid will be in charge of disbursing and servicing all Federal Student Loans beginning in 2010. This will require an effective strategic plan to effectively prepare for this huge undertaking.

Public Law 105-244 requires the Secretary and Federal Student Aid's Chief Operating Officer to make available to the public, a performance plan for the Performance Based Organization for the succeeding 5 years that establishes measurable goals and objectives for the organization. That law also directs the Secretary and the Chief Operating Officer to consult with institutions of higher education, Congress, lenders, and other interested parties not less than 30 days prior to the implementation of the performance plan or revision.

When was the most recent 5-year plan published and what years did that plan cover; if a plan has not been submitted covering 2009 or 2010, when will it be submitted?

FEDERAL STUDENT AID FIVE-YEAR PLAN

Secretary Duncan: The most recent 5-year plan approved by the Department and published in March 2006 covered the period 2006 – 2010, and can be found at http://www2.ed.gov/about/offices/list/fsa/06-10performanceplan.pdf.

Pending Department approval, the target for publishing the Strategic Plan 2010-2015 is July 2010.

Mr. Obey: How does the Department plan to carry out the consultation with all parties designated by statute?

Secretary Duncan: In January, Federal Student Aid (FSA) started to build the strategic plan that will determine our direction for the next 5 years. McKinsey & Company was engaged to orchestrate the process within FSA and provide expertise in strategy development and organizational transformation. As part of this process, several external groups were interviewed to provide insight on the current student aid landscape

and to offer input on changes that may happen over the next 5 years. The insights that these groups provided influenced the draft 5-year plan for 2010-2015.

GROUPS CONSULTED DURING FSA FIVE-YEAR PLAN DEVELOPMENT

The following organizations have been consulted:

Advisory Committee on Student Financial Assistance: Allison G. Jones, Chairperson; Assistant Vice Chancellor, Academic Affairs, The California State University

Students: US PIRG; United States Students Association

Institutions of Higher Education: National Association of Student Financial Aid Administrators; American Council on Education

Congress: House Committee on Education and Labor (George Miller D-Calif., Chairman); Senate Committee on Health, Education, Labor & Pensions (Tom Harkin, D-IA, Chairman; Mike Enzi, R-WY, Ranking Member)

Guaranty Agencies: Student Loan Guarantee Foundation of Arkansas, California Student Aid Commission, EdFund, CollegeInvest, Nelnet Guarantor Solutions, in collaboration with College Assist, Florida Office of Student Financial Assistance, Georgia Student Finance Commission, Illinois Student Assistance Commission, Iowa College Student Aid Commission, Kentucky Higher Education Assistance Authority, Louisiana Office of Student Financial Assistance, Finance Authority of Maine, American Student Assistance, Michigan Higher Education Assistance Authority, Missouri Department of Higher Education, Montana Guarantee Student Loan Program, National Student Loan Program, New Hampshire Higher Education Assistance Foundation, New Jersey Higher Education Student Assistance Authority, New Mexico Student Loans, New York State Higher Education Services Corporation, North Carolina State Education Assistance Authority, Student Loans of North Dakota, Oklahoma Guaranteed Student Loan Program, American Education Services/PHEAA, Rhode Island Higher Education Assistance Authority, South Carolina Student Loan Corporation, Tennessee Student Assistance Corporation, Texas Guaranteed Student Loan Corporation, Utah Higher Education Assistance Authority, Vermont Student Assistance Corporation, Northwest Education Loan Association, Great Lakes Higher Education Guaranty Corporation, United Student Aid Funds, and Education Credit Management Corporation

Other interested parties: Council for Opportunity in Education

Pending Department clearance, a link to the 2010-2015 5-year performance plan will be available on the Department's web-site.

FSA FTE, PERSONNEL COMPENSATION AND BENEFITS

Mr. Obey: For Federal Student Aid, the FY 2010 appropriated amount and FY 2011 President's request assumes an increase of over 400 FTE or a 37 percent increase in staffing from FY 2009 through FY 2011. Given this large increase requested, the Committee realizes that FSA must increase its capacity to hire. For FSA, please provide FTE recruitment and attrition levels by month for the last 12 months. Include principal office, GS or ES level, starting pay and position description for all new hires, and GS or ES level, ending pay, and position description of all separations.

Secretary Duncan: Below is the list of new hires and separations by month for the last 12 months (April 2009-April 2010).

		Month-By-Month New Hires and Losses				
Action	Org Name	Date Effective	Pay Plan	Grade	Position Title Opm	Salary
Apr-09						
NEW HIRES	Business Operations	04/13/2009	AD	00	INFORMATION TECHNOLOGY SPECIALIST	$114,000
NEW HIRES	Business Operations	04/27/2009	AD	00	INFORMATION TECHNOLOGY SPECIALIST	80,000
LOSSES	Admin Services	04/11/2009	GS	15	SUPVY HUMAN RESOURCES SPECIALIST	140,969
LOSSES	CIO	04/13/2009	GS	06	PROGRAM SUPPORT ASSISTANT	40,792
LOSSES	Admin Services	04/19/2009	GS	08	PROGRAM SUPPORT ASSISTANT	45,639
May-09						
NEW HIRES	Admin Services	05/24/2009	GS	14	HUMAN RESOURCES SPECIALIST	$123,269
LOSSES	EPMS	05/09/2009	GS	11	PROCUREMENT SUPPORT SPECIALIST	60,989
LOSSES	Admin Services	05/23/2009	GS	13	MANAGEMENT & PROGRAM ANALYST	95,620
LOSSES	Admin Services	05/30/2009	GS	07	PROGRAM SUPPORT ASST (STEP)	41,210
LOSSES	Admin Services	05/30/2009	GS	04	PROGRAM SUPPORT CLERK (STEP)	29,736
LOSSES	Program Compliance	05/31/2009	GS	12	GUAR & LENDER REV SPEC	96,083
Jun-09						
NEW HIRES	Admin Services	06/01/2009	GS	04	PROGRAM SUPPORT CLERK (STEP)	$29,736
NEW HIRES	Admin Services	06/02/2009	GS	07	PROGRAM SUPPORT ASST (STEP)	41,210
NEW HIRES	Program Compliance	06/07/2009	GS	11	INSTITUTIONAL REVIEW SPECIALIST	76,350
NEW HIRES	Program Compliance	06/08/2009	GS	11	INSTITUTIONAL REVIEW SPECIALIST	63,397
NEW HIRES	Program Compliance	06/08/2009	GS	09	INSTITUTIONAL REVIEW SPECIALIST	71,520
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	29,736

Action	Org Name	Date Effective	Pay Plan	Grade	Position Title Opm	Salary
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	$29,736
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPPORT CLERK	29,736
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Admin Services	06/08/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
NEW HIRES	Admin Services	06/08/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
NEW HIRES	Admin Services	06/08/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
NEW HIRES	Admin Services	06/08/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
NEW HIRES	Admin Services	06/08/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
NEW HIRES	Admin Services	06/08/2009	GS	05	PROGRAM SUPPOST ASSISTANT	33,269
NEW HIRES	Admin Services	06/08/2009	GS	05	PROGRAM SUPPORT ASSISTANT	33,269
NEW HIRES	Admin Services	06/08/2009	GS	05	PROGRAM SUPPORT ASSISTANT	33,269
NEW HIRES	Admin Services	06/08/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Admin Services	06/08/2009	GS	07	PROGRAM SUPPORT ASSISTANT	41,210
NEW HIRES	Admin Services	06/08/2009	GS	05	PROGRAM SUPPORT ASSISTANT	33,269
NEW HIRES	Admin Services	06/15/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Program Compliance	06/21/2009	GS	12	AUDIT RESOLUTION SPECIALIST	73,100
NEW HIRES	CFO	06/21/2009	GS	14	ACCOUNTANT	102,721
NEW HIRES	CIO	06/22/2009	AD	00	IT SPECIALIST	91,000
NEW HIRES	CFO	06/22/2009	GS	13	ACCOUNTANT	98,518
NEW HIRES	C&O	06/29/2009	AD	00	CHIEF OPERATING OFFICER	177,000
LOSSES	Program Compliance	06/02/2009	GS	14	SUPV. CASE MGMT SPEC	132,382
LOSSES	EPMS	06/06/2009	GS	11	PROCUREMENT SUPPORT SPECIALIST	60,989

Action	Org Name	Date Effective	Pay Plan	Grade	Position Title Opm	Salary
LOSSES	EPMS	06/06/2009	GS	14	MANAGEMENT AND PROGRAM ANALYST	$106,145
LOSSES	EPMS	06/20/2009	AD	00	EXECUTIVE BUSINESS ADVISOR	118,734
LOSSES	Admin Services	06/20/2009	GS	14	HUMAN RESOURCES SPECIALIST (ER/LR)	109,570
LOSSES	Program Compliance	06/26/2009	GS	13	INSTI REVIEW SPECIALIST	101,844
Jul-09						
NEW HIRES	CFO	07/19/2009	GS	12	MANAGEMENT & PROGRAM ANALYST	$73,100
NEW HIRES	Business Operations	07/20/2009	AD	00	MANAGEMENT & PROGRAM ANALYST	73,100
LOSSES	CFO	07/01/2009	GS	12	ACCOUNTANT	87,717
LOSSES	Program Compliance	07/03/2009	GS	15	MANAGEMENT & PROG ANALYST	153,053
LOSSES	Business Operations	07/03/2009	GS	14	LEAD MGMT AND PROGRAM ANALYST	135,029
LOSSES	CFO	07/03/2009	GS	14	ACCOUNTANT	130,118
LOSSES	Admin Services	07/03/2009	GS	13	MANAGEMENT AND PROGRAM ANALYST	113,007
LOSSES	Business Operations	07/04/2009	GS	12	MANAGEMENT & PROG ANALYST	73,236
LOSSES	EPMS	07/04/2009	GS	12	MANAGEMENT/PROGRAM ANALYST	82,845
LOSSES	EPMS	07/17/2009	AD	00	MANAGEMENT AND PROGRAM ANALYST	122,069
LOSSES	CIO	07/18/2009	GS	15	SUPVY INFORMATION TECHNOLOGY SPEC.	140,969
LOSSES	CIO	07/18/2009	GS	14	MANAGEMENT & PROG ANALYST	133,543
LOSSES	EPMS	07/18/2009	GS	14	OPERATIONS RESEARCH ANALYST	102,721
LOSSES	Business Operations	07/20/2009	GS	11	MANAGEMENT & PROG ANALYST	60,989
LOSSES	EPMS	07/24/2009	AD	00	EXECUTIVE BUSINESS ADVISOR	135,182
LOSSES	Business Operations	07/31/2009	GS	13	MANAGEMENT & PROG ANALYST	109,152
LOSSES	Business Operations	07/31/2009	AD	00	SERVICE DIRECTOR	164,654
Aug-09						
NEW HIRES	Program Compliance	08/03/2009	GS	12	INSTITUTIONAL REVIEW SPECIALIST	$72,002

Action	Org Name	Date Effective	Pay Plan	Grade	Position Title Opm	Salary
NEW HIRES	Business Operations	08/17/2009	AD	00	MANAGEMENT & PROG ANALYST	$90,300
NEW HIRES	Students	08/17/2009	GS	09	MANAGEMENT & PROG ANALYST	50,408
LOSSES	Business Operations	08/01/2009	GS	14	MANAGEMENT & PROG ANALYST	133,543
LOSSES	Business Operations	08/02/2009	GS	13	MANAGEMENT & PROG ANALYST	104,314
LOSSES	CFO	08/03/2009	GS	07	OFFICE AUTOMATION ASSISTANT	46,705
LOSSES	Admin Services	08/07/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
LOSSES	Admin Services	08/07/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
LOSSES	Admin Services	08/14/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
LOSSES	Admin Services	08/14/2009	GS	05	PROGRAM SUPPORT ASSISTANT	33,269
LOSSES	Admin Services	08/14/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
LOSSES	Admin Services	08/14/2009	GS	04	PROGRAM SUPPPORT CLERK	29,736
LOSSES	Program Compliance	08/15/2009	GS	13	MANAGEMENT & PROG ANALYST	86,927
LOSSES	Admin Services	08/21/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
LOSSES	Admin Services	08/29/2009	GS	14	SUPVY HUMAN RESOURCES SPECIALIST	106,145
LOSSES	Business Operations	08/31/2009	GS	13	MANAGEMENT & PROG ANALYST	104,468
Sep-09						
NEW HIRES	Business Operations	09/13/2009	GS	09	MANAGEMENT & PROG ANALYST	$52,089
NEW HIRES	Business Operations	09/14/2009	GS	13	MANAGEMENT & PROG ANALYST	104,314
NEW HIRES	Students	09/14/2009	GS	09	MANAGEMENT & PROG ANALYST	50,408
NEW HIRES	Admin Services	09/27/2009	GS	06	PROGRAM SUPPORT ASSISTANT	38,320
NEW HIRES	Admin Services	09/27/2009	GS	08	PROGRAM SUPPORT ASSISTANT	45,639
NEW HIRES	COO	09/28/2009	AD	00	SENIOR ADVISOR FOR BUSINESS PRACTICES	176,500
NEW HIRES	COO	09/28/2009	AD	00	BUSINESS TRANSFORMATION OFFICER	170,000
NEW HIRES	EPMS	09/28/2009	GS	11	CONTRACT SPECIALIST	79,280

Action	Org Name	Date Effective	Pay Plan	Grade	Position Title Opm	Salary
NEW HIRES	EPMS	09/28/2009	GS	12	CONTRACT SPECIALIST	$95,026
NEW HIRES	EPMS	09/28/2009	GS	11	CONTRACT SPECIALIST	79,280
NEW HIRES	EPMS	09/29/2009	AD	00	GENERAL MANAGER FOR EPMS	175,000
LOSSES	Business Operations	09/17/2009	GS	13	INFORMATION TECHNOLOGY SPECIALIST	107,211
LOSSES	Business Operations	09/26/2009	GS	13	MANAGEMENT & PROG ANALYST	92,723
LOSSES	Admin Services	09/26/2009	GS	07	MANAGEMENT & PROG ANALYST	41,210
LOSSES	Program Compliance	09/30/2009	GS	13	GUARANTOR & LENDER REVIEW SPEC	117,009
LOSSES	Admin Services	09/30/2009	GS	04	PROGRAM SUPPORT CLERK (STEP)	29,736
LOSSES	Admin Services	09/30/2009	GS	03	PROGRAM SUPPORT CLERK	26,487
Oct-09						
NEW HIRES	CFO	10/11/2009	GS	14	ACCOUNTANT	$102,721
NEW HIRES	EPMS	10/11/2009	GS	09	CONTRACT SPECIALIST	52,089
NEW HIRES	Admin Services	10/11/2009	GS	13	HUMAN RESOURCES SPEC (CLASSIFICATION)	86,927
NEW HIRES	CFO	10/13/2009	GS	07	ACCOUNTANT (CAREER INTERN)	41,210
NEW HIRES	CFO	10/13/2009	GS	07	ACCOUNTANT (CAREER INTERN)	41,210
NEW HIRES	EPMS	10/13/2009	GS	11	CONTRACT SPECIALIST	79,280
NEW HIRES	COO	10/19/2009	EF	00	CONSULTANT	73
NEW HIRES	Admin Services	10/25/2009	GS	15	SUPVY HUMAN RESOURCES SPECIALIST	132,914
NEW HIRES	CFO	10/26/2009	GS	05	ACCOUNTANT (CAREER INTERN)	42,142
NEW HIRES	CFO	10/26/2009	GS	14	INFORMATION TECHNOLOGY SPECIALIST	116,419
NEW HIRES	Admin Services	10/26/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
NEW HIRES	Admin Services	10/26/2009	GS	04	PROGRAM SUPPORT CLERK	29,736
LOSSES	Business Operations	10/03/2009	GS	11	LOAN ANALYST	76,052
LOSSES	CFO	10/05/2009	GS	13	ACCOUNTANT	92,723

WEDNESDAY, APRIL 21, 2010.

FY 2011 BUDGET OVERVIEW: DEPARTMENT OF HEALTH AND HUMAN SERVICES

WITNESS

HON. KATHLEEN SEBELIUS, SECRETARY

OPENING STATEMENT BY CONGRESSMAN OBEY

Mr. OBEY. Well, good morning, Madam Secretary. Sorry to be late. I don't really have any good excuse. I just got involved in some things.

Secretary SEBELIUS. I don't think the chairman is ever late, sir.

Mr. OBEY. Well, I think so. I detest being late.

Anyway, let me welcome you here today. It is good to have you at a historic time, as you and your department begin to implement the health reform legislation we just passed. That debate has been going on a long time, and the Congress and the President have finally made some decisions. And, to me, the job at hand now is to try to implement it, make it work, see whether adjustments need to be made down the line, and make certain that it develops in a way which is beneficial to the American people.

In this subcommittee, we have been doing a number of things to make health care more accessible, more affordable, and more effective. In the Recovery Act, for instance, we accelerated those efforts. For example, we have been expanding education and training programs to address the shortage of nurses, primary care doctors, and other health professionals and to encourage more practitioners to go into primary care and to practice in places where they are most needed. As far as I am concerned, that means especially rural areas.

Our regular appropriation bills have increased funding for health professional programs by 35 percent over the past 4 years, and the Recovery Act included another $500,000,000 for that purpose.

Another focus has been on prevention. We have provided a billion dollars for prevention and wellness activities to jump-start new efforts in this area. I should add at this point that one of my special concerns is the area of hospital infections. It just seems to me that that has to be at the top of our list, in terms of priorities. We don't do people any favors if we give 30,000,000 people additional access to health care and then they wind up dying because of something that they caught in a hospital. That happens at a disgracefully high level lately, and I think we need to be very aggressive in doing something about it.

Our subcommittee has also emphasized medical research. That includes basic and applied research supported by the National Institutes of Health. It includes patient-centered health research to help practitioners decide which treatment works most effectively

for their patients and thereby improves outcomes. The Recovery Act added $1,100,000,000 to support a major expansion of patient-centered research.

Yet another priority has been to encourage a more widespread use of information technology and electronic health records to reduce medical errors and to make health-care delivery more efficient. In the 21st century, piles of paper are not the way we ought to be managing records that are vital to patient care. And, as you know, the Recovery Act included $19,000,000,000 to launch a major push for adoption of those technologies.

Finally, we have the need to combat fraud and abuse in health programs. We increased discretionary funding for this purpose by 57 percent last year to support a wide range of activities, from reviewing Medicare claims to prevent improper payments to conducting criminal investigations. We held a separate hearing on that issue several weeks ago.

While these and other health-care priorities are at center stage, HHS also has many other responsibilities. Its human services programs help families with access to child care, help low-income people pay their winter heating bills, and assist older Americans through programs like Meals on Wheels, to give just a few examples. The need for these services has grown during the current recession, and we have given the Department resources to respond in both the Recovery Act and our regular appropriations bills.

The President's budget request provides further increases in some high-priority areas, including biomedical research at NIH, child care, Head Start, mental health and substance abuse programs, and health fraud and abuse control.

On the other hand, I am not at all thrilled at the proposed 35 percent cut to LIHEAP, and I am also concerned that we are not yet well prepared to deal with public health emergencies like a flu pandemic or bioterrorism.

I should also mention again that the administration has put us in a box—not you, but, frankly, the White House has—by one aspect of their budget submission because they have left a very large hole to fill with respect to Pell grants. And if we are going to meet our obligations in that area, we need to have that problem addressed, or a lot of people's priorities, including the administration's, will suffer greatly.

So, with that, let me welcome you. I look forward to hearing from you. But first let me call on Mr. Tiahrt for whatever comments he might have.

Mr. TIAHRT. Thank you, Mr. Chairman.

As always, it is good to have Secretary Sebelius, the former Governor of Kansas, before the committee today. I have a great many questions for the Secretary, so, in the interest of time and the hope that we will get to at least two rounds of questions, I am going to be brief.

Like many Americans, I have some very serious concerns about the recently enacted government takeover of health care in this country, what many refer to as "Obama-care." I have concerns about what it will do to the quality of care people in this country currently receive, what it will do to small businesses and the peo-

ple who work for them. And I have concerns about what it will do to our already-hemorrhaging Treasury.

The level of spending authorized under this new law is breathtaking, not to mention the audacity of the Federal Government under this new law telling individual American citizens what they must do in regard to health insurance. Many of us opposed the new law and have serious concerns about what it means both in terms of the cost as well as the role of the government in health-care decisions.

Over the last 2 years, the President has made a number of promises regarding this new health-care law. On June 15th, 2009, the President said, "If you like your doctor, you will be able to keep your doctor, period. If you like your health-care plan, you will be able to keep your health-care plan, period. No one will take it away, no matter what." Well, with $130,000,000,000 in cuts to the Medicare Advantage plans, it sure seems like 11,000,000 seniors will be in jeopardy of losing their plan.

The President also said, on March 25th of this year, that if you already have insurance, this reform will make it more secure and more affordable. Apparently, that is true unless you are one of the millions of Americans who buy an individual policy that you like and want to keep.

I am also concerned about the pressure that the host of newly authorized programs will force on other important programs in this bill. There are at least $100,000,000,000 in specific authorizations that Congress will be expected to fund and countless billions in programs with wide, open-ended authorizations. We have no idea how high those costs will be.

I could go on, but the bottom line for me is: What was promised isn't what was delivered. I look forward to the opportunity to ask a few questions.

And I thank the chairman and yield back.

Mr. OBEY. Mr. Lewis.

Mr. LEWIS. Mr. Chairman, I would prefer to wait and listen to the Secretary and then ask questions.

Mr. OBEY. All right. Thank you.

Ms. Secretary, please proceed.

SECRETARY SEBELIUS OPENING STATEMENT

Secretary SEBELIUS. Well, thank you, Mr. Chairman. It is good to be here in the subcommittee with you, with Congressman Tiahrt, and other members of the subcommittee.

I want to thank you, first, for inviting me here today to talk about the 2011 budget, and I look forward to the opportunity to respond to questions. But I want to spend just a couple of minutes framing our budget, which I think advances the Department's central goals: improving the health of all Americans; expanding access to high-quality health care; and providing children, families, and seniors with the critical health services that give them a chance to thrive.

To do that, we have tried to make prudent investments that actually echo the goals that the members of this subcommittee have championed for years: attacking health-care fraud with new tools and more resources; a new focus on preventing chronic disease and

promoting wellness; emphasizing a reduction in medical errors and improving the overall quality of care; and strengthening our public health system so that we will be better prepared for new threats that come at us.

At a time when so many American families are trying to balance their own household budgets, we think it is appropriate that we not let taxpayer dollars go to waste. So the budget reflects the difficult, time-consuming work we have done over the last year to try to eliminate waste and fraud and focus our resources so they can make the biggest impact on Americans' lives.

Last month, you heard from our department's Deputy Secretary, Bill Corr, about some of the expanded efforts to identify, prosecute, and prevent health-care fraud as part of the new partnership with the Justice Department known as HEAT. And this budget, Mr. Chairman, builds on that progress. It adds new fraud-fighting funds to help us expand proven strategies, like putting Medicare fraud strike forces in cities that we know are hubs for fraudulent activities, and invests in promising new approaches like the systems that will help us analyze claims for suspicious activity in real time. When the budget takes effect, it is going to be a lot harder for criminals to get rich stealing from seniors and from the health-care system. And, over time, we believe the anti-fraud efforts will pay for themselves many times over.

The budget also takes aim at medical errors. We know that the quality of health care in America varies widely, and, most tragically, in the case of tens of thousands of Americans who die every year from health-care associated infections, many of which are preventable. Chairman Obey, you have been a national leader for eliminating these unnecessary deaths, and our budget is aimed at helping to do that by doubling the size of the CDC National Healthcare Safety Network to 5,000 hospitals.

You also mentioned the need to be ready for immunizations, and I want to thank you for your support of the CDC Section 317 immunization program, which we have asked to receive additional funds to make sure that all Americans have access to vaccines that are the best protection against some of our most dangerous diseases.

Investments like these will help make sure that Americans get the best possible care when they are sick, but we also have to do a much better job keeping Americans healthy in the first place. So this budget builds on the Recovery Act's significant investment in health information technology, which moves us closer to nationwide interoperability and helps providers make health IT part of their daily routine.

We try to build on the historic investment in prevention and wellness that Congress made last year in the Recovery Act with new efforts that will reduce the harmful effects of chronic disease in our cities and create a new health prevention corps and aim at preventing unintended pregnancies.

And because minorities and low-income Americans are likely to be sick and less likely to get the care they need, our fiscal year 2011 budget makes critical investments in areas like community health centers and HIV/AIDS prevention and treatment so we can

address the disparities that have plagued our health system and our country for far too long.

HHS has spent our Recovery Act funds responsibly, balancing the need for getting these dollars into the economy with assuring the proper stewardship of taxpayer dollars. By January 2010, HHS Recovery Act recipients reported having created at least 30,000 new jobs and saving millions of jobs. The April report period has not yet concluded, but we fully expect those numbers to rise. By the end of September, we fully expect to obligate the remaining $6,800,000,000 in Recovery Act discretionary dollars available for fiscal year 2010.

So these are just a few ways that our department will work to build a healthier America. At the same time, we will continue our work, which is already under way, to effectively implement many of the provisions in the historic health insurance reform legislation that Congress passed last month. The Affordable Care Act enshrines the principle that every American should have access to the health care they need. It also begins the transformation of our health-care system, with a wide range of new programs and incentives to promote the kind of coordinated, patient-centered, evidence-based care that has been shown to generate far better health outcomes.

These changes, along with the investments in our fiscal year 2011 budget, will mean that Americans getting access to care as part of the Affordable Care Act will be joining a health-care system that is more consumer-friendly, provides more security, and, more importantly, does a better job at keeping them healthy.

Those are the goals, but we cannot accomplish any of them alone. We rely on partners across the Federal Government and States and communities across the country. And no one has a more important role than those of you in the United States Congress.

So I want to thank you again for the opportunity to be here today, and I would be happy to respond to the questions.

[Prepared statement of Secretary Kathleen Sebelius follows:]

COMMITTEE ON APPROPRIATIONS

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES

10:00 a.m. – **Wednesday, April 21, 2010**

HEARING:
Secretary Kathleen Sebelius, Department of Health and Human Services

STATEMENT OF
KATHLEEN SEBELIUS
SECRETARY

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

THE PRESIDENT'S FISCAL YEAR 2011 BUDGET

BEFORE THE

SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES

COMMITTEE ON APPROPRIATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

APRIL 21, 2010

Chairman Obey, Representative Tiahrt, and Members of the Subcommittee, thank you for the invitation to discuss the President's Fiscal Year (FY) 2011 Budget for the Department of Health and Human Services (HHS).

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

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

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

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

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

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

This budget is a major step toward a healthier, stronger America. And it compliments the historic health insurance reform legislation that many of you helped pass last month.

The Patient Protection and Affordable Care Act (Affordable Care Act) will give Americans with insurance a new level of security by creating common sense rules that require insurance companies to treat them fairly.

It will make insurance affordable for millions of Americans by creating a new insurance marketplace and providing tax credits for those who need additional help.

And it will start to bring down costs for families, businesses, and governments with the broadest health care cost-cutting package ever.

As one of the federal government agencies implementing this law, my department is already working with partners across the country to make sure we carry out this law responsibly and effectively.

Our guiding principle as we do so is putting Americans back in charge of their health care. We will provide information and education if it's needed; set basic guidelines to help create competitive insurance markets; serve as an umpire to make sure insurance companies treat Americans fairly; and provide targeted resources to help empower consumers.

Investing in Prevention

Reducing the burden of chronic disease, collecting and using health data to inform decision-making and research, and building an interdisciplinary public health workforce are critical components to successful prevention efforts. In addition to what is in the President's Budget, the Affordable Care Act provides a significant investment in prevention through the Prevention and Public Health Fund for HHS to further its prevention efforts. This investment will allow HHS to expand and sustain efforts in prevention, wellness, and public health programs authorized within the Public Health Service Act to improve the health of the nation and help restrain health care costs.

The FY 2011 Budget reflects the HHS commitment to prevention. The Budget includes $20 million for the Centers for Disease Control and Prevention (CDC) Big Cities Initiative to reduce the rates of morbidity and disability due to chronic disease in up to 10 of the largest U.S. cities. These cities will be able to incorporate the lessons learned from implementing evidence-based prevention and wellness strategies of the American Recovery and Reinvestment Act of 2009 (Recovery Act) Communities Putting Prevention to Work Initiative. This Recovery Act initiative is key to promoting wellness and preventing chronic disease, and we appreciate the support of Congress in making these funds available. In March, HHS awarded $373 million for the cornerstone of this initiative, funding communities to implement evidence-based strategies to address obesity, increase physical activity, improve nutrition, and decrease smoking. The Big Cities Initiative requested in FY 2011 will allow us to build on the success of the Recovery Act. I'd like to particularly thank Chairman Obey for his leadership in providing funds for the CDC Section 317 Immunization program to provide many of the vaccines public health departments provide to children and adults. The FY 2011 Budget includes $579 million, an increase of $17 million, for the Section 317 program to increase vaccination coverage and to support States in obtaining reimbursement of immunization services provided to children with private health insurance.

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

To support teen and unintended pregnancy prevention and care activities in the Office of Public Health and Science and CDC, the Budget provides $222 million in funds. Of this,

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

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

Reducing Health Care Fraud

When American families are struggling to make every dollar count, we need to be just as vigilant about how their money is spent. That's why the Obama Administration is cracking down on criminals who steal from taxpayers, endanger patients, and jeopardize the future of our health insurance programs. It is also why Deputy Secretary Bill Corr welcomed the opportunity to testify before this Subcommittee on Combating Health Care Fraud and Abuse in March. We look forward to continuing to work with you to strengthen our efforts to reduce health care fraud.

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

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

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

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

The Budget also includes a set of new administrative and legislative program integrity proposals that will give HHS the necessary tools to fight fraud by enhancing provider enrollment scrutiny, increasing claims oversight, and improving Medicare's data analysis capabilities, which will save approximately $14.7 billion over 10 years. Along with the $9.9 billion in savings from the discretionary investments, these new program authorities will save nearly $25 billion in Medicare and Medicaid over 10 years.

Improving Quality of and Access to Health Care

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

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

For example, $110 million will support the first year of a comprehensive Health Care Data Improvement Initiative (HCDII) to transform CMS's data environment from one focused primarily on claims processing to one also focused on state-of-the art data analysis and information sharing. Without this funding CMS would not be able to transform Medicare and Medicaid into leaders in value-based purchasing and in data sources for privacy-protected patient-centered health research. This funding is imperative for CMS to meet the needs of future growth, financial accountability, and data content and availability. The HCDII is the cornerstone of a business strategy that will

optimize the delivery of efficient, high-quality health care services. CMS needs this funding to strengthen disaster recovery and security operations to protect against loss of data or services; to enable timely data sharing and analysis to fight fraud, waste, and abuse; and to transform payment processes to support quality outcomes.

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

The Budget includes an increase of $290 million to ensure better access to health centers through further expansions of health center services and integration of behavioral health into health centers' primary care system. This funding builds on investments made under the Recovery Act and will enable health centers to serve more than 20 million patients in FY 2011, which is 3 million more patients than were served in FY 2008. The Affordable Care Act provides $1 billion in FY 2011 to health centers to expand service capacity to underserved and uninsured patients and increase the comprehensive, culturally competent, quality primary health care services provided. In addition, the Affordable Care Act investments in construction and renovation of health center sites will expand health centers capacity to provide primary and preventive health services.

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

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

Promoting Public Health

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

The Budget includes over $3 billion, an increase of $70 million, for CDC and HRSA to enhance HIV/AIDS prevention, care, and treatment. This increase includes $31 million

to support the National HIV/AIDS Strategy currently under development and for CDC to integrate surveillance and monitoring systems, address high-risk populations, and support HIV/AIDS coordination and service integration with Viral Hepatitis, STDs, and TB. The increase also includes $40 million for HRSA's Ryan White program to expand access to care for underserved populations, provide life-saving drugs, and improve the quality of life for people living with HIV/AIDS.

To improve CDC's ability to collect data on the health of the Nation for use by policy-makers and Federal, State, and local leaders, the Budget provides $162 million for Health Statistics, an increase of $23 million above FY 2010. This increase will ensure data availability on key national health indicators by supporting electronic birth and death records in States and enhancing national surveys. CDC will support 10 states that have not begun implementing electronic birth records and will work with States to gradually phase in electronic death records through a 50-50 match.

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

The FY 2011 Budget continues and builds on the important work of reducing healthcare-associated infections, such as by expanding CDC's National Healthcare Safety Network from 2,500 to 5,000 hospitals. We appreciate the Chairman's leadership in this area and we are committed to addressing this serious public health issue.

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

Protecting Americans from Public Health Threats and Terrorism

Continued investments in countermeasure development and pandemic preparedness will help ensure that HHS is ready to protect the American people in either natural or man-made public health emergencies. The Budget includes $476 million, an increase of

$136 million, for the Biomedical Advanced Research and Development Authority to sustain the support of next generation countermeasure development in high-priority areas by allowing the BioShield Special Reserve Fund to support both procurement activities and advanced research and development.

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

Improving the Wellbeing of Children, Seniors, and Households

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

The Budget provides critical support of the President's Zero to Five Plan to enhance the quality of early care and education for our Nation's children. The Budget lays the groundwork for a reauthorization of the Child Care and Development Block Grant and entitlement funding for child care, including a total of $6.6 billion for the Child Care and Development Fund, an increase of $800 million in the Child Care and Development Block Grant, and $800 million in the Child Care Entitlement.

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

To enable families to better care for their aging relatives and support seniors trying to remain independent in their communities, the Budget provides $102.5 million for a new Caregiver Initiative at the Administration on Aging. This funding includes $50 million

for caregiver services, such as counseling, training, and respite care for the families of elderly individuals; $50 million for supportive services, such as transportation, homemaker assistance, adult day care, and personal care assistance for elderly individuals and their families; and $2.5 million for respite care for family members of people of all ages with special needs. This funding will support 755,000 caregivers with 12 million hours of respite care and more than 186,000 caregivers with counseling, peer support groups, and training.

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

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

Investing in Scientific Research and Development

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

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

Recovery Act

Since the Recovery Act was passed in February 2009, HHS has made great strides in improving access to health and social services, stimulating job creation, and investing in

the future of health care reform through advances in health IT, prevention, and scientific research. HHS Recovery Act funds have had an immediate impact on the lives of individuals and communities across the country affected by the economic crisis and the loss of jobs.

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

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

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

Conclusion

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

My department cannot accomplish any of these goals alone. It will require all of us to work together. And I am eager to work with you to advance the health, safety, and well-being of the American people. Thank you for this opportunity to speak with you today. I look forward to answering your questions.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
KATHLEEN SEBELIUS

Kathleen Sebelius was sworn in as the 21st Secretary of the Department of Health and Human Services (HHS) on April 28, 2009. As Secretary, she leads the principal agency charged with keeping Americans healthy, ensuring they get the health care they need, and providing children, families, and seniors with the essential human services they depend on. She also oversees one of the largest civilian departments in the federal government, with nearly 80,000 employees.

Since taking office, Secretary Sebelius has been a leader on some of the Obama administration's top priorities. As the country's highest-ranking health official, she has been a powerful voice for reforming our health insurance system. She has also been charged by the President with coordinating the response to the 2009 H1N1 flu virus. And under her leadership, HHS has provided a wide range of services from health care to child care to energy assistance to help families weather the worst economic crisis since the Great Depression.

Secretary Sebelius has answered President Obama's call to form partnerships across government to improve the lives of Americans. She is the Co-Chair, with Secretary Vilsack, of the President's Food Safety Working Group. With Attorney General Holder, she chairs the new Health Care Fraud Prevention and Action Team (HEAT). She has teamed up with Secretary Duncan improve early childhood education. As part of President Obama's "Year of Community Living," she is working with Housing and Urban Development Secretary Shaun Donovan to improve the lives of seniors and people with disabilities who wish to live at home.

Secretary Sebelius has been a leader on health care, family, and senior issues for over 20 years. As Governor of Kansas from 2003 to 2009, she fought to create jobs, improve access to affordable health care, and give every Kansas child a quality education. In 2005, Time Magazine recognized her achievements by naming her one of America's Top Five Governors.

Before being elected Governor, she served from 1995 to 2003 as the first Democrat to be elected Kansas Insurance Commissioner. In that role, she was recognized as a strong advocate for consumers while streamlining the Department's budget. For her efforts, Governing Magazine selected her as their Public Official of the Year for 2000. Prior to her service as Insurance Commissioner, she was a member of the Kansas House of Representatives from 1987 to 1995.

Secretary Sebelius is the first daughter of a governor to be elected governor in American history. She holds a Master of Public Administration degree from the University of Kansas and a Bachelor of Arts degree from Trinity Washington University. She is married to Gary Sebelius, a federal magistrate judge. They have two sons, Ned and John.

Mr. OBEY. Thank you.
Mr. Tiahrt.

HEALTH CARE REFORM

Mr. TIAHRT. Thank you, Mr. Chairman.

A while back, I found the comments made by our Speaker of the House, Ms. Pelosi, quite interesting. Specifically, she said on March 9th before the legislative conference of the National Association of Counties that—and I quote—"we have to pass the bill so that you can find out what is in it." My preference is that the American people know what was in the bill before it is passed, but I suppose that is just a philosophical difference.

I was even more interested in a recent Rasmussen poll that shows that 56 percent of Americans believe that we should repeal Obama-care. In Kansas, it is over 70 percent, probably because four out of five jobs are small-business jobs, and there is a great deal of concern about what it will do to small employers. To be honest, I am not particularly surprised by that number, and I expect it will grow, since the American people are only now beginning to find out what has been done in the bill.

This bill is widely unpopular. What is the most difficult part for the administration to sell to the American people?

Secretary SEBELIUS. That is——

Mr. TIAHRT. Yeah, which part of this bill will be the most difficult to convince the American people that it is going to be good for them?

Secretary SEBELIUS. Well, Congressman, I think there has been an extraordinary amount of misinformation about what the law is and what it isn't. And one of the jobs that we have, I think, moving forward and that I look forward to, frankly, is telling people what is in the bill.

For instance, for small-business owners, there is a lot of misinformation about mandates that currently are not part of the law, and were never part of the law. So any employer who has less than 50 employees has not only no mandate but may be eligible for tax breaks that begin this year at 35 percent, helping to secure employee coverage, and, eventually, in 2014, will have access to a new market.

You and I know in Kansas that small employers are often squeezed out of the marketplace, priced out of the marketplace, don't have the leverage, whether they are a farm family or a small-business owner, that the large employers have. They don't have negotiating power. And they will have——

COST OF INSURANCE PREMIUMS

Mr. TIAHRT. Bringing up the costs——

Secretary SEBELIUS [continuing]. Opportunity through a State-based exchange.

Mr. TIAHRT. I am sorry. I have limited time.

Because of the cost, there was an article in the New York Times that talks about the effects the new law will have on insurance premiums that are routinely paid by ordinary Kansans, as you mentioned. Specifically, the article focuses on mandates contained in

the new law that have been in place in New York, in Massachusetts, and a few other States.

The article concludes that people who buy their own insurance—and that includes the self-employed, people who work for small businesses, and early retirees, those who do not yet qualify for Social Security—will have to pay, on average, an additional $2,100 for their health insurance.

How does the administration justify forcing Americans who form the backbone of our economy, specifically those associated with small businesses, to pay an additional $2,100 for their insurance? Did we learn anything from Massachusetts, New York, and other States that have been doing some of these things that are contained in this new law, or is the New York Times wrong?

Secretary SEBELIUS. Well, I would suggest that the New York Times may be pricing a policy in Massachusetts but is not pricing what will eventually be a State-based exchange in Kansas.

The law is set up in a way that Kansas will have an opportunity, if they choose, to put together a State-based exchange to have the policies and programs be State-based. It doesn't import the mandates from Massachusetts and impose them on Kansas. It really is the law of the State of Kansas.

So I haven't read the article, but the State-based exchanges, I would suggest, will make it much more affordable for those in the individual market or the small-group market to have affordable care, because they currently don't have the bargaining power and they are squeezed out or priced out of the market.

Mr. TIAHRT. I will submit that article for the record, Mr. Chairman, if it is okay with you.

[The information follows:]

April 17, 2010

New York Offers Costly Lessons on Insurance

By **ANEMONA HARTOCOLLIS**

When her small executive search firm in New York City canceled its **health insurance** policy last year because of the recession and rising premiums, April Welles was able to buy her own plan and still be covered for her **cancer** and **multiple sclerosis**.

She was lucky to live in New York, one of the first states to require insurance companies to offer comprehensive coverage to all people regardless of pre-existing conditions. But Ms. Welles, 58, also pays dearly: Her premium is $17,876 a year.

"That's a lot of groceries," she said.

New York's insurance system has been a working laboratory for the core provision of the new federal health care law — insurance even for those who are already sick and facing huge medical bills — and an expensive lesson in unplanned consequences. Premiums for individual and small group policies have risen so high that state officials and patients' advocates say that New York's extensive insurance safety net for people like Ms. Welles is falling apart.

The problem stems in part from the state's high medical costs and in part from its stringent requirements for insurance companies in the individual and small group market. In 1993, motivated by stories of suffering **AIDS** patients, the state became one of the first to require insurers to extend individual or small group coverage to anyone with pre-existing illnesses.

New York also became one of the few states that require insurers within each region of the state to charge the same rates for the same benefits, regardless of whether people are old or young, male or female, smokers or nonsmokers, high risk or low risk.

Healthy people, in effect, began to subsidize people who needed more health care. The healthier customers soon discovered that the high premiums were not worth it and dropped out of the plans. The pool of insured people shrank to the point where many of them had high health care needs. Without healthier people to spread the risk, their premiums skyrocketed, a phenomenon known in the trade as the "adverse selection death spiral."

"You have a mandate that's accessible in theory, but not in practice, because it's too expensive," said Mark P. Scherzer, a consumer lawyer and counsel to New Yorkers for Accessible Health Coverage, an advocacy group. "What you get left clinging to the life raft is the population that tends to have pretty high health needs."

Since 2001, the number of people who bought comprehensive individual policies through HMOs in New York has plummeted to about 31,000 from about 128,000, according to the State Insurance Department.

At the same time, New York has the highest average annual premiums for individual policies: $6,630 for single people and $13,296 for families in mid-2009, more than double the nationwide average, according to America's Health Insurance Plans, an industry group.

Rates did not rise as high in small group plans, for businesses with up to 50 workers, because the companies had an incentive to provide insurance to keep employees happy, and so were able to keep healthier people in the plans, said Peter Newell, an analyst for the United Hospital Fund, a New York-based health care research organization.

While premiums for large group plans have risen, their risk pools tend to be large enough to avoid out-of-control rate hikes.

The new federal health care law tries to avoid the death spiral by requiring everyone to have insurance and penalizing those who do not, as well as offering subsidies to low-income customers. But analysts say that provision could prove meaningless if the government does not vigorously enforce the penalties, as insurance companies fear, or if too many people decide it is cheaper to pay the penalty and opt out.

Under the federal law, those who refuse coverage will have to pay an annual penalty of $695 per person, up to $2,085 per family, or 2.5 percent of their household income, whichever is greater. The penalty will be phased in from 2014 to 2016.

"In this new marketplace that we envision, this requirement that everybody be covered, that should draw better, healthier people into the insurance pool, which should bring down

rates," said Mark Hall, a professor of law and public health at **Wake Forest University**. But he added, "You have to sort of take a leap of faith that that's going to happen."

As part of the political bargain to get insurance companies to support insurance for all regardless of risk, called community rating, New York State deregulated the market, allowing insurers to charge as much as they wanted within certain profit margins. The state can require companies to retroactively refund overcharges to consumers, but it seldom does.

Now, Gov. **David A. Paterson** has proposed to reinstate prior approval by the state of rate increases for the small group and individual plans, as a way to reverse New York's death spiral of healthy people fleeing the market. The change would affect about 3 million of the 10 million New Yorkers insured through private plans, according to the Insurance Department. Most of those are in small group plans, though the biggest beneficiaries might be those seeking individual coverage, where premiums are highest.

New York's insurance companies are vigorously fighting prior approval. Mark L. Wagar, the president of Empire BlueCross BlueShield, said New York's problem was not deregulation of rates, but the lack of an effective mandate for everyone to buy insurance. To illustrate, he offered a statistic on how many people in the 18-to-26 age group, who are largely healthy, have bought individual insurance coverage through his company: 88 people out of 6 million insured by his company statewide.

New York is "the bellwether," Mr. Wagar said. "We have the federal health reform on **steroids** in terms of richness and strictness."

The federal health care overhaul contains some protection for people who buy into the new insurance exchanges — organized marketplaces — created by the law. Beginning in 2014, states will be able to recommend that the **Department of Health and Human Services** ban companies from the exchanges if they impose rate increases the states consider unreasonable.

Mr. Wagar also said that New York's medical costs, universally acknowledged as being among the highest in the country, were a factor in its high premiums. He noted that the state already regulated insurance company profit margins, allowing them to allocate no more than 25 cents of every dollar for profits and administration in small group plans and 20 cents for individual plans. The governor is proposing to lower both margins to 15 percent.

Troy Oechsner, deputy superintendent for health at the State Insurance Department, blamed the insurance companies for raising rates beyond what was necessary — by being off on their projections — thus accelerating the exodus of healthy people.

"What we saw them do is they really jacked up rates because they could," Mr. Oechsner said.

To a large extent, insurance companies police themselves, according to Mr. Oechsner. From 2000 to 2007, insurance plans reported that they exceeded state profit allowances just 3 percent of the time, resulting in about $48 million in refunds to policyholders, Mr. Oechsner said. Yet subsequent Insurance Department investigations found that insurers should have refunded three times as much.

The governor's budget projects that reinstating prior approval would help the state close its $9 billion deficit, saving taxpayers $70 million in the first year, and $150 million after that, by stemming the exodus of people from high-priced plans into state-subsidized plans.

An analysis of the governor's plan released recently by the Business Council of New York State, whose membership includes insurance companies, contested the governor's savings estimate, saying that it was "at best speculative," and that the savings would probably be nominal.

Mr. Hall, the Wake Forest professor, said that with the risk spread over a bigger pool of insured people under federal changes, insurers would be expected to reduce their prices, especially in New York. But Mr. Hall said that insurers might hesitate to do that until they were sure people were going to buy coverage, which could lead to a sort of mutual paralysis.

"You can literally think of people standing around a swimming pool, saying let's jump in at once," he said.

As for Ms. Welles, she is not sure how much longer she can keep paying rising rates.

"This is not something that will be sustainable for the rest of my life," she said. On the other hand, she added, "frankly, with the kind of cancer I have, I don't think I'll be paying this for too many years."

INDIVIDUAL MANDATES

Mr. TIAHRT. While I am not a lawyer, I am aware——

Secretary SEBELIUS. I am not either.

Mr. TIAHRT [continuing]. That the Supreme Court has declared unconstitutional many Federal laws that contain individual mandates. However, the new health-care law contains a provision that appears to mandate that every individual in the United States must have some form of health-care insurance.

Regardless of the lessons we have learned in Massachusetts and New York with respect to individual mandates, what makes this administration think that it can constitutionally mandate that every American must buy health insurance?

And I ask specifically because there appears to be a fairly large segment of the American population that chooses, for one reason or another, not to buy health insurance even though they can afford it. This is a basic issue of liberty for me, not unlike deciding to purchase a house or rather to rent.

So what is it about the mandate that we think we can impose on the American people? And do you think it will survive a constitutional test?

Secretary SEBELIUS. Well, Congressman, I am also not a lawyer, but I have discussed the constitutional challenges with both our legal team and the legal team at the Justice Department, who feel that the Commerce Clause gives strong constitutional basis for the personal responsibility section of this bill.

As you know, when Governor Romney signed the Massachusetts law, he felt that a critical piece of expanding health coverage was personal responsibility, that those who could afford, actually, to purchase coverage would do so; and if they needed assistance, that the State, in that instance—and, in our instance, the Federal Government—would provide that assistance, and there would be a waiver for those who couldn't afford it.

It is the framework that we used to put together the Affordable Care Act, and I think at least the lawyers will debate this in the courtroom, but I am convinced that it does stand on the strong constitutional grounds.

Mr. TIAHRT. Thank you, Mr. Chairman.

Mr. OBEY. Mrs. Lowey.

MEDICAL LOSS RATIO

Mrs. LOWEY. Thank you, Mr. Chairman.

And welcome, Madam Secretary.

Throughout the health-care debate, one of my highest priorities was to enable the Federal Government to better track and prevent premium increases for consumers. One of the provisions in the new law involves medical loss ratio, requiring insurance to spend at least 80 percent of premiums on health-care services. This will a great benefit to those who cannot continue to pay skyrocketing premiums. The law includes a host of other cost-control measures, including allowing exchanges to bar access to insurers with unreasonable premium increases.

By the way, I found in my district—I had countless meetings with large employers, small employers, individuals, hospitals, doc-

tors, and I cannot tell you how many people talked about their rates being doubled in the last 5 years. So we have to do something about this in this bill.

And if you could share with us, how does the budget request enable HHS to police insurers and protect consumers from abusive practices? And, more generally, are there any changes to the budget request that are necessary now that health-care reform has been signed into law?

First, let's talk specifically about the medical loss ratio, and then whatever time is remaining, I would appreciate it.

Secretary SEBELIUS. Well, the medical loss ratio, Congresswoman, as you suggest, is part of the Affordable Care Act. I am a former insurance commissioner, and I am familiar with looking at the kind of data that is currently going to be requested. So we have already reached out to the National Association of Insurance Commissioners to, as suggested by the law, have them help to frame the definitions that are used as part of the formula for the loss ratio.

I have actually reached out, also, to my former colleagues, Governors across the country to remind them—and in some States there is the full range of rate review authority, and in other States they are really missing big pieces of it, like California and others who found themselves in a situation where they do not have prior approval of rate increases—to remind them that that may be a good thing to address in their legislative session.

So we are aggressively putting together the framework for a review of medical loss ratios and working in very close connection with the State insurance commissioners and the Governors to do just that.

I think that our budget, what we have done, Congresswoman, as part of the implementation of the Affordable Care Act is to stand up a new Office of Consumer Information and Insurance Oversight that is going to be charged with not only implementing the medical loss ratio standards but a whole host of the market conduct standards for insurance companies and working very closely with the State offices.

STATE INSURANCE COMMISSIONERS

Mrs. LOWEY. Before we get to the next question, from your experience—and you interacted, I know, with other State commissioners before you took on these responsibilities—are there any States that are actually monitoring this issue effectively now? And I appreciate the fact that you said you had been meeting with the State commissioners of insurance. Are there any States that do it effectively?

Secretary SEBELIUS. I think there are. There are some models out there that we look at very closely.

Again, the State laws vary. So some States have what they call "prior approval." Before a company can actually impose a rate increase, they have to submit actuarial data to the Department, have it reviewed, look at administrative costs, overhead costs, CEO salaries, and what portion of the premiums they are actually paying out in health benefits. Others have what they call "file and use," where the company actually notices you that you have a rate in-

crease and just files it with the Department. And some don't even have that. So there is a wide range of oversight.

We are very hopeful that we can—this isn't, as you know, a Federal takeover of anything. It really is a State-based insurance regulatory system that stays a State-based insurance regulatory system. But we are working very hard with the States to remind them that this responsibility is theirs.

We have asked—I actually went to the health insurers and asked that companies submit to our office at a minimum their actuarial information of what their overhead costs are, and what their benefit payouts are, so we can at least make it transparent to the American public. So far, we haven't had a terribly robust response, but I am hoping that we will.

Mrs. LOWEY. I look forward to your keeping us up to date on this. Because, from my perspective and many of my colleagues', we were moved to pass this legislation because, frankly, everybody, from small business to large small business, was just getting rate increases.

And my time is up. And I look forward to continuing to hear from you and getting this information.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Lewis.

SINGLE-PAYOR SYSTEM

Mr. LEWIS. Thank you, Mr. Chairman.

Welcome, Madam Secretary. I don't envy you the challenge you have before you. All of us face the same thing, but you are in a very special hot seat.

In general, I would like to talk about medical errors a bit and a bit about Medicare. But before getting to that, as we have gone through this debate over the last year, it has become very apparent to any observer who has looked closely that the key players on the majority side—the President; the Speaker; the Speaker's closest advisor, Mr. Miller of Oakland; indeed, Henry Waxman—have been supportive of a single-payor system.

Now, I know that is not the bill that we produced, but it lays the foundation for exchanges to become a lot more than State-based but, rather, Federal-dominated. And it concerns me an awful lot that we ignore that.

Would you respond to you and your office's view of a single-payor system at the Federal level?

Secretary SEBELIUS. Certainly, Congressman. I would be glad to.

I think, from the outset of this discussion, there were certainly those in the House and the Senate who favored a single-payor system and felt that that was by far the preferable option. From the beginning, the President made it very clear that he did not, in spite of the fact that he had, in years in the legislature and even when he came to the United States Senate, talked about that as an option that would be ideal. The more he looked at the situation, with 180,000,000 Americans having insurance coverage that was preferable to them and that they liked, he felt that what we needed to do was build on the current system. And that is really the structure that the bill took from the outset, in spite of, I think, the dis-

appointment of some in the caucuses who would have preferred to really dismantle the third-party-payor system.

So this really starts at the States. States put together exchanges either as a single State or in a multi-State area, if that is what they choose. We provide technical assistance to the States to do that. And even though the timetable for exchanges doesn't begin until 2014, we intend, starting next year, to begin very robust discussions so that we don't wait until the last minute and have States in a situation where they can't do this.

We have already had lots of positive discussions, and States are very eager to do this. And I think it will very much be a State-based program. And particularly, Congressman, it is not to dismantle what is in place right now. It is really to replace the market for self-employed Americans, many of whom cannot find affordable coverage, don't have any leverage, a lot of small-business owners who find themselves in the same situation.

MEDICAL ERROR RATES

Mr. LEWIS. Madam Secretary, if I could take you to medical errors——

Secretary SEBELIUS. Yes. Yes.

Mr. LEWIS [continuing]. You suggest that, within the Department, you want to at least model some evaluation of medical errors to see how we can improve on that pattern within the health-care delivery system. Might I suggest that one of the major Federal medical health-care delivery systems lies within our military. There is plenty of evidence that there is rampant across this system an error-based system of delivery.

I would suggest that you might start there and help us, with you, to evaluate what is going on in that medical health-care delivery system that supposedly is serving the most important servants we have in our society, the men and women who have fought for this country.

Huge problem there. I would be interested in your reaction.

Secretary SEBELIUS. I am sorry. I want to understand what you are saying, Congressman. We have begun, certainly, discussions with not only the VA but the Department of Defense on their system. But you are suggesting that there are rampant medical errors within the health-care system for——

Mr. LEWIS. That is correct. There is evidence at the highest levels that system deliveries are, at best, producing an awful lot more errors than the norm. And we might start that examination right there.

Secretary SEBELIUS. Well, I think that is a good point, and I will follow up on that. Thank you.

MEDICARE ADVANTAGE

Mr. LEWIS. One of the President's major promises was that, if you like your health care, you can keep it. And yet, to pay for the new health-care plan, the law, it appears, would cut in a major way Medicare Advantage by more than $130,000,000,000. I have 50,000–plus seniors in my district who enjoy Medicare, and, indeed, they are concerned about what these proposed cuts might do to that service and existing delivery.

What can my seniors expect relative to implementing this program?

Secretary SEBELIUS. Well, I think that there is a provision, as you know, as part of the law that, over a decade, a portion of the overpayment to the Medicare Advantage plans will gradually be phased out. There are about 400 companies right now offering about 1,100 plans throughout the country. About 11,500,000 seniors taking advantage of those plans.

We have just actually put out the 2011 Medicare Advantage updates, which will have the same rate payments for 2011 as they did for 2010, and noticed plans across the country. There will be a robust array of choices for Medicare recipients, as there are right now.

I don't think there is any question that we are going to begin to pay more attention and collect more data, and the CMS, on medical outcomes, will be looking at not only the fee-for-service side of Medicare but also the Medicare Advantage side of Medicare to make sure that, if enhanced payments are going out the door, it is really for higher-quality health outcomes. And we know bundled care produces that, medical home models produce that. And there are a number of Medicare Advantage plans who are very eager to engage in that.

But I think that the misinformation to seniors about the fact that Medicare Advantage is somehow not going to be a choice is just wrong. We anticipate that there will be no shortage of choices of Medicare Advantage plans throughout the country.

Mr. LEWIS. Thank you, Mr. Chairman.

I must say, Mr. Chairman, that what she just mentioned is a major stumbling block. But if I were going to point to the greatest stumbling block, it is when the average family, let's say 25 to 45, suddenly finds a mandate, with the IRS looking over their shoulder, that they must start putting money into a pool for some future service delivery.

Thank you.

Mr. OBEY. Well, I would say the greatest stumbling block is when people with insurance have to pay $1,000 a year to subsidize people who don't have it because we didn't have, until now, a program like this.

Ms. Lee.

DIVERSITY IN HEALTH PROFESSIONALS

Ms. LEE. Thank you very much, Mr. Chairman.

Good to see you, Madam Secretary.

First of all, let me just thank you so much for your leadership in helping to move the historic health-care reform bill forward, for your steady leadership and your choice and your experience.

And also, for those of us who were adamant about a public option in terms of keeping costs down and holding the insurance companies accountable, we are counting on you to make sure that that happens, short of having a public option. And so, thank you very much for understanding how important that is.

Myself, Congressman Honda, Congresswoman Roybal-Allard, the Tri-Caucus was lockstep, very adamant, on addressing racial and health disparities as part of the health reform bill. And I would

like for you to elaborate on how this budget actually supports the goal of diversity in the health professions through recruitment and training; how you increase diversity at NIH institutions and researchers, ensuring that the racial and ethic minorities benefit from any new, innovative health research at NIH; also, in terms of the direct support for our Nation's minority medical colleges, the targeted support to help eliminate these disparities within communities where we see them the most.

And so, in this budget, I just want to see how you are shaping this. I know that this year the Office of Minority Health, through I think it is called the National Partnership for Action to End Health Disparities, has produced a draft report, a national plan of action on disparities. So I just want to get a sense of where you are on that.

Secondly—and I will ask all my questions right away, and then you can respond. Secondly, national AIDS strategy: Current budget allocation? Who is going to lead the implementation of the national AIDS strategy? And what part of the current budget allocation—I think it is $70,000,000—that is going to HRSA and CDC will be dedicated to the national HIV-AIDS strategy?

Thirdly, let me ask you about nursing, because I had a long conversation with the dean of the Samuel Merritt Nursing School in Oakland, and she indicated that just in the Bay Area alone, 40 percent of all new nursing graduates since October 2008 have yet to find a job. Yet I thought there was a nurses shortage in our country.

I spend a lot of time, as I say to many, I spend a lot of time in hospitals. My mother is 85 years old. My sister has multiple sclerosis. And these are very good nurses, but we are always being treated by traveling nurses, nurses who have retired and who come to the hospitals to work because, I am told, that there is a shortage. And yet now the dean of the nursing school says nurses cannot find a job.

So I would like to, kind of, get some sense of what you think is going on out there and what we can do to ensure that qualified nurses are being hired.

And if I have any more time, I will ask some more questions, but go on and respond to those.

Thank you again, Madam Secretary, and good to see you.

Secretary SEBELIUS. Well, thank you, Congresswoman. I will try to hit the high points on the issues you raised.

First, health disparities is, I think, a glaring failure of the health delivery system over years. And while our department I think has done a fairly decent job documenting health disparities, there has not been a very good strategy to actually reduce or eliminate health disparities.

So the National Action Plan that you refer to is really the first time since 1985 that there will be a secretarial-level plan addressing health disparities. And it is one that I take very seriously. It is in draft form right now. We look forward to having a chance to preview it with you and to work on it.

I don't think there is any question that passage of the Affordable Care Act is one of the most important steps we can make toward closing the gap. Over and over again, it has been identified that the

lack of insurance, the lack of access to affordable health care is one of the underlying causes of health disparities. So a big step was made.

Our budget, actually, will build on that effort in a number of ways. Not only will the Office of Minority Health focus with a strategic roadmap on this National Plan—and we see it not only within our department, but an across-government-agency effort, where health is impacted by neighborhoods, by food availability, and by the air you breathe. There are a lot of things that actually add or subtract from people's health. So we see this as a government-wide effort.

We do have additional resources in the 2011 budget that look at recruitment of health providers from minority communities to make sure that we have not only people serving in underserved areas, but actually minority providers—nurses, doctors, health technicians, mental health professionals.

As you know, the Affordable Care Act also made the Center for Minority Health and Health Disparities into an Institute at the National Institutes of Health which raises it to a level where it will have serious strategic focus and attention. So there are a whole host of assets coming together in a way that really hasn't been organized in our department.

And, again, we look forward—I know this has been not only a cause that you have taken very seriously but your fellow Tri-Caucus members have been focused on for years, and I really look forward to working with you as we address these gaps and these underlying health causes.

I would suggest, also, that the increased footprint for the Community Health Centers, which actually started in the Recovery Act and are, again, targeted to the underserved areas, as well as the efforts in wellness and prevention grants, will also help to close this gap.

I can't respond very well to the nursing job shortage situation that you talked about because that is the first time I have ever heard of nurses not being snapped up immediately to be hired. I hear the other side of the story over and over again, that people need more nurses in the pipeline. And that is exactly what we have been doing, is trying to fill that workforce pipeline with more scholarships being paid off, more increases to the National Health Service Corps, more people in underserved areas. So I need to follow up on that.

And then, finally, in the AIDS area, there is a national AIDS plan that is currently being formulated. It is not finalized at this point. As you know, President Obama has identified the fact that, while we had a very robust international HIV-AIDS strategy, we had kind of lost the attention and focus at the national level.

We have already launched, under CDC, an outreach program on testing and particularly identified some of the most vulnerable communities that we are beginning to interact with, using social networking.

But we look forward to the strategic plan, which will be led by the White House Office of National AIDS Policy and others who are focused on AIDS. There is a new AIDS Council, which will have a

national and international focus. And we are going to be very intimately working with them.

Mr. OBEY. Mr. Rehberg.

HIGH RISK POOLS

Mr. REHBERG. Thank you, Mr. Chairman.

Temporary high-risk pools in Montana—I understand you have been in contact with our auditor already about it. But I noticed in the appropriations $5,000,000,000 was taken out of the general fund to pay for the high-risk pools around the country, but CMS is suggesting that the money will run out in 2011 and 2012. And, of course, they don't have to be in place until 2014.

Why the shortfall? Well, why the anticipated shortfall? And are there other areas that you see it is already coming in over-budget?

Secretary SEBELIUS. Congressman, we don't know exactly how many people will be able to be enrolled in the high-risk pool. A lot of States offer high-risk pools right now. I think Montana—

Mr. REHBERG. Which is one of the reasons we wondered why we did this in the first place. If we already had the high-risk pool in place, why supplant it with something created by the Federal Government to do something that we already had in place?

Secretary SEBELIUS. Again, this is a totally voluntary program, first of all. Secondly, it won't be created by the Federal Government. If Montana chooses to set up what is a parallel pool, the money that is allocated in the Affordable Care Act is to subsidize rates so——

Mr. REHBERG. The point is——

Secretary SEBELI [continuing]. They don't rise above 100 percent in Montana.

Mr. REHBERG. Correct.

Secretary SEBELIUS. They are well over 100 percent of the market right now, and it makes it very unaffordable for lots of folks.

Mr. REHBERG. But my question is, you asked for $5,000,000,000, you got $5,000,000,000, and CMS is already anticipating it will not last through 2011 or 2012. And the high-risk pools are not to be in place by 2014. A shortage, a shortfall, an overexpenditure. How are you going to deal with it? Are you going to limit access?

Secretary SEBELIUS. Again, sir, this is not a Federal program. If Montana chooses to participate, they will have an allocated set of resources, which helps subsidize care for Montanans who currently are uninsured and uninsurable.

Mr. REHBERG. Madam Secretary, you——

Secretary SEBELIUS. If they choose not to participate, that is a choice that the State will make.

Mr. REHBERG. Let's go back to the question. The question was, the legislation created high-risk pools, or the opportunity to create a high-risk pool——

Secretary SEBELIUS. That is correct.

Mr. REHBERG [continuing]. By 2014.

Secretary SEBELIUS. No, sir. Right now. This is the bridge strategy to a new market——

Mr. REHBERG. Correct.

Secretary SEBELIUS [continuing]. In 2014. Not by 2014.

Mr. REHBERG. That is correct. But, by 2014, an alternative structure needs to be in place.

Secretary SEBELIUS. The exchanges.

Mr. REHBERG. Correct. But if the exchanges are in place in 2014 but you are using Montana and the other States' temporary pool, and if you appropriated $5,000,000,000 and it is not going to make it to 2014, you are going to have to come back to this Appropriations Committee and ask for more money.

You have already anticipated that it is going to cost more than you told us it was going to, in asking that the legislation be passed in the first place.

Secretary SEBELIUS. Sir, currently, the Federal Government pays a fraction of a State's high-risk pool. It puts about $50,000,000 into an overall plan. This is an attempt to provide a safety-net coverage if the money actually is going to have a shortfall.

Mr. REHBERG. Madam Secretary, with all due respect, that doesn't answer the question of the shortfall. I understand the bridge. I understand that you are going to cooperate or participate or help the States. But you said it was going to cost $5,000,000,000, your anticipated expenditure, and it is not.

Secretary SEBELIUS. Well, we don't know what it is going to cost, and I would——

Mr. REHBERG. So you disagree with CMS?

Secretary SEBELIUS. We don't even know how many States want to participate in the program at this point. We put out a letter to Governors. I talked to my former colleagues yesterday. We will, by April 30th, have some idea. I mean, we really don't know, at this point, sir.

PROHIBITION ON LOBBYING WITH FEDERAL FUNDS

Mr. REHBERG. Okay.

The second line of questioning that I would like to go down the path—in the stimulus package, the law certainly says you can't lobby.

Secretary SEBELIUS. Correct.

Mr. REHBERG. You know, a bastion of information from CNN. State of New York, obesity, educate leaders and decision-makers about trans fat—this is a $3,000,000 grant award. Santa Clara, California, advocating for an increased statewide tobacco tax. The city of Chicago, tax increase at the city, county, and State levels. Iowa Department of Public Health, $3,300,000,000, inform local policymakers about evidence- and practice-based pricing.

That sounds like lobbying.

Secretary SEBELIUS. Congressman, I read the same information from the same news source. I can assure you that we will follow to the letter of the law the Federal law which prohibits Federal funds and has, not just in the Recovery Act but consistently, prohibited lobbying with Federal dollars. We will track that very carefully. We have already notified a whole host of folks that that is the law of the land. That was part of the grant application and will continue to be part of the monitoring.

Federal funds will not be used for lobbying.

Mr. REHBERG. Okay. Because those were all quotes from the grant application in the first place.

Secretary SEBELIUS. A lot of the applicants have a whole host of strategies that they employ, have employed historically, and will continue to employ. We are funding programs that are not lobbying programs. They are actual prevention——

Mr. REHBERG. But your oversight missed it in the initial grant application.

Secretary SEBELIUS. Pardon me?

Mr. REHBERG. Your oversight missed it in the initial grant application. The grant application had those exact quotes in it.

Secretary SEBELIUS. They have been notified that there is an absolute prohibition for using any Federal funding for lobbying. And we will follow up on that very carefully.

Mr. REHBERG. Thank you.

Thank you, Mr. Chairman.

Mr. OBEY. Ms. Roybal-Allard.

Ms. ROYBAL-ALLARD. Welcome, Madam Secretary.

PREVENTION AND WELLNESS FUNDING

Last year, the American Recovery and Reinvestment Act made $650,000,000 in prevention and wellness funding available for chronic disease prevention and management. And this year, when Congress passed the Affordable Care Act, it included a $15,000,000,000 Prevention and Public Health Fund, of which $500,000,000 is, I believe, available this year. And, as I understand it, these new funds are not restricted to chronic diseases but are meant to fund the entire spectrum of public health efforts.

I have been told that your office is currently working on a system to distribute the funds this year. However, there seems to be significant concern in the infectious disease community that, in an effort to obligate the $500,000,000 by September 30th of this year, the Department will fund only existing grant applications for the ARRA of chronic prevention grants and that infectious disease programs will once again receive no funding.

Can you please outline how you plan to allocate these funds and whether you will include new applications for prevention funds to target infectious diseases such as HIV-AIDS, viral hepatitis, sexually transmitted diseases, tuberculosis, many of which are at crisis levels in many communities? And what strategies is your department undertaking to address these infectious-disease disparities in our minority communities?

Secretary SEBELIUS. Congresswoman, I would suggest that, at this point, as you have identified, conversations are going on with Members of the House and the Senate about the strategies for allocating these funds. So no decisions have been made, at this point, about either using traditional applications or not. But we absolutely want that kind of input and, you know, look forward to working with you on a plan.

I think that the effort will be to actually build on—as you know, the investment in the ARRA funds was really a first-time-ever investment in wellness and prevention and strategically focused, at least in the community grant applications, on two underlying causes of chronic disease, which were tobacco cessation and obesity.

This is likely to be a broader area. There are lots of ideas and good strategies about how to use this. We are looking carefully at

the scientific data, at the evidence-based programs. I can guarantee you that what actually has been demonstrated to work will be one of the guiding lights.

But I would say that discussion is very much under way, and we would appreciate your input.

Ms. ROYBAL-ALLARD. So they are still open with regard to funding infectious disease?

Secretary SEBELIUS. Yes.

REDUCING CESAREAN BIRTHS

Ms. ROYBAL-ALLARD. Okay.

As you are aware, the United States spends more on maternity care than any other country in the world. However, we rank 41st in the world in maternal mortality and rank 30th in infant mortality.

While we know there is an extensive body of research regarding best evidenced-based practices in maternity care, our health-care providers seem not to be following that research. For example, despite Healthy People 2010 goals of reducing Cesarean births to 15 percent, the United States continues to have a 31.8 percent Cesarean section rate.

Given the risks that are associated with medically unnecessary Cesareans and the extraordinary costs associated with Cesarean births, is the administration doing anything to refine our care system to support the best and most cost-effective, evidence-based care to reduce the rate of C-sections?

Secretary SEBELIUS. Congresswoman, I am not sure I can speak with any specificity about what actions are currently being taken in dialogue with providers about the C-section rate beyond just publishing the data and highlighting the data.

I can tell you that our Office of Women's Health is very focused on maternal and child health issues and, frankly, what are pretty dismal health results, as you suggest—high expenditure and not terrifically good results.

I, again, think that the Affordable Care Act makes a big step in the direction of getting affordable prenatal care to pregnant women. That will be a major step forward——

INCREASING BIRTHING CENTERS

Ms. ROYBAL-ALLARD. I am sorry to interrupt, because I see my time is up, but I did want to know whether or not, since the new law requires Medicare to cover care provided in all free-standing birth centers at a cost of $6,000 less, is there any consideration in the initiatives to increase the availability of licensed birthing centers across the country?

Mr. OBEY. Very brief answer.

Ms. ROYBAL-ALLARD. Is that being looked at?

Secretary SEBELIUS. I can't answer that, but I will look into it.

[The information follows:]

INCREASING BIRTHING CENTERS

Thank you for your interest in the Medicaid program and the availability of licensed, free-standing birthing centers. As you know, section 2301 of the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) requires the

States to cover services provided by freestanding birth centers as a mandatory service under Medicaid. Currently, we are focused on implementing and providing technical assistance to the States on this provision. We expect that States with licensed, freestanding birthing centers will build a foundation for expanding these services to the Medicaid population and that their experience will be instructive to other States considering expanding the availability of such centers.

Ms. ROYBAL-ALLARD. Okay. Thank you.

Mr. OBEY. Mr. Alexander.

FMAP FORMULA

Mr. ALEXANDER. Thank you, Mr. Chairman.

Madam Secretary, I have two questions. One is about FMAP. Congressman Cao and all of the Louisiana delegation, as cosponsors, are supporting a piece of legislation to address Medicaid reimbursements or Medicaid costs. Governor Jindal is supporting the legislation, as well as Secretary Levine from the Louisiana Department of Hospitals. They are in a legislative session today dealing with the shortfall there of a half a billion dollars.

My question is, what is being done to prevent States like Louisiana, who were unfairly, when you look at the FMAP formula—because we got a lot of money, as the State of Louisiana was recovering from the hurricanes. Louisiana was looked at as being a State that was financially better off than they really are.

So what are we doing to prevent Louisiana or any other State, like yours, that received financial help from appearing to be wealthier than they really are and, therefore, suffering because of the Medicaid?

Secretary SEBELIUS. Congressman, we have spent a good deal of time with not only your State health officials, your Medicaid director, the mayor-elect of New Orleans, and others, Senator Landrieu, on this situation. Frankly, one of the reasons I think that there is now a legislative discussion is because the law is pretty clear that we don't have administrative flexibility to change the calendar years for which the income level is calculated; and that is really the situation, is when the count began what the income level is and how it was calculated. But we are working very closely with them, well aware of the anomaly that income appeared to go very high because half the population was, frankly, gone and not counted and probably inaccurately reflects what is the true medical count.

And if we can have a legislative fix, we will try to move it very, very quickly. But we have our hands tied in terms of what administratively we can do for this situation. But I think it is really worth looking at.

As you suggested, it is not only Louisiana but what happens post-disaster in an area where Federal funding may come in as an aid after the fact, but then the result is a calculation that isn't a very accurate picture of what the financial wherewithal is.

HEALTH CARE FRAUD

Mr. ALEXANDER. Thank you.

Chairman Obey a little earlier said something about a meeting that we had a few weeks ago about fraud. During that meeting, we heard all kind of reports about the number of physicians and other health care providers that were using sometimes information ob-

tained from the inside to defraud the taxpayers. I asked the question about the number of individuals from the inside that might have been found doing something wrong.

Again, I am not pointing fingers, but I just find it almost impossible to believe that there are numbers of individuals on the outside committing fraud at the numbers that we are hearing about without getting some help from the inside.

When we talk about organized crime—and that term was mentioned—organized means at least two. You can't have organized crime with one. So I asked the question. I have not gotten an answer. I have had staff members to try to find out if in fact there are any individuals on the inside of any of the departments at all levels who have been found guilty of helping those on the outside. Can't get an answer. There is no answer or either they won't give it to us.

Secretary SEBELIUS. Congressman, I can tell you I am not aware—and I will make sure we get this data and get it right back to you—I am not aware of if you are talking about State and Federal employees who have been charged and found guilty. I do know if "inside" means providers and not necessarily just doctors but so-called equipment providers and home health providers, there are dozens and dozens of insiders in that instance who have been charged and prosecuted, which is really the only way that we would be able to document if they have actually been found in some case. But I can get that information to you.

That is the kind of thing that I think the new fraud effort is attempting to crack down on, people who pretend to be providers, if you will, set up sham operations, bill. But they are not necessarily part of organized crime. They are just operating as insiders but really conducting fraudulent activities. But we will circle back right away and get you that information.

[The information follows:]

HEALTH CARE FRAUD

The HHS Office of Inspector General's (OIG) Office of Investigations (OI) has one known case where an employee was complicit in a health care fraud scheme. In the Los Angeles Region, two Centers for Medicare & Medicaid contractors admitted to receiving money, $15,000 and $5,000 respectively, from an outside source to process provider applications. One individual received 3 years probation and was fined $1,000, while the other received 2 years probation and was fined $5,000.

Because many of the providers who had applications expedited are subjects of ongoing investigations, the total loss to the Medicare program has not been fully determined. However, it was determined that one provider involved in this scheme, caused a $3.2 million loss to the government. Additionally, it is believed that at least one entity bribing the employees in this case is connected to an organized criminal enterprise, and there may be additional employees identified in this scheme.

Instance of "insider" fraud within the Department or involving its employees are extremely rare, and when identified, are taken very seriously and investigated to the fullest extent by our law enforcement partners.

Mr. ALEXANDER. Thank you.

Mr. OBEY. Ms. McCollum.

MEDICARE REIMBURSEMENT

Ms. MCCOLLUM. Thank you, Mr. Chair.

To the gentleman's question, I know the Department, unfortunately, I have to report, in Minnesota found two internal problems

with fraud. So you do do internal audits, and I am sad to report that there were people in Minnesota involved in it. I am happy that they got caught.

I would like first, though, however, to commend Chairman Obey for his ongoing instrumental leadership in fighting for the best value and quality in health care. That just leads to a lot of hearings that you have had before and the hearing we are having today.

I would like to congratulate you on the passage of the health reform bill. Your work and the work of the administration were key to ensuring that health care reform became a reality. I believe that the current Medicare payment system is deeply flawed and too many hospitals and providers shoulder the burden of unfair Medicare reimbursement for high-quality, low-cost care that they deliver, my State being one of them. I look forward to working with you as you convene the National Summit on Geographic Variation, Cost, Access, and Value in Health Care this year. And on this issue and the timing implications for some of the fact finding that you are looking at and for the implementation of change, I am going to submit some of those questions for the record.

HOSPITAL ACQUIRED INFECTIONS

Ms. MCCOLLUM. So I would like to spend my remaining time talking about hospital-acquired infections. We are here today to learn how to work more effectively with you to improve the quality of our health care system for all Americans. Hospital-acquired infections contributed to almost a hundred thousand deaths. In a recent report, HHS concluded that hospital infections merited urgent action. We know that hospital infections add $28 to $33 billion to our national health care costs. This is a serious public health care concern, because are we not only paying the cost, there are patients paying for these mistakes with their lives.

HHS has set out a goal to reduce hospital-acquired infections by 10 to 20 percent in 2 years, and 50 percent within 10. But we are far from reaching that goal. We know that most of these infections are preventable through low-cost techniques. There is a New York Times article that even talks about how we have had remarkable progress in reducing infection rates but how many of the hospitals have not yet worked to overcome these infection rates because they are in an entrenched medical culture which is not changing.

My State has worked to lower infections, and I know others are doing that as well. You have examples at your Department on how we can reduce infection rates. But the report also points out that infection rates have gone up 8 percent.

So here are my questions:

Is the 8 percent increase because of better reporting, whether it is voluntary or mandatory? Because you can't address a problem until you know and you face the fact that the problem exists. What are some of the obstacles to addressing this issue? Does the agency need this committee or the policy committee to work more closely with you to address this public health care concern moving forward?

Secretary SEBELIUS. First of all, Congresswoman, I think your targeted concern is one that is a huge issue, and it is not only a

huge cost issue, it is a huge safety issue. I know the Chairman has been working with you and sort of focused like a laser beam on this. The notion that we have a hundred thousand deaths a year from what happens to people when they are in the hospital, not what brought them in the first place, is, frankly, totally unacceptable. And hundreds of thousands more in just high-cost, longer-care strategies and lingering diseases. So it is a very serious issue.

We know what works. It has been demonstrated and proven. It has never been taken to scale.

So I think a couple of things are happening simultaneously. First of all, the notion of increases, I would say, is a part of better reporting. It also is a snapshot of the past. We are hopeful that more current data gives more encouraging signs. This focus by the Department, by this Committee, through the Recovery Act, through the Affordable Care Act, and through our budgets, I think is relatively recent.

Secondly, there is no question that it is a question of focus by hospitals. You have required as part of the Affordable Care Act that all hospitals now have to report, which is a big step forward, and that reporting will be much more transparent to consumers and others, which is, again, a big step forward.

Third, we are putting real resources both to States for more frequent inspections and to hospital systems to encourage the adoption of the strategies that we know work.

Fourth is the electronic medical records. I was in a hospital in Cincinnati 2 weeks ago, in Children's Hospital, which does some of the most complicated surgeries on infants and even prenatally that I have ever seen. They have embedded into their electronic records system the checklist that we know works to reduce hospital infections. They have gone a thousand days without any safety concern. It is a great example of what meaningful use in an electronic records system can do, which is embed the kind of safety checklist, make sure it is done time and time again. If you can do it in that type of environment, we can do it everywhere.

So I think there are some resources coming together, but I can tell you that it is something that we take very, very seriously. And I think it is not only huge costs, but we are killing people by our health care system.

Mr. OBEY. Mr. Cole.

MEDICARE REIMBURSEMENT RATES

Mr. COLE. Thank you, Mr. Chairman.

Madam Secretary, thank you for being here today.

As I talk to hospitals in my district, and it is a pretty rural district, a lot of small town, lot of Medicare- and Medicaid-intensive facilities, most of them are expecting, and this is not through your actions or through the health care bill, the Medicare reimbursement rates are being cut. They are going down. They look on the Medicaid new population that they will be getting under the health care bill as largely a break-even deal for them. They are really not making money off of that. They are very worried about what is going to happen to the private provider part of reimbursement.

Because the point has been made here earlier, private insurance subsidizes the uninsured, but it also subsidizes Medicare and Medi-

care to a large degree, because those programs don't break even on costs. So they are looking at their future, and they are wondering where the dollars will come from for them to literally keep their doors open. And then the people in the larger cities wonder what happened to those smaller hospitals that closed and that population base is moved into their facilities.

So I would like you to just walk through how you see hospital reimbursement rate developing over the course as you phase in the new health care bill.

Secretary SEBELIUS. Congressman, I think that is a great question. Whether it is in rural areas in your district or in a State like Kansas, or in urban areas, I think every hospital administrator who I have talked to in the last 10 years has seen their uncompensated care rate rise. So there is currently a population with no payment stream at all and then insufficient payment streams and then private-payer streams.

So I think one of the features of the Affordable Care Act is to actually have a payment stream arguably under every patient who comes through the door. It is one of the reasons that a lot of the hospital systems worked carefully with us on the framework of health reform.

I do think that there also is an effort where the kind of bundled care strategies—again, hospital providers are very eager to have a payment system which actually looks at ways that they can be more appropriately compensated for keeping people out of the hospital. Right now, the only way they actually get compensated is if somebody actually comes back into the hospital.

And the sorts of embedded directional changes in the delivery system for health homes and bundled care and accountable care organizations actually have, I think, some huge advantages for hospital systems to have a more appropriate reimbursement system and actually keep people healthier in the long term. I would say the third piece of the puzzle is a lot of hospitals right now, particularly through emergency rooms, are delivering care which could much more effectively be delivered in a primary care setting, in a community health center, in a variety of areas. They have begun to work on strategies to kind of triage that care so they don't have to have this robust sort of preventive care, and that I think is also part of the new structure.

Mr. COLE. A lot of, again, my facilities are concerned with, again, on the private end of it is where they make the money to, frankly, reinvest in technology and facilities. They don't make that off Medicare. They don't make it off Medicaid. So they are really worried, are we going to crowd out the private market here and they won't have the money they need to give patients the best service that they possibly can give.

Secretary SEBELIUS. Well, I think with the exchange opportunities, the private market, I would suggest, may be stronger. What is happening right now, and has happened over the last 5 years certainly, is more and more small employers have dropped their private coverage because they can't any longer pay the premium. A lot of individuals lost insurance when they lost their jobs, but I think the restabilization of a marketplace, of a private marketplace

with larger purchasing pools but then stabilizing that coverage that people have is actually going to be good news.

Mr. COLE. I hope so. I think that is a point worth making, though. Because a lot of my friends who favor the public option think, forget where the money comes from that actually allows health care to be delivered. It is very heavily from the private sector. You overpay, quite frankly, if you are on private insurance already. We know that problem was alluded to earlier. But that also supports Medicare, Medicaid, and, frankly, the new health care insurance bill as well. So I would be very careful about killing the goose that has actually provided the eggs for everybody else.

Secretary SEBELIUS. Well, as you may know, of the 32 million or so estimated new enrollees in a health insurance system, the majority of those individuals will be in the private market, will not be in the public market.

Mr. COLE. Thank you, Mr. Chairman.

Mr. OBEY. Mr. Honda.

HEALTH INSURANCE COSTS

Mr. HONDA. Thank you very much.

Welcome, Madam Secretary.

Just to pick up with your last comment, the additional 32 million that will be added to the population, would that tend to drive the costs down across the board in terms of insurance premiums if we have the other things in place like the antitrust provision and a public option?

Secretary SEBELIUS. Congressman, what I think is anticipated to cost less is—first of all, the market right now is pretty fragmented. So if you are an individual buying your own coverage, or a small business owner, one health incident, one cancer survivor, one heart attack puts you in a very expensive category. Pooling that risk into an exchange, a much bigger purchasing pool, I think helps balance the costs overall. I think it is one of the reasons that costs will come down. Hopefully, a number of the underlying features that actually lower the overall health care costs also are impactful in terms of the health insurance costs.

Mr. HONDA. It seems to me that that is something that we can work towards and anticipate. We do know, though, if we don't do anything, we have 47 million people without insurance and the costs continue to rise. In the last 18 months, at least in California, the premiums have gone from 30 percent one year, 38 percent this past year, in terms of premiums increase, in light of the debate we had already. So I am not sure the word is arrogant, but it sure is pretty bold to do that while we are having a debate on the high cost of insurance.

I want to thank you for taking on this job. It is a massive job; and I think it is a very complicated, complex job that you have. But I am looking forward to working with you on this.

I would note that the State you do come from is a very active State and very vigorous folks. I was pleased to see that a Congressperson did vote for the bill.

I think that in my own district, District 15, which is Silicon Valley, which has probably the highest per capita post-graduate folks, probably the highest average income in this country, I had some-

thing like 70,000 folks who were uninsured. That is almost 10 percent of my population. It doesn't mean that they were unemployed, but they were uninsured.

A fellow who ran against me for office when I first ran, a young man, a good friend of mine, said that in the current situation he would not be able to go into business for himself because his child has a pre-existing condition. My past opponent and friend said, go for it. It is important for our country.

What is important for our country also is that we know that we have a viral hepatitis issue in America and globally, and we know that more Americans have chronic viral hepatitis. There is more of an incidence of that than HIV/AIDS, and the disease is 100 times more infections than HIV. While I am grateful to the President for requesting an increase for the division in your 2011 appropriation budget, I am glad that Assistant Secretary Koh, with whom we had met, had begun two major interagency tasks forces on this issue. We are very appreciative of that activity.

PREVENTION AND PUBLIC HEALTH FUND

I am also aware that there is about $500 million for prevention and wellness funds that is made available through this bill. But there is nothing that says how it is going to be spent. Do you have any idea how your Department will be looking at that and how it will be spent?

Secretary SEBELIUS. Congressman, I think that we are still seeking guidance from Members in the House and the Senate about that 2010 appropriation for the prevention funds. We did invest in prevention in 2009 and 2010 as part of the Recovery Act, and we see this as an opportunity to amplify and maybe look in some other directions, but those conversations are under way, and we would appreciate your feedback.

Mr. HONDA. We certainly will be willing to do that.

Mr. OBEY. The gentleman's time has expired.

Mr. Ryan.

PREVENTION AND MINDFULNESS

Mr. RYAN. Thank you, Mr. Chairman.

I want to personally thank you for all your leadership with regard to the health care reform efforts in trying to push it through. I think history will judge us well, bringing a level of social justice to this country that we haven't seen.

One of the things I mentioned before when you were here that I have been dealing with and working with for the past few months and years is the issue of stress in our society. I think as we talk about health care reform and the technology and everything else that there is a growing body of evidence, not just in the area of health care, of mindfulness and contemplative practices and their benefits on reducing stress levels and allowing our body to heal itself.

So as we are moving 30 million more people into the system, there is inevitably going to be more costs, and I think we have dealt with that. And it will reduce costs, and I think we have dealt with that.

But we need to, I think, pursue—and Mr. Honda just mentioned prevention. I know there is going to be a panel to evaluate what preventive measures actually work. So if you can just talk about that.

But I would also like to encourage you that on that panel should be somebody who has been in the field, working in the field of mindfulness-based stress reduction. I think it is the most cost-effective way to drive down health care costs. It is about individual responsibility. It is about teaching people to manage their own health right in line with everything else we are talking about. So I want to encourage you to do that.

It is not just in the area of health. The Defense Department is now doing this for pre-deployment for soldiers who are going over, allowing them to—and hopefully prevent a lot of the post-traumatic stress that goes on when these kids go into battle. So I want to encourage you to do that.

If you can talk for just a second about the panel that is going to be created to evaluate adequate preventive measures in the health care reform bill.

Secretary SEBELIUS. First, Congressman, I am all for looking at any strategy we can find that is successfully reducing stress. I am at the front of that line. I would be grateful for that evidence. I think that whether it is in this instance or the framework for the services, with the exchanges or others, certainly we will put together a very broad-based group of experts and look at what the evidence says. And in this area I think there are a number of cost-effective sort of patient-centered strategies that really do work. And so I look forward to getting the information from you and making sure that is part of the discussion.

Mr. RYAN. I will get it to you.

I was at a conference this past week and there was someone from Ms. McCollum's district at the University of Minnesota. They are offering basically a stress reduction class for incoming freshman. There is a 50-person wait list. So this is something that is throughout our society. So I think your leadership on this could be critical.

PRIMARY CARE PHYSICIAN SHORTAGE

Another question I have, and it is something one of my colleagues mentioned, the shortage of nurses, is the issue with primary care physicians. If you can touch upon that and how we are going to try to bridge our way through that.

Secretary SEBELIUS. I think there is no question we need more health care providers altogether, but we also need more of the providers to choose primary care, gerontology, family practice. So a couple of strategies simultaneously. One is using more of our loan repayment and scholarship funds to attract people to those fields at the outset and pay off more of the debt for health care provider training in the areas that we see the biggest needs.

As you know, the Affordable Care Act had a feature which actually, again, moves primary care providers for a couple of years with 100 percent Federal funding from Medicaid rates to Medicare rates, which I think is, again, a big step forward to more adequately compensating the kind of work they are doing.

Mr. RYAN. How about the bridge between those kids that they are going into school now maybe and they are saying, yeah, it looks like primary care is going to be an opportunity for me. But in 2014 they will be just getting their bachelor's degree or their BS degree and moving on.

Secretary SEBELIUS. We are changing the Medicare pay rates, also. I think payment of debt once you get your medical degree is also a pathway to a much more robust primary care system. That is what I hear from medical students all the time, that they are in a real financial box in terms of not being able to pay off their loans and being inadequately compensated once they become providers. So we are looking at both ends of that puzzle.

Mr. RYAN. So you think they will move over immediately.

Secretary SEBELIUS. I do. Actually, we have seen an increase already this year in primary care choices made by first-year residents. It is up about 20 percent.

Mr. RYAN. Great. Thank you.

Mr. OBEY. Ms. DeLauro.

HEALTH REFORM COMPLIANCE AND ENFORCEMENT

Ms. DELAURO. Thank you, Mr. Chairman.

Welcome, Madam Secretary. Thank you for your efforts in helping us to pass what is historic legislation.

I know that your Department is working overtime to make sure that we begin the implementation of this legislation and that the people of this country can really experience the benefits as quickly as possible, whether they are small business owners or seniors or young adults or parents or people who have a pre-existing condition.

We have already seen a couple of instances where insurance companies seem to be changing their behavior in response to the bill.

On the positive side, we have seen several companies who plan to move ahead of schedule to let adult children stay on their parents' plan until age 26.

But there are instances in which we will need to watch insurance companies closely to make sure they are following the new rules that have been laid out. For example, some reports, including the Senate Commerce Committee, indicates that insurers may be manipulating their medical loss ratios, reclassifying certain expenses to make it look like they are spending at a higher percentage of the premium dollar on medical care in order to meet the standards in the law. The Affordable Care Act included rate review provisions, including grant funding to assist States carrying out rate reviews to stop insurance from hiking those premiums to unacceptable levels. This law now bans a host of insurance company abuses: rescissions, denials of coverage for pre-existing conditions, gender rating, and health status rating.

Let me just lay out the three pieces of this question, and I will let you go.

What resources and tools does HHS and the Department of Labor need for enforcement of health reform and holding insurance companies accountable?

With regard to medical loss ratio, how are you going to work with the National Association of Insurance Commissioners to en-

sure that terms like clinical services, activities to improve quality are defined appropriately, that do not include more routine activities that are more typically classified as administration expenses?

Today, in the New York Times, there is an article that says, Senate bill sets a plan to regulate premiums. The Federal Government could regulate rates in States where State officials do not have sufficient authority and capability to do so. Let me ask you to comment on that.

So if you could address those three pieces, I would appreciate it.

Secretary SEBELIUS. In terms of the resources and tools, Congresswoman, we are working very closely with both Labor and with Treasury that has a sort of piece of some of these puzzles on the initial regulations. That has gone pretty well. We have put together our Office on Consumer Information and Insurance Oversight. It is going to be led by a former insurance commissioner who also has worked in many States around the country on regulatory oversight.

We are working very, very closely with my former colleagues at the National Association of Insurance Commissioners because this has got to be, frankly, a State-led, on-the-ground program. They are the ones who have this ability and information.

I think there is a very robust discussion. They are in the midst of identifying the terminology and definition for the medical loss ratio. We are looking at some laws that are in place and work very well and what the actuaries can actually take a look at. So it is something we are going to take very seriously.

In terms of the rate review, the original Senate bill had a provision that Senator Feinstein was promulgating of a rate authority that would actually be the interim strategy between the time the bill passed this year and the time that the new exchanges were in place. That rate authority was not part of the reconciliation measure and I think would set up a framework where, absent State review authority, there would be a fallback review authority.

So I think that debate is likely to go on and may be an important piece of this puzzle, because, right now, unless a State changes the laws and takes on this responsibility, there really is not fallback, other than highlighting what rating is under way. But there is no rating authority right now with the Department of Health and Human Services, and we are encouraging States to do just that.

Ms. DELAURO. I am really pleased to hear that.

As you know, I come from the State of Connecticut. We probably are the insurance capital of the country. Over and over again, as my other colleagues have experienced, the insurance companies, we have lived in their world a very long time. It is now time for them to live in our world.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Moran.

PREVENTION ISSUES

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

Let me join the chorus of gratitude for your leadership, Madam Secretary. But it does seem as though you are paddling upstream against the current. When you look at your budget, about 85 percent of it is really not under your control. It is reimbursement after

people have gotten sick, and it is to the elderly. Medicare and most of Medicaid is still nursing home care for seniors.

But something dramatic is happening in the health care of this current generation of young people that bodes ill for the future costs of care. Asthma rates have tripled in this past generation. One in every six American children now has a developmental disorder—attention deficit disorder, mental retardation, dyslexia. One in every 59 boys is diagnosed with autism today. After accidents, cancer is the leading cause of death among children. Primary brain cancer has gone up about 50 percent. Childhood obesity has quadrupled in the last 10 years. Diabetes is out of control, about 25 million people now. In fact, they now say one in two minority children will develop diabetes during their lifetime. That is unbelievable.

So it would seem that somehow we have got to get a handle on prevention. What is causing all this? Because it really is a dramatic change in the last generation. The First Lady's emphasis upon obesity, upon what people eat, is critically important. I would like to know how you are integrating that in terms of your program priorities.

It also may have something to do with the chemicals in the air we breathe or the water we drink or the food we eat. In fact, there was an analysis of umbilical cord blood in 2007 and 2008 that showed that the average infant had 232 industrial compounds present in the umbilical cord blood. So many people think there may be an endocrine-disrupting effect on health care that is contributing to this massive increase in certain diseases.

I ask you because you have responsibility for the National Institute of Environmental Health Sciences. I know they have some indication this may be what is behind these massive changes in childhood illnesses. I am wondering if you have any plans to enable them to take a more robust, aggressive approach in terms of the environment's effect as well as what you are doing in coordinating with the First Lady's initiative on obesity.

Secretary SEBELIUS. Thank you, Congressman.

The statistics you recite are alarming and, unfortunately, very real and ones that we have to take incredibly seriously. The shorthand is that we spend more, live sicker, and die younger than most developed countries; and there is something fundamentally wrong with that picture.

The First Lady's initiative, as you know, is not only focused on what you eat. That is a piece of the puzzle. But I think it is a strategy that really looks across the areas and understands that the health of kids is impacted by what they eat in and outside their houses, what goes on in school, how much exercise they get, whether there is a safe place to play and walk, a whole host of strategies that I think provide a template for the kind of thing that you are talking about.

I don't think there is any question that, first, reporting is better in this generation. Some of what you are talking about is probably highlighted by better monitoring, better reporting. But that doesn't nearly compensate for the incredible increases. Some of it is preventable in terms of what we are doing to ourselves, and some of it is likely to have environmental impact.

My Assistant Secretary for Health, Dr. Koh, has reengaged our Department in a very robust fashion in working with the Environmental Protection Agency and others in looking at the health impact of environmental issues. HHS had kind of withdrawn from that space for a while, and we are very much back at the table. So whether it is looking at carbon content or water-based diseases or air quality, which has a huge impact on asthma, there are huge health impacts from environmental issues. And I would suggest also that the Food and Drug Administration is taking very seriously a whole host of investigations in terms of chemical content, which may well impact people not in terms what they are eating, but the kind of cans, the bottling, a whole host of other areas.

So this is all something that I think we are reengaging in a very active way and share your alarm and what the current health profile is for this country.

Mr. MORAN. Thank you, Madam Secretary.

Mr. OBEY. Madam Secretary, I have a number of questions that I would like you to answer for the record, one on health professions workforce, another on pandemic flu, a third on LIHEAP, one on health-care associated infections, oral health, health information technology, and several others.

HEALTH CARE REFORM

Mr. OBEY. But let me ask a couple of questions about the bill that we just passed.

Mr. Tiahrt and I are friends, but we often disagree. We are not disagreeable friends, but we are disagreeing friends very often. But in light of his characterization of the health care bill as a government takeover, let me ask a few questions. Is the VA a government agency?

Secretary SEBELIUS. Yes, sir.

Mr. OBEY. Is Medicare a government program?

Secretary SEBELIUS. Yes, sir.

Mr. OBEY. Is Medicaid a government program?

Secretary SEBELIUS. Yes.

Mr. OBEY. I thought so, too. Is this health care bill like Canada or Britain, or is it more based on a private-sector system?

Secretary SEBELIUS. The system is based on building out a private-sector strategy with new health exchanges.

Mr. OBEY. Will the doctors under the system work for the government?

Secretary SEBELIUS. Not unless they do right now. Some do for the VA, as you know, and for the Department of Defense. But, no.

Mr. OBEY. What about the nurses? Are we adding millions of nurses to the Federal payroll?

Secretary SEBELIUS. No, sir.

Mr. OBEY. What are these things called insurance companies? Are they public entities or are they private?

Secretary SEBELIUS. Private-sector companies.

Mr. OBEY. Are they usually profit-making private entities?

Secretary SEBELIUS. From everything I can tell, yes, sir.

Mr. OBEY. I thought so, too.

What does the health reform bill do for the fiscal solvency of the Medicare program?

Secretary SEBELIUS. Well, the estimate that was made when the reconciliation bill was proposed was that it added a minimum of 10 years to the life of the Medicare trust fund.

Mr. OBEY. What does it do to change the payment system from one based on frequency of procedures to one based on quality of medical outcomes?

Secretary SEBELIUS. Congressman, it sets a direction for Medicare to become, I would say, a quality-based purchaser as opposed to the current strategy of fee-for-service, which is more about content than about quality.

Mr. OBEY. I agree with all of that.

Let me just tell you a story, because we have had such controversy and such points of disagreement about the details of this plan.

Between 1930 and 1938, a fellow by the name of Gerry Boileau represented my congressional district. He was the last of the LaFollette Progressive Republicans. When Fiorello LaGuardia became mayor of New York, he succeeded LaGuardia as the spokesman for the Progressive Republicans in the House; and then he was beaten in 1938.

My dad ran a supper club when I was much younger. Gerry came home and became a local judge. He came into our place one evening, and we started talking, and I finally asked him, Gerry, what beat you in 1938?

He said, senior citizens. He said, I was strongly for Social Security and in my district the seniors were against it.

I said, what on Earth are you talking about? How can seniors possibly be against Social Security? Not the seniors I know today.

He said, in those days, it was different. He said, in those days, we had Social Security as one alternative, which is a contributory program. And then we had the Townsend plan, old Doc Townsend from California, who didn't want a contributory plan. He just wanted, I think, a hundred-dollar-a-month welfare payment to every senior. And he said, we all knew that couldn't survive very long because the country doesn't like welfare. So he said, I strongly supported Social Security. And old Doc Townsend came into my district and helped organize Townsend clubs; and he said, they beat me.

The point of the story is this: We look today, shortly after the health reform bill is passed, and we see all of these little fights that we had—regional, ideological, philosophical—but I think 20 or 25 years from now we are going to look back at the bill and say, what on Earth was that fight all about? How on Earth could we ever have functioned without this program? I think all of these little fights that were so important to people as we were going through them, none of them are going to be remembered. What will be remembered is that we finally put this country in the rank of civilized societies that do not require people with very little money to beg in order to get health care. That, to me, is basically the lesson of Gerry Boileau's story.

I mean, I lost a whole lot more fights than I won on the health reform bill. I favored public option. I have no objection to single payer. I, frankly, didn't care as long as we got two things, as long as we covered as many people as possible and as long as we

changed the rules of the game so that little people weren't squeezed by corporate giants called insurance companies. That is basically all I wanted. Everything else is candy.

I just want to thank you for the work that you did on this package and to thank everybody who voted for it and to thank those who opposed it and raised constructive questions along the way. Because, to me, regardless of all these little debates that we had, the obligation that all of us have now is to simply try to make it work and to think through whether there have to be adjustments down the line, make certain we have got plenty of oversight, and especially make certain we have got a huge expansion of our efforts to go after waste, fraud, and abuse. Because you have got lots of jerks in this society who will try to take advantage of this and rip off the taxpayer and rip off customers. If we believe in expanding these services, we just can't let that nonsense happen.

Secretary SEBELIUS. Well, I appreciate that, Mr. Chairman.

I spent Easter weekend with my father, who turned 89 on the 22nd of March. He served in the United States Congress on the Energy and Commerce Committee 45 years ago when Medicare was passed. He told me a number of stories about how ferocious that battle was, how ferociously a number of people opposed Medicare's passage, and how differently it looked then than it does now, where he is now a pleased beneficiary, and reminded me that over 45 years there have been changes, there have been a number of improvements, but the basic tenet that, once you turn 65 in this country, that you have health security, was a promise made then and a promise that we intend to keep now. It was interesting having his historic perspective on the beginning of this new chapter in American health security.

Mr. OBEY. Thank you. I am going to have to go over to the House for action on a bill that is going to be pending shortly. And so if I have to leave before the hearing is done, it is nothing you said. I just have to get over there.

Secretary SEBELIUS. I am pleased to hear that.

Mr. OBEY. I will ask Ms. DeLauro to take over if we are not done. Meanwhile, I would like to run a second round for about 3 minutes apiece.

Mr. Tiahrt.

UNFUNDED PROGRAMS IN HEALTH REFORM

Mr. TIAHRT. Thank you, Mr. Chairman. I want to remind you the hearing isn't done, so maybe there will be something come up that won't make you want to leave early.

One of the things that concerns me greatly is about the cost of this. Because, quite frankly, we have overspent this year by more than $800 billion this fiscal year. We know that there are at least 80 programs that are in the bill that require discretionary appropriations, and we have about $110 billion for these 80 programs. There are also 36 programs, at least—three dozen programs—that are open-ended.

I have asked the Congressional Budget Office to give us some estimate as to what they are going to cost. They don't sound like very cheap programs. Of the 36, community health insurance option, design and implementation of regional systems for emergency care,

trauma care centers and service availability, oral health care prevention activity, programs relating to congenital hart disease, multi-State qualified health plans, community-based collaborative care networks, to name a few.

So, in addition, it is my understanding the CBO has estimated that CMS and the IRS will need an additional $20 billion in order to set up the systems just to implement ObamaCare. So has your Department developed a cost estimate for all these new programs that are not in the President's budget, and when will you be sending an addendum to the President's budget for next year to cover these costs, and where will the money come from?

Secretary SEBELIUS. Well, Congressman, you have our 2011 budget presentations; and there is not an intent to send an addendum to the budget.

Mr. TIAHRT. How will you cover the cost of these programs that are not in the budget? It says in the law such sums as required. Where are such sums going to come from?

Secretary SEBELIUS. Well, my understanding is, the way that process works, if there isn't authorization in the bill itself, this will be a discussion that you and your colleagues will have here in Congress.

Mr. TIAHRT. So we are going to have to come up for the funding for these programs?

Secretary SEBELIUS. If the priorities are to move ahead on those programs, I assume they will be funded. But you have our 2011 budget submission before you.

Mr. TIAHRT. So the 302(a) allocation that we have and the 302(b) allocation for your Department right now doesn't have a request from the President for such sums as required on these 36 programs.

Secretary SEBELIUS. That is correct.

Mr. TIAHRT. So, Mr. Chairman, where are we going to get the money for these programs that we don't have any budget for and we won't have any allocation for?

I guess he is involved in another conversation.

My concern is that we don't have the funding for this and we have no idea how much it is going to cost and, again, we don't know where the money is coming from. China is not lending us money on long-term Treasury bills now. The Fed has loaned money to the United States. They already owe us—or we owe them $5.5 trillion as taxpayers. Where is the money going to come from?

Secretary SEBELIUS. Congressman, again, I think that the programs are likely not to exist unless they are funded by Congress. That is not currently part of the authorized bill. I think the very good news for the American public is that, unlike the last major health initiative move forward, the prescription drug benefit, this bill is paid for. It is paid for over time. In fact, the Congressional Budget Office has estimated an $100 billion decrease in the deficit in the first 10 years and closer to a trillion dollars decrease over the next 10 years. This is fully paid for over the life of the program.

Mr. TIAHRT. You can't count Medicare dollars twice. We are taking money out of Medicare and adding them to the program that you are going to administer. Where is the money for the $500 billion for Medicare? There are a lot of programs, Mr. Chairman, that

don't have funding. They are not in the President's budget. We won't get the allocation for them. I am just wondering how we are going to fund them.

Mr. OBEY. First of all, the gentleman's time has expired.

But let me simply answer the gentleman's question by saying there is a big difference between programs that are authorized and programs that are mandatory. These are not mandatory programs, to my understanding.

Mr. TIAHRT. Are we not going to fund the community health insurance option, the oral health care prevention activities?

Mr. OBEY. Given the fact that we have a good $17 billion hole in the budget on Pell Grants, I have no idea what we are going to be funding on anything.

Mr. TIAHRT. Thank you, Mr. Chairman.

Mr. OBEY. I don't think anybody else does, either.

Who is next? Ms. Roybal-Allard.

UNDERAGE DRINKING

Ms. ROYBAL-ALLARD. Secretary Sebelius, Congresswoman DeLauro and I have been working together for over 10 years to reduce the dangerous incidence of underage drinking in this country, and we were very pleased that your administration recommended an increase to the STOP grants this year to enable more communities to address the critical problem. We have heard, however, that the HHS is looking to further expand its efforts in underage drinking prevention.

The questions that I have are, first of all, CDC and NIH are recognized leaders in developing evidence-based strategies on underage drinking. So what are you doing to ensure that the rest of HHS uses their guidance and guidelines in implementing programs directed at preventing and reducing underage drinking? How will you ensure that the State public health agencies with their own rich experience in tobacco control and other public health insurance are fully engaged in collaboration with State substance abuse agencies? And what will be the roles and resources available to the various HHS agencies to ensure that all of this happens?

Secretary SEBELIUS. Congresswoman, as you say, we do have a recommended budget increase for the STOP Act. I think that is a step of directing more resources.

We also have a talented new leader in the agency as my Assistant Secretary of Substance Abuse and Mental Health Services, Pam Hyde, who not only has run State systems but has worked in the private sector and run medical systems and is very tuned into this issue and is very much at the table looking at collaborative strategies.

So we have the Substance Abuse and Mental Health Services Administration at the table. We have our scientific-based evidence from CDC and the strategies that work on the ground, and we are working in collaboration with State and local partners to make sure what we know is effective actually is drilled down. So this is an effort.

One of the things that the President made clear to all of his Cabinet officers is that he wants us to leverage our assets not only

across departments but within our own agencies. So we have a number of cross-agency collaborations, and this is one of them.

SECTION 317 VACCINATION PROGRAM

Ms. ROYBAL-ALLARD. That is great to hear.

In fact, you mentioned in an earlier statement, the 317 vaccination program. This program historically has been used for vaccinating children. However, each year, hundreds of thousands of American adults are hospitalized and tens of thousands die from diseases that could have been prevented through vaccination.

It is estimated that the cost of the health burden to society from vaccination-preventable diseases is approximately $10 billion annually. How will HHS use existing funding streams to address the issue of increasing adolescent and adult vaccinations, and has the Department considered developing an adult immunization strategy? And, in particular, what could be done to increase vaccination rates among health care workers?

Mr. OBEY. If we could have a fairly short response, please.

Secretary SEBELIUS. We are working on this. I was just at the 44th annual vaccination week-long conference. We learned a lot of lessons from H1N1 that we intend to apply across the board, and one of them is how to deal more effectively with not only minority communities but with health care workers.

Ms. ROYBAL-ALLARD. Hopefully, we can follow up on this.

Mr. OBEY. Mr. Cole.

Mr. COLE. Thank you, Mr. Chairman.

I was listening to that wonderful story about Gerry Boileau. And I must say, the moral I drew was that progressive Republicans always get beat by liberal Democrats that say they love them. So it is kind of a warning story there for me.

On a more serious note, I share Mr. Tiarht's——

Mr. OBEY. But he got beat by another Republican.

PROJECTED COVERAGE RATES

Mr. COLE [continuing]. I share Mr. Tiahrt's concern about some of the financial bases of the bill, the one he particularly highlighted about the transfer of Medicare funds out for, really, a new entitlement program at a point when we have a baby-boom generation hitting Medicare age. I just don't think it is going to hold.

Let me ask you about another part of it that concerns me greatly, Madam Secretary. Right now we assume that there is—and I think you said the majority of people moving into the system would be insured by private insurance. I am not 100 percent sure that is accurate, because the numbers I saw suggested about half were going to be, actually, Medicaid patients. So, at best, it is pretty close as to whether they are going to be purchasing insurance.

And, as I understand the bill, frankly, those younger people are going to have an option—well, it is, quote, "mandatory." They can pay a penalty as opposed to just buy insurance. The penalty that I have seen is cheaper than the insurance. And I would suggest a lot of them are going to do what most people in their 20s and early 30s do, and that is take the cheaper road out. Whether that is wise or not is debatable, but I think that is true.

So how confident are you that the new people showing up to be insured, given the fact that many of them are Medicaid and given the fact that many of them have a way out when they are young and healthy, are actually going to provide the revenue stream that the bill envisions?

Secretary SEBELIUS. Well, Congressman, the experience in Massachusetts, which is one that we looked to—and there are other States who have—Wisconsin, again, has a pretty near-universal insurance avenue. But in Massachusetts, a fairly similar structure—an individual mandate with a relatively low penalty for failing to buy insurance, plus a hardship waiver—has produced 97, 98 percent insurance coverage.

The experience that they have found is that people really wanted insurance; they just felt that there were too many financial barriers or health barriers, frankly, to get into the marketplace.

So, at least in the instance that that fairly similar structure has been tried, there actually was a very robust take-up in spite of some skeptics who thought that people would opt out if they were younger and healthier.

PHYSICIAN-OWNED HOSPITALS

Mr. COLE. Let me ask you—my time is about to run out, and it is a totally unrelated question. But one of the provisions of the bill that really concerned me, the treatment of physician-owned hospitals—and I realize there is a philosophical divergence in Congress over that particular issue. In my State, they are some of the highest-performing hospitals that we have. By every rating they provide excellent care, and we have been very pleased with them.

What is the general attitude of the administration toward physician-owned hospitals, looking forward?

Secretary SEBELIUS. I can honestly tell you I haven't ever been involved in a, sort of, philosophical discussion. There isn't any directional discussion. I think it has more come from Congress, frankly, and the alarm in certain areas of the country of the proliferation to what some have seen as the disadvantage of community hospitals trying to run emergency rooms and contributing to graduate medical education and then being cherry-picked by provider-based hospitals.

But I don't think the Department, itself, has a directional strategy. It really is looking at high-quality, cost-effective health-care delivery. And, as you say, some are in physician-owned hospitals and others are sometimes in community hospitals. But that is really our goal.

Mr. COLE. I would just say in closing on that, just so you know, in our State most of the physician-owned hospitals operate emergency rooms, they take Medicare patients. So they really stack up pretty favorably. And I would just commend you to consider that as one of the models, going forward. I am glad to hear that there is not an administration position per se.

Thank you.

Mr. OBEY. Mr. Honda.

CHILDREN'S HEALTH TASK FORCE

Mr. HONDA. Thank you, Mr. Chairman.

The health reform issues are also going to be including our concerns of children's health issues. And children probably compromise 50 percent of our Medicaid rolls. Will there be any thought about establishing a children's health task force?

And leading up to that, my county of Santa Clara County recently has had the third-highest rate of TB in California, and it has really grown from almost an elimination of TB in our county to being third in the State of California.

Given that rise and given the work that you are going to be required to do, as far as travelling and everything else like that, I was just concerned that you had sufficient resources to be able to do the kind of travel and create the kind of presence that is going to be expected when you are going around the country to make the negotiations and be an advocate for this program.

Those two questions, if I could have a quick response.

Secretary SEBELIUS. Congressman, I think in terms of the travel and presence responsibility, cloning would come in very handy in this instance, because I do think there is a lot of confusion and concern and also a lot of eagerness about people wanting to know about the bill, how it is going to work, how it is going to be implemented. And I can assure you, I am going to do my best, as are lots of members of our department, to be out and about everywhere.

The Children's Health Insurance Program, which you all extended in 2009 prior to the passage of the Affordable Care Act, I think is a great focus on making sure that children have appropriate intensive care, particularly at the youngest ages. And we are undergoing a very aggressive outreach effort in conjunction with faith-based and neighborhood groups, with health-care providers, with State and local partners, to identify and enroll the approximately 5,000,000 children who are eligible but currently not enrolled. It continues to be a challenge.

The good news is, even last year in very difficult budget times, States and local governments signed up an additional 2,500,000 American children. We would like to see that continue to rise. And I think that, as you know, the SCHIP program continues during the life of the Affordable Care Act. And I think that is going to focus that kind of attention and services on the children's population and one that we take very seriously.

Mr. OBEY. Mr. Ryan.

FORUM HEALTH BANKRUPTCY

Mr. RYAN. Thank you, Mr. Chairman.

Madam Secretary, you know Ohio well. I represent a district in Youngstown and Akron. And in the city of Youngstown, we have two health-care systems. One of them is Forum Health, which employs approximately 4,000 people in the region, and it is now trying to emerge from bankruptcy. Youngstown has about a 15 or 16 percent unemployment rate. The city of Warren has one very similar.

In adding 30,000,000 new people to the system and many in Ohio and western PA, I don't think now is a good time to see a hospital close down. And I was wondering if there is anything in your sights or from the administration that could help address this issue.

Secretary SEBELIUS. Well, my understanding is we solved one of the problems, in terms of a payment stream that will continue during the discussion, which I think is important. And, again, I think that the framework of having a payment system under the individuals who will seek hospital care in the future is a big step forward. And hospitals have really struggled.

I also think that there were huge improvements made in the bill over the course of the discussion dealing with disproportionate share allocation, where originally there was a thought that it could disappear entirely, and I think that was recalculated appropriately based on the fact that there are huge disparities in terms of the patient load that is likely to hit various hospitals.

But I think you are absolutely right that we need a robust health-care delivery system. And it is something that we are going to be working with local communities, looking at ways we can provide resources in this kind of bridge strategy to make sure they continue to provide services.

Mr. RYAN. Well, in the meantime, until 2014 when everyone comes in, I mean, hospitals like this could potentially close down. And I think in the Department of Agriculture there are some loan guarantees. And maybe we can come up with some ways to help these hospitals refinance. Because, you know, between now and then, a lot could happen, and the other hospital in town can't handle the influx that they could potentially receive.

Secretary SEBELIUS. With the Community Development Block Grant money, I think which is in HUD, and some other funding streams, I think we have to be more creative about bringing other agencies in. HHS really doesn't have either operational money or construction money, with regard to hospitals. But I think having that dialogue with my Cabinet colleagues is something that I am going to pursue, because it has come up in a number of areas, and it is a very critical piece of the health-care system. I think just like closing a school in a small town, you can't close a hospital, or people won't stay in the community.

Mr. RYAN. Right. So I look forward to working with you on that, because it is urban development, it is health, it is education, it is everything. So I appreciate that.

Mr. OBEY. Ms. DeLauro.

FOOD SAFETY

Ms. DELAURO. Thank you, Mr. Chairman.

Madam Secretary, let me just ask a food safety question of you. The volume of FDA-regulated imports has increased substantially over the past decade. The statistics say that FDA recorded 8,200,000 imported food lines in 2007; fewer than 2,800,000 entry lines a decade earlier.

You have just over 1 percent of these lines that were physically examined and/or tested. It is often reported that, even with increased funding that the Congress has provided to the agency in these past 3 fiscal years, the FDA will still inspect less than 2 percent of import lines in 2011.

This is mainly because the FDA relies on a very weak border inspection system. I also might add that there are indications that

there potentially will be more inspectors but we could have fewer inspections.

Again, can you tell us how do you think the FDA can improve in this area? There is the FDA food safety bill pending before the Congress in the Senate. How can that help to change this equation? And how do we deal with improving the inspection ratios in the next 5 years?

Secretary SEBELIUS. Well, Congresswoman, first of all, thank you for your long-time leadership and expertise and interest in this area. And it is one that has changed dramatically over time. We no longer have an American-based food system, and I think that the regulatory framework is 20th-century at best and the system is global and increasingly global. Half our fruits and vegetables come from outside our borders; about two-thirds of the seafood comes from outside our borders, just to name a couple of products.

No question that the new framework passed by the House and pending in the Senate is a huge step forward and has a lot of the expertise of this committee's stamp on it—not this committee, but your expertise as part of moving that ahead.

I do think that part of the strategy also is the FDA establishing a much more robust footprint in other parts of the world. So there are now four new offices in China, there are offices in Mexico, there are offices elsewhere, to not wait until products actually come across the borders, but look at the origins of those products.

Secondly, I think it is critical that we have a much more robust and a different relationship with the private sector. The food industry often takes the hit. At a time of a recall, they have enormous financial risk, but have been, I think, not as engaged and involved in self-reporting, identification, quick recalls. The FDA needs some additional subpoena power and automated recall power, but also engagement of the industry at a much earlier stage, which, again, is part of the framework moving forward.

Ms. DELAURO. Mr. Chairman, just one final comment.

I just would say this to you, Madam Secretary. For years and years and years, the whole issue has been that trade in this area of food safety has trumped public health. I will be vigilant—I am hopeful, but vigilant that that will continue not to occur, that trade will get in the way of what we can do with regard to the public health as it regards food safety. Thank you.

Thank you, Mr. Chairman.

Mr. OBEY. Thank you.

Madam Secretary, thank you for being here. We kept you a few minutes over, but not much. Good luck to you.

Secretary SEBELIUS. I appreciate it. Thank you so much.

HEALTH PROFESSIONS WORKFORCE

Mr. Obey: While so many people struggle to find jobs in this tough economic time, the demand for highly trained health care professionals continues to grow. In fact, the health care sector added more than 600,000 jobs since December 2007. The Bureau of Labor Statistics predicts that more than half of the top 30 fastest-growing occupations through 2018 are related to health care.

Last year this subcommittee instructed your Department and the Labor Department to establish an interagency taskforce to work on health professions training issues. What is the status of this task force? Can you provide an update on its progress so far?

Secretary Sebelius: The interagency task group composed of staff from HRSA and the Department of Labor has been engaged in discussions regarding collaborative strategies since last fall. Key areas of attention are strengthening and expanding career ladder programs to allow individuals to enter and advance through the workforce as well as examining the potential for collaboration in area of workforce data activities. HRSA expects the report to be available within the next few months. The report will identify key areas of collaboration and outline a strategy to proceed forward aligning similar interests and activities.

Mr. Obey: In the Recovery Act, Congress provided $200 million to HHS for health professions training to give more Americans the opportunity to enter this growing industry. How have you used this funding?

Secretary Sebelius: The American Recovery and Reinvestment Act (ARRA) provides funding to support health professions training programs to address the health professions workforce shortage as well as improve workforce diversity, including:

- Training of underrepresented minority students, including recruitment and retention to increase diversity in the workforce and to increase access to healthcare to underserved populations;
- Training of the primary care medical and dental workforce to help address the primary care workforce shortage and to make primary healthcare services more available to the American public in all areas of the country;
- Training of the public health workforce and the training of preventive medicine residents to address the public health workforce shortage; and
- Education and training of nursing students and faculty as well as the provision of loan repayments and scholarships to address the nursing shortage and to increase the supply and diversity of the nursing workforce and to address the shortage of nursing faculty.

ARRA funding was also used to provide access to support the purchase of equipment to be used to expand the capacity and improve the quality of health professions training programs.

Mr. Obey: Future workforce shortages are predicted in almost every field in health care. Given those predictions, can you explain why the President's budget request provides no increase at all for most health professions training programs?

Secretary Sebelius: The FY 2011 President's Budget provides a $169 million, a $27 million increase, for scholarships and loan repayments in the National Service Corps which will add 400 providers to the more than 8,100 that will be providing primary care services across the country. The Budget continues support for programs aimed at increasing the supply of health professionals focusing on primary care and public health and increasing the diversity of the workforce. The Budget also supports the provision of clinical training experiences in medically underserved areas to increase the likelihood that providers will go on to practice in underserved areas. The President's 2011 Budget requests increased funding for workforce information and analysis. These funds will be used to strengthen and expand the analytical efforts that inform program investments for the future.

ORAL HEALTH CARE

Mr. Obey: Oral health should be an inseparable component of general health and we need to do a better job of making that happen. Dental problems can cause severe physical suffering and disrupt a child's ability to learn. They can also be the first sign of other serious illnesses.

Statistics show that Americans do not have proper access to oral health care. For instance, tooth decay is the most common chronic childhood disease and yet almost one-fourth our children did not have a dental visit in the last year. The budget request includes an additional $25 million for service expansion grants for Health Centers. Can you tell me why oral health care was not included within this request?

Secretary Sebelius: The $25 million for behavioral health is an expanded initiative to address the behavioral health needs of health center patients, in particular focusing on the addiction service needs of patients. The President's budget does include continued support for the Increase Demand for Service grants that included a significant expansion in oral health services. As of March 31, 2010, health centers reported having expanded oral health services to more than 300,000 additional patients, supporting more than 700,000 oral health visits and more than 500 additional oral health professionals.

Mr. Obey: Can you tell me why the request for the Maternal and Child Health Block Grant Program did not increase oral health grants when the request included an additional $1.4 million for Special Projects of Regional and National Significance?

Secretary Sebelius: The President's 2011 Budget request maintains funding for the oral health set-aside at the FY 2010 amount of funding. The increase in Special Projects of Regional and National Significance funds will support innovative projects to improve maternal and child health.

Mr. Obey: What steps have you taken to ensure that, at each agency within HHS, dentists are part of the leadership team that shapes public health policy? For example, the Agency for Health Research and Quality plays an important role in identifying and publishing best practices for medical treatment. Despite the importance of oral health, there are no dentists on the agency's National Advisory Council.

Secretary Sebelius: While currently there are not any dentists on AHRQ's National Advisory Council (NAC), the NAC has addressed the issues of improving access to and quality of dental care. Title IV of the Children's Health Insurance Program Reauthorization Act (CHIPRA; Public Law 111-3) called for the Secretary to identify an initial core set of children's health care quality measures to be posted for general comment by January 1, 2010. AHRQ, working in very close partnership with CMS, was responsible for identifying the initial core set of measures.

As part of their effort to use a transparent and evidence-based process for identifying initial measures, AHRQ asked its NAC to establish a time-limited Subcommittee (SNAC) to look at Children's Healthcare Quality Measures. The SNAC agreed to recommend to the NAC 25 measures for the initial core measure set, which included measures to improve quality of and access to dental care. When AHRQ makes its next public call for individuals interested in serving on the NAC, I will take into careful consideration those individuals who have backgrounds in dentistry and oral health.

SECTION 317 IMMUNIZATION PROGRAM

Mr. Obey: How many children, adolescents, and adults were served or are estimated to be served by the CDC Section 317 program in FY09, FY10, and FY11?

Secretary Sebelius: CDC has estimates for the number of children and adolescents served for all three fiscal years and for the percentage of vaccine purchase funds used to purchase adult vaccines in FY 2009. CDC does not have numbers of adults vaccinated or estimates for the percentage of vaccine purchase funds used to purchase adults vaccines in FY 2010 or FY 2011 until CDC can analyze provider orders for those fiscal years. Grantees prioritize their Section 317 funds to meet the needs of their priority populations, which includes children and adolescents, and vaccines are provided to adults as funding allows. Because provider priorities can change, relying on actual order information is a more accurate data source to use to estimates the number of adults vaccinated. Based on provider orders from FY 2009, approximately 12 percent of Section 317 vaccine purchase funds (approximately $31 million) were used to purchase adult vaccines.

	Number of Children Able to Be Fully Vaccinated[1]
FY 2009	208,249
FY 2010	194,098
FY 2011	207,858

[1]Provide all ACIP routinely-recommended vaccines for a child from birth through 18 years of age with the following vaccines: DTaP, Hib, polio, MMR, hepatitis B, varicella, PCV, hepatitis A, Tdap, MCV, rotavirus, influenza, and HPV (females only). Adolescents served are included in the category of 0-18 year olds.

Mr. Obey: With the $4.8 million requested to conduct needs assessments and develop plans that will enable health departments to bill private insurance programs for immunization services provided to cover patients, how many States are estimated to be supported and at what estimated funding levels?

Secretary Sebelius: With the $4.8 million requested, CDC estimates than ten Section 317 grantees could be supported with an average award of $480,000 per grantee.

VECTOR-BORNE DISEASES

Mr. Obey: What is the rationale for eliminating the vector-borne diseases portfolio at CDC? Will the surveillance program, ArboNet, continue to operate in FY2011 and beyond despite this elimination?

Secretary Sebelius: The FY 2011 budget request does not include specific funding vector-borne activities, including West Nile Virus (WNV) surveillance. Several years of CDC funds have allowed states to develop and enhance their WNV activities. FY 2011 funds include $155.2 million for the emerging infectious disease budget line, an increase of $18.9 million above FY 2010. These Emerging Infectious disease funds can support vector-borne activities in FY 2011, including WNV if determined a priority by States and the CDC. Because the priority determination for these funds has not yet been made, the continuation of ArboNet is uncertain at this time.

Mr. Obey: If not, how will data be collected for vector-borne disease surveillance, such as for the following nationally notifiable diseases that use this surveillance system to detect disease: Dengue fever, West Nile virus, St. Louis encephalitis, Yellow Fever, Eastern equine encephalitis, Western equine encephalitis, California serogroup virus, Powassan virus, etc.? Plus there are other diseases for which CDC collects data using ArboNet, but are not considered nationally notifiable - how will data be collected for those diseases?

Secretary Sebelius: The States are required to report only human cases of dengue, yellow fever, West Nile, St. Louis encephalitis, western equine, LaCrosse, and Powassan viruses. These will continue to be reported to the National Electronic Disease Surveillance System (NEDSS). For diseases not considered nationally notifiable which CDC collects data using ArboNet, if CDC does not continue ArboNet, then CDC will not collect data on diseases that are not nationally notifiable.

HEALTHCARE-ASSOCIATED INFECTIONS (HAI's)

Mr. Obey: People go to the hospital to get better. But according to CDC, 1.7 million Americans get sicker and nearly 100,000 die every year in health care facilities when they acquire a healthcare associated infection. I have made preventing and reducing healthcare-associated infections a major funding priority for this subcommittee. Since fiscal year 2009, we have invested $139 million into an aggressive campaign to eliminate these easily preventable infections. Funding has been provided for establishing a National Action Plan; supporting hospitals and States to fund prevention, research, and monitoring efforts; and launching a National Consumer Education Campaign.

I am pleased to see that your budget request includes $27 million for CDC's National Healthcare Safety Network, which is a $12 million or 80 percent increase. This funding will support health care-associated infection and prevention activities in all 5,000 short stay and critical access hospitals. But in the last three years, the Committee's investments have not

focused solely on CDC. Based on HHS' own action plan to prevent healthcare-associated infections, increased resources have also been provided to the Office of the Secretary, the Agency for Healthcare Research and Quality (AHRQ), and the Centers for Medicare and Medicaid Services.

A report released just last week by AHRQ states that healthcare-associated infection rates are not declining and are, in fact, getting worse. So why hasn't HHS prioritized additional resources in 2011, beyond the CDC increase, to address these preventable infections?

Secretary Sebelius: We appreciate your leadership and support in the Department's efforts to reduce healthcare-associated infections. Both CDC and CMS are implementing programs for the one-time funds of $50 million provided to States under the Recovery Act for healthcare associated infections. With Recovery Act funds, CDC is supporting States in leveraging the National Healthcare Safety Network, and CMS is expanding State Survey Agency inspection capability of Ambulatory Surgery Centers nationwide. The FY 2011 Budget includes $79 million across AHRQ, CDC, and the Office of the Secretary, an increase of $12 million above FY 2010. This increase builds on CDC's Recovery Act efforts to expand the National Healthcare Safety Network and continues the healthcare-associated infections activities of other agencies and offices.

Mr. Obey: What more needs to be done to eliminate these infections from occurring in U.S. healthcare facilities?

Secretary Sebelius: The HHS Action Plan to Prevention Healthcare-Associated Infections provides a vision for addressing these infections. Specifically, the plan identifies priority measures and five-year national prevention targets for assessing progress in healthcare-associated infections prevention and can be accessed at http://www.hhs.gov/ophs/initiatives/hai/infection.html.

BLOOD DISORDERS

Mr. Obey: Please tell the Committee how the current blood disorders portfolio at CDC will be impacted by the change requested in the FY 2011 budget request.

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

Mr. Obey: For example, the CDC budget justification indicates that CDC is proposing to shift the focus away from its traditional clinical orientation and towards a population-based public

health model. Does this mean that CDC's support for the 140 hemophilia treatment centers, 8 hemostasis and thrombosis centers, and 6 thalassemia centers will end in FY2010?

Secretary Sebelius: CDC anticipates increased program efficiencies by merging and re-designing data collection systems from those that focus on single disorders to a single system that collects data needed for monitoring health outcomes for multiple disease and disorders. CDC does not anticipate a discontinuation of funding in FY 2010; rather, these efficiencies will be achieved as grant awards expire over the next two years and new funding opportunities are developed. For instance, CDC has a long and robust history of partnership with a national network of 135 hemophilia treatment centers that has a documented history of improved health outcomes for hemophilia patients. CDC plans to continue this national network for the hemophilia population as well as those suffering from the most prevalent blood disorders.

INTEGRATION OF PUBLIC HEALTH SURVEILLANCE SYSTEMS

Mr. Obey: CDC and State and local public health departments have numerous surveillance systems in place to monitor infectious diseases. CDC has BioSense, the National Electronic Disease Surveillance System, Global Disease Detection centers, and disease-specific outbreak response networks, such as FoodNet, the Laboratory Response Network, the National Healthcare Safety Network, etc. Each State and some large cities also have their own surveillance systems in place. Do all of these systems feed into a larger national surveillance system?

Secretary Sebelius: Each of these systems, whether electronic or paper-based is part of a larger national surveillance enterprise that relies on trained and well qualified public health practitioners to integrate data from various systems. The larger enterprise is made up of Federal, State, and local public health agencies working with private providers to collect longitudinal data at both the clinical and population level. Each part contributes to a more comprehensive picture of the health status of the nation's communities that can only be found in integrating biosurveillance information from numerous sources. This integrated information is the basis for enhanced decision making across the biosurveillance enterprise. This cannot be accomplished through a single technology solution. Rather, it can only be accomplished through integration of data from various sources by well qualified and trained public health professionals.

Mr. Obey: What is CDC doing to integrate these systems?

Secretary Sebelius: CDC is completing its organizational improvement efforts, which includes the creation of the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) to integrate information and data across CDC programs and with partners. Currently, CDC is cataloguing all the biosurveillance/surveillance systems, programs, tools, collaboratives, and registries at CDC. At the completion of the initial compilation of this catalogue, information about existing human health-related biosurveillance/surveillance assets will be more visible across disciplines and tiers of government which will foster improved programmatic decision-making and coordination of public health efforts. This will also give agency decision makers a better understanding of where gaps and redundancies are across the enterprise and will provide a roadmap for resource uses in the future.

Mr. Obey: What is CDC doing to standardize public health disease data collection across jurisdictions to facilitate better information sharing?

Secretary Sebelius: The Nationwide Health Information Network (NHIN) and the standards for biosurveillance published by the Health IT Standards Panel (HITSP) are expected to serve as the foundation for a nationwide health information exchange. Interconnected networks will share common services and adhere to standards and requirements to enable interoperability. The enriched data-sharing environment will allow both clinical and public health professionals automated processes for entering information, access to health information when they need it, automated analyses that support notifiable disease detection and outbreak cues, query abilities for additional investigation when warranted, and feedback loops to validate findings and enact countermeasures.

Mr. Obey: What specific gaps remain in coordinating public health surveillance and what steps are being taken to address these gaps?

Secretary Sebelius: The optimum surveillance approach for event detection varies by locality and is affected by such considerations as population density, healthcare provider density and distribution, geographic area under observation, nature of healthcare provision, availability of laboratories, endemic diseases, and other local factors. The National Biosurveillance Strategy for Human Health (Strategy) provides the foundation for a long-term effort to improve a nationwide capability to manage health-related data and information. The Strategy identifies six priority areas to address critical gaps and suggest opportunities for improvement. They are as follows: Electronic Health Information Exchange, Electronic Laboratory Information Exchange, Unstructured Data, Integrated Biosurveillance Information, Global Disease Detection and Collaboration, and Biosurveillance Workforce of the Future.

There are still some significant gaps from State to State in the capabilities of Electronic Laboratory Information Exchange. This is the ability to exchange electronic information from labs with public health epidemiologic programs. Laboratory reporting is required in all States for test results related to State reportable and nationally notifiable conditions. Thus, this information, when combined with other epidemiologic data, forms the basis for public health investigations. Additional examples in gaps for this and the other priority areas can be found in *The Strategy.* (http://www.cdc.gov/osels/ph_surveillance/bc.html). CDC is working with Federal, State, local, tribal, and territorial partners to monitor and support the implementation of the Strategy.

BIOSENSE

Mr. Obey: CDC's BioSense program as it was initially designed was criticized for not sharing information at the State and local public health levels and for being solely data focused and not focused on public health outcomes. As the Committee understands it, CDC has revised the BioSense program to address some of the concerns. Please update the Committee on the status of the BioSense program. Is it now fully operational or are more changes envisioned?

Secretary Sebelius: BioSense is operational across the current participating healthcare facilities, health systems, and health department surveillance systems. However, because the BioSense Program is not yet fully integrated with State and local health department syndromic

surveillance programs, future changes are envisioned to correct this. These changes include efforts to ensure distribution of data to all levels of public health and to support State and local public health systems' capacity development to ensure they are able to analyze and interpret the data for public health action. The BioSense program will use an approach that puts more emphasis on supporting and coordinating the ongoing development and use of automated surveillance systems in States and supports a more collaborative approach to the development and direction of BioSense.

Mr. Obey: Are there efforts within CDC to integrate other already existing CDC and State surveillance program data into BioSense?

Secretary Sebelius: BioSense is now being integrated into the operating picture at more state health departments since data are now available to both CDC and states. Furthermore, CDC is continuing to request input from partners to make BioSense a more user-friendly and meaningful system to those on the front lines of public health in State and local health departments. This input will be supplemented with the recommendations of a Technical Expert Panel (TEP), which will be constituted once the new BioSense design and prototype development solicitation is awarded. The solicitation is in progress. The TEP will assist in reviewing and making recommendations to further increase the utility of BioSense to the public health community at large and to the response community for situation awareness specifically. It is likely that BioSense program stakeholders will identify some existing CDC and State surveillance program data that should be integrated into BioSense to improve the utility of the data for population health assessment and improvement.

Mr. Obey: Currently, there are over 1,800 healthcare facilities reporting data – 573 hospitals and 1,239 DoD and VA facilities - along with some State-wide and health system-wide data feeds going into the BioSense system, but there remains geographic distribution issues. How many facilities, health systems, or public health departments and laboratories would be ideal to support the BioSense program?

Secretary Sebelius: There is no definitive number of facilities, systems, or public health departments and laboratories that would ideally support BioSense. The BioSense program intends to expand its coverage to provide more comprehensive surveillance of the U.S. population. Expansion will be guided by the information priorities and capabilities of State, local and Federal public health systems while maintaining information quality, timeliness, and utility to support population health assessment and improvement.

Mr. Obey: What is the strategy to recruit additional participants into the BioSense program and to address geographic disparities?

Secretary Sebelius: CDC will pursue a new BioSense system design and prototype development solicitation to transform a closed, rigid, proprietary network and system architecture to an open, distributed, collaborative one that is jointly governed by representatives of the entire public health community. CDC will also integrate State and local BioSense investments, where practical, with surveillance efforts funded under the current Public Health Emergency Preparedness (PHEP) and the Epidemiology and Laboratory Capacity (ELC) cooperative agreements. More emphasis will be placed on supporting and coordinating the ongoing

development of automated surveillance systems in States and implementing a more collaborative approach to how data are used and shared to support health improvement. Additionally, increased attention will be given to the potential value for providing surveillance data for a broader spectrum of public health programs

FUTURE OF PUBLIC HEALTH AND COMMUNITY-BASED PREVENTION

Mr. Obey: The four leading causes of death are chronic conditions: heart disease, cancer, stroke, and chronic lower respiratory disease. These conditions account for 75 percent of U.S. health care costs. Everybody agrees that we need to do more to prevent these diseases rather than just treating people once they're sick. Doing so both saves money and makes people healthier. Health reform will begin that process with a significant emphasis on coverage for preventive health services.

In addition to screening and tests done in medical settings, we know that there are also many evidence-based, proven interventions that are implemented in communities, schools, and worksites. The Department of HHS conducts or supports these community-based interventions with partnerships at the State and local levels. What is the Department's plan to review its public health programs to determine what changes in public health and community-based programs will be necessary over the next few years as health reform is implemented?

Secretary Sebelius: As part of the annual budget formulation process, HHS assesses its current investments to inform what programmatic and policy changes would achieve the greatest health impact. As the Administration formulates the FY 2012 budget, HHS will include within its assessment the impact health reform implementation has on its programs to inform what changes may be necessary over the next few years.

Mr. Obey: In Massachusetts, funding for public health has drastically decreased since the State implemented health reform legislation, on the theory that people who used to be uninsured and get their screenings and immunizations at the public health department would now be getting these services at the doctor's office. Yet, it turned out that some people continued to go to the health department for basic screenings, immunizations, and health services.

What can we learn from the Massachusetts experience? Do you envision that public health will continue to play a role in providing access to health services or will the focus shift to community-based prevention and education efforts?

Secretary Sebelius: Currently, both public health efforts and community-based efforts are components for successfully preventing illness and disease. Both will continue to play a role in prevention.

SUICIDE RATE INCREASES

Mr. Obey: Although the CDC statistics for suicide rates are only available through 2006, there are many other indicators that suicide rates are increasing. Both the Department of Defense and the Department of Veterans Affairs have reported an increase in suicide rates, and the National Suicide Prevention Lifeline received 15 percent more calls in 2009. Suicide remains the

eleventh leading cause of death in the United States and among the top three causes in ages 15-24. What do you see as the key factors that may be causing the suicide rate to increase? What actions has the Department taken to increase prevention efforts?

Secretary Sebelius: The strongest risk factors for attempted suicide in adults are depression, alcohol abuse, cocaine use, and separation or divorce. The strongest risk factors for attempted suicide in youth are depression, alcohol (including binge drinking) and other substance use, and aggressive or disruptive behaviors. The major risk factors for completed suicide among people who abuse alcohol are: (1) current drinking, (2) major depression, (3) suicidal thoughts, (4) loss of support from family and friends, (5) living alone, and (6) unemployment. While economic circumstances themselves are generally regarded as insufficient to cause a suicide, unemployment is associated with depression, substance abuse, and marital turmoil, all of which are independently linked to suicide risk. People who have alcohol and substance use disorders have increased social and financial problems that may lead to high-risk behaviors that include self-harm. In addition, the economic downturn has led to significant cutbacks in State and local mental health services, reducing available help at the very time that need may be greatest. Thus, even as suicide prevention efforts in the United States have intensified for groups such as youth and veterans, the impact may be overshadowed in the general population by the impact of unemployment, home foreclosure, and cutbacks in mental health services.

The FY 2011 President's Budget includes an increase of $6 million for activities to prevent suicide. This funding will expand the capacity of the National Suicide Prevention Lifeline, expand suicide prevention activities in American Indian and Alaska Native communities, and support youth suicide prevention efforts.

These proposed investments will build on ongoing suicide prevention efforts and collaborations. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) has developed a Treatment Improvement Protocol (TIP-50) that focuses on substance abuse prevention/risk assessment for substance abuse providers and has been widely disseminated. SAMHSA is also supporting the identification, development and dissemination of best practices in suicide prevention, focusing on risk and protective factors related to suicide – with particular attention to mental health and substance abuse issues affecting suicide risk. SAMHSA has also been working closely with the Veteran's Administration and the Department of Defense on suicide prevention efforts across the lifespan. SAMHSA and the Veterans Administration collaborated in making the Veterans Hotline available to all callers to the National Suicide Prevention Lifeline and made a Veterans Chat service available. SAMHSA has also participated on the Department of Defense Task Force on Prevention of Suicide in the Armed Forces, and is providing support to military families.

Mr. Obey: Depression is a major indicator for suicidal behavior risk. What steps has the Department taken to ensure that depression and suicide risk are screened for?

Secretary Sebelius: Depression is a major indicator for suicide risk, and the Department continues to undertake efforts to screen for depression and suicide risk. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) has incorporated screening for depression and suicide risk into several of its programs, plans to incorporate such screening into additional programs, has introduced standards to assure that every caller to the

National Suicide Prevention Lifeline is screened for suicide risk, and supports the National Depression Screening Day. Similarly, the Health Resources and Services Administration (HRSA) is working to increase the capacity to its community health centers to respond to behavioral health needs such as depression and risk for suicide.

PROGRAM INTEGRITY - UPDATE ON PREVENTION AND SHARING

Mr. Obey: Earlier this year this subcommittee held a hearing on Combating Health Care Fraud and Abuse, an issue of joint concern. We have a joint obligation to meet the needs of the people who qualify for programs covered by Health and Human Services. In so doing, we have an obligation to assure taxpayers' funds are used effectively-and not wasted or lost to fraud, as you understand.

In the earlier hearing, HHS Deputy Secretary Bill Corr indicated that HHS was planning to take steps to increase the sharing of best practices, data, and information with the private sector to further leverage the industry-wide investments toward this effort. In addition, we had discussions on tension between "pay and chase" - that is, pay the bill first and then try to get the money back if the payment turns out to have been unwarranted and paying claims right the first time.

Please provide an update on what actions have occurred or have been planned since the last hearing to increase sharing with the private sector and within HHS to detect fraudulent and improper claims before they are paid?

Secretary Sebelius: This Administration is committed to combating waste, fraud and abuse and reducing the amount of improper payments in our Federal health care programs. HHS continues to explore ways to work with the private sector to fight health care fraud while balancing sensitivities about protecting personally identifiable information and the integrity of ongoing investigations and law enforcement activities. For example, OIG has increased outreach to and collaboration with the National Health Care Anti-fraud Association to work through these issues.

The Office of Inspector General also will conduct a compliance training program for health care providers, compliance professionals, and attorneys in a series of sessions across the country. The training will focus on methods to identify fraud risk areas and compliance best practices so providers can strengthen their own compliance efforts and more effectively identify and avoid illegal schemes that may be targeting their communities.

Furthermore, several new authorities within the Affordable Care Act will enable HHS and CMS to bring new tools to bear in addressing these problems. For example, CMS recently issued an interim final rule to implement Affordable Care Act provisions that require providers or suppliers submitting claims to Medicare or Medicaid to include a National Provider Identifier (NPI) on enrollment applications and claims in Medicare & Medicaid. It also required physicians and practitioners who order and refer certain items and services for Medicare beneficiaries to enroll in Medicare. Furthermore, it required providers, physicians, and other suppliers participating in the Medicare program to maintain and provide access to documentation, upon request when they refer or furnish covered items or services at high risk of waste and abuse –

including durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) and home health services.

HIGH RISK POOLS

Mr. Obey: The budget request does not provide funding for the High Risk Pools programs and notes the expectation of funding from another source. In FY 2010, this sub-committee provided $55 million of support to continue funding of risk pools. We understand that a significant amount of current funds may be available to support the FY 2011 requirement.

Please explain the plan, risk, and if other sources of funds are available in FY 2011 to support this program. Also, if the budget level of zero is supported, what is the potential impact in FY 2011 on the individuals being covered?

Secretary Sebelius: As you know, the Affordable Care Act provides $5 billion in Federal funds to support a temporary high risk pool program to provide coverage to people who are uninsured because of preexisting conditions. The establishment of these new high risk pools is one of our first tasks in implementing the Affordable Care Act and will help individuals who cannot get affordable health coverage through the private market obtain the coverage they need.

Regarding the existing State high risk pool programs, we recognize that funding is only available through FY 2010 and that the President's FY 2011 budget did not request funding for FY 2011 because of ongoing health reform negotiations at the time. We understand how important Federal funding is for State high risk pools and we appreciate your interest in assuring that States have the funding they need to ensure coverage for this vulnerable population. I look forward to working in partnership with you and other members of Congress to ensure that vulnerable populations continue to receive access to insurance through high risk pools.

LIHEAP

Mr. Obey: The President's budget would cut the Low-Income Home Energy Assistance program, or LIHEAP, by 35 percent-from $5.1 billion in FY 2010 to $3.3 billion in FY 2011. That concerns me very much. Energy prices are not coming down, and with the recession, needs are up. This winter, the number of households seeking assistance with their heating bills reached record numbers for the third year in a row. About 8.8 million households are estimated to have gotten help from LIHEAP this winter, 1.2 million more than the winter before. In Wisconsin, applications were up 25 percent over last year. This is not the time to be cutting LIHEAP by a third.

I understand that the President's budget proposes authorizing legislation which would make additional funds available to LIHEAP on a mandatory basis, triggered by energy prices and incomes. However, there is no legislation moving to enact that proposal, and probably little chance of finding the offsets that would be required under pay-as-you-go rules to turn part of LIHEAP into an entitlement.

While theoretical discussions may be underway about the proper budgetary treatment for LIHEAP, this subcommittee has the concrete problem of finding funds to keep LIHEAP going for

next winter. Frankly, the Administration's budget leaves us in a lurch. Any thoughts on how we solve this problem? What do you think the impact would be if we reduced discretionary appropriations for LIHEAP to the amount recommended in the President's budget?

Secretary Sebelius: We believe that the inclusion of a mandatory funding trigger is the best way to fund LIHEAP because it will automatically provide additional funding in response to increases in need. Under current economic predictions, the trigger proposal would provide $2 billion in mandatory funds in FY 2011. Adding the $3.3 billion discretionary funding requested, a total of $5.3 billion is requested for LIHEAP in FY 2011, an increase of $200 million over the amount provided for FY 2010.

ADMINISTRATION ON AGING: SENIORS' NUTRITION AND MEALS ON WHEELS

Mr. Obey: I'm concerned about the President's budget for senior citizens' nutrition services through the Administration on Aging at HHS. In particular, I'm talking about the "meals on wheels" program that delivers meals to seniors who have trouble leaving home, and the related program that provides meals at senior citizens centers and similar locations.

These programs are important: more than 90 percent of people receiving meals on wheels say that service makes it possible for them to continue living in their homes, and more than a quarter of people receiving help from any of the seniors' nutrition programs say those programs provide the majority of their daily food. With the tough economic times, need for these programs are increasing. At the same time, funding from state and local governments and private contributions is decreasing. To help meet these challenges, the Recovery Act added $100 million for fiscal years 2009 and 2010.

The President's budget does propose an increase for senior's nutrition, but that increase is just 1 percent - not enough to make up for cost increases, declining contributions, and the end of the Recovery Act funding. According to the budget documents, the number of meals supported has been dropping for the past two years, and would decrease again by 14.7 million meals under the Administration's budget for FY 2011. Shouldn't we be worried about this trend?

Secretary Sebelius: As you note, the President's Budget requests an increase of $8 million for nutrition programs administered by the Administration on Aging. These programs have strong partnerships with State/Tribal and local governments, philanthropic organizations, and private donors that contribute funds in greater proportions than is the case for other Older Americans Act programs.

HEALTH INFORMATION TECHNOLOGY

Mr. Obey: Health Information Technology is an important tool in our effort to improve health care delivery and reduce medical errors. The Recovery Act appropriated $2 billion for the Office of the National Coordinator to award grants that would help advance the adoption of electronic health records published.

But having an electronic health record is not enough; doctors need to use it to capture medical history, coordinate patient treatment, and ensure that the correct medications are ordered.

So, the Recovery Act also provided a financial incentive for providers who make meaningful use of electronic health records. A great deal has already been accomplished to ensure the smooth implementation of this incentive program. However, there are things that still need to happen if physicians and hospitals are to qualify for meaningful use payments in 2011. When can physicians and hospitals expect to begin receiving incentive payments? What do you see as the greatest challenge to this process?

Secretary Sebelius: Under the statute, Medicare and Medicaid incentive payments to eligible hospitals and professionals must begin in FY 2011 and CY2011 respectively. We are currently finalizing the regulation, with the final publication expected during FY 2010 to meet the statutory deadline to make the first year's incentive payments for meaningful use of certified electronic health record (EHR) technology as authorized by the HITECH Act.

States have already begun to receive federal matching funds for state planning activities necessary to implement (EHR) incentive payments under Medicaid. The HITECH Act provides for a 90 percent federal match for state planning activities to administer the incentive payments to Medicaid providers, to conduct adequate oversight of the program and pursue initiatives to encourage adoption of EHR technology to promote health care quality and the exchange of health care information.

The most significant challenges to this process will be ensuring that eligible providers and hospitals are in compliance with the "meaningful use" regulation. CMS is working closely with the HHS Office of the National Coordinator of Health Information Technology (ONC) on a number of health information technology initiatives authorized by the HITECH Act, including establishing 60 Regional Extension Centers (REC) across the country. These RECs will offer technical assistance, guidance, and information to support and accelerate health care providers' efforts to become meaningful users of EHRs.

Mr. Obey: What concerns have hospitals and providers expressed about this program and the published rules and what actions has the Department taken to address these concerns?

Secretary Sebelius: The Department has undertaken numerous education and information events to educate physicians, hospitals, vendors and other interested parties about the HITECH proposed rule. These efforts include CMS' second annual Multi-State Health IT Collaborative for E-Health Conference (held in February 2010), and ongoing stakeholder engagement through meetings and conference calls.

The biggest concern hospitals and providers have conveyed to CMS is meeting the requirements of demonstrating meaningful use of EHRs. CMS has been working with the HHS Office of the National Coordinator (ONC) to ensure aligned and consistent policies toward certified electronic health record (EHR) technology in order to reduce barriers to its adoption. Understanding the difficulties faced by providers in re-engineering their practice workflow to incorporate EHRs, CMS is determined not to set the meaningful use bar so high as to impede adoption while assuring that providers who receive incentive payments are adopting and using EHRs in a manner that improves the quality of care. CMS and ONC have been diligently working toward the President's vision for health information technology as a core component of the U.S. health system, but we know this is an incremental process. As such, the Department is

committed to continue working with and listening to providers across the nation to encourage participation in the CMS EHR incentive payment programs.

PANDEMIC FLU

Mr. Obey: Since 2004, we have invested more than $13 billion to help the Nation get better prepared to deal with a flu pandemic, and to respond to the HINI flu outbreaks. One major element of preparedness is the ability to quickly produce and distribute safe and effective vaccine. As we have discussed time and time again in this subcommittee, flu vaccines in the U.S. are still produced using 1940s egg-based technology. The funding previously appropriated included seed money to modernize U.S. vaccine production, reduce the amount of time it takes to produce vaccine, and increase the number of domestic vaccine manufacturers. But that seed money rightfully shifted to respond to the H1N1 pandemic. How do we get the research and development efforts back on track to create a modem flu vaccine infrastructure in the U.S.?

Secretary Sebelius: The 2009 H1N1 pandemic clearly demonstrated the need to continue pandemic preparedness efforts, including building a modern influenza vaccine infrastructure in the Nation. Following a comprehensive review of H1N1, we will assess the next steps and report back to you.

Mr. Obey: Of the $7.7 billion appropriated in last year's emergency supplemental for pandemic flu, about $1.3 billion remains unallocated. Why hasn't this remaining funding been allocated? When will it be allocated and for what purposes?

Secretary Sebelius: HHS is in the process of evaluating pandemic influenza needs in light of lessons learned from 2009-H1N1 influenza response. Plans for pandemic influenza balances will be based on these lessons learned, as well as on the National Pandemic Influenza Plan, including increasing domestic vaccine production capacity, and advanced development of vaccines and antivirals.

Mr. Obey: I am also very disappointed that the FY 2011 budget proposes to fund $156 million for ongoing CDC flu activities, including the salaries of 170 CDC staff, with the 2009 emergency supplemental resources. Congress intended that funding to be used for emergency response, development and purchase of vaccines, antivirals, medical supplies, and personal protective equipment, vaccine delivery, upgrading State and local public health capacity, and surveillance. What is the rationale for taking base salaries and expenses costs out of an agency's annual budget and funding it through an emergency supplemental? Won't this approach lead to a significant funding cliff in future years once the supplemental funding is exhausted?

Secretary Sebelius: Using existing pandemic influenza funding for CDC's pandemic influenza activities in FY 2011 is fiscally responsible, since HHS does not need to request additional FY 2011 funding for this purpose. This transfer will also allow CDC to begin some pandemic preparedness activities sooner than FY 2011, since the supplemental funding can be used at any time. Pandemic influenza needs will be re-examined in a year to determine the appropriate source and level of funding for CDC in FY 2012.

WORLD TRADE CENTER TREATMENT AND SCREENING PROGRAM

Mrs. Lowey: The last administration was not always responsive to the medical needs of World Trade Center rescue and recovery workers. While there have been significant improvements over the last year, and I am pleased that the FY 2011 budget request includes $150 million for the program, I am still concerned that we are not doing enough to care for these people who have multiple, and often severe, medical problems. What is HHS doing to evaluate the long-term medical needs for these individuals?

Secretary Sebelius: CDC's National Institute of Occupational Safety and Health supports the World Trade Center (WTC) Healthy Registry. This registry is the largest public health registry, which tracks the health of over 70,000 people directly exposed to the WTC disaster. The Registry collects data, analyses data, and distributes the findings to track the long-term physical and mental health effects of the WTC attacks.

Mrs. Lowey: How much would a comprehensive medical services program for these victims cost?

Secretary Sebelius: The WTC Program that CDC implements provides monitoring and treatment services for both responders and non-responders of the WTC attacks for conditions associated with exposure to smoke, dust, debris, and psychological trauma in the September 11, 2001 WTC attacks. To continue these services, the FY 2011 President's Budget requests $150 million, which is +$79 million above FY 2010.

Mrs. Lowey: Could you provide a report outlining these long-term needs and the estimated cost of such a program?

Secretary Sebelius: In response to the FY 2010 House Appropriations Committee Report, CDC will continue providing quarterly reports requested on the WTC Program. These reports include information on the program's budget request, obligations, number of people served, and on the prevalent health conditions impacting participants.

Mrs. Lowey: Is your Department planning to address this need, and will it be done through a more comprehensive contract for the national responders?

Secretary Sebelius: WTC National Responder Health Program (NRHP) provides monitoring and treatment to responders outside of the NYC-NJ metropolitan area. The NRHP contractor explains to members the covered health conditions, procedures, and medications offered under the WTC NRHP; guides them to available social service resources as needed (e.g., food, housing, non-covered medical expenses); assists with applying for Workers' Compensation benefits; provides program information via letters and summaries of services provided; and makes efforts to locate enrolled responders that have been inactive or lost to the program. The WTC Responder Program in NYC, the Community Program, and the WTC Health Registry all conduct outreach activities and coordinate to refer enrollees with health conditions related to the WTC attacks to the appropriate WTC treatment programs and services.

CHILDHOOD OBESITY

Mrs. Lowey: As part of First Lady Michelle Obama's childhood obesity initiative, HHS will dedicate up to $20 million in Community Economic Development program funds to the Healthy Food Financing Initiative to award competitive grants to support projects that finance grocery stores, farmers markets, and other sources of fresh, nutritious food. How many grants does HHS plan on making with $20 million?

Secretary Sebelius: We estimate we will fund 25 grants.

Mrs. Lowey: How does the FY11 budget request help combat child obesity?

Secretary Sebelius: The FY 2011 President's Budget supports child obesity-related activities across HHS agencies as part of the Department's obesity related efforts. For instance, the budget includes $58 million, in CDC to fund 25 States to implement State-wide programs to prevent obesity through activities such as population-based interventions, evaluation, surveillance, policy and environmental change, and translation of research to practice. Of the $58 million, $20 million is for CDC's new Big Cities Initiative, which will reduce rates of morbidity, disability, and premature mortality due to chronic diseases in up to ten of the largest U.S. cities. Activities for this new program will include obesity prevention activities for children through improved nutrition and increased physical activity. The Big Cities Initiative will incorporate lessons learned from the Recovery Act Communities Putting Prevention to Work Initiative, which implements evidence-based prevention and wellness strategies to address, in part, obesity.

In addition, the Budget includes $5 million in FDA, $784 million in NIH, and $26 million in AHRQ for obesity-related research that will inform obesity prevention and control efforts across all ages, including children. Finally, NIH, CDC, and the Robert Wood Johnson Foundation together launched the National Collaborative on Childhood Obesity Research in February 2009. In FY 2011, this collaborative will continue to focus on efforts that have the potential to benefit children, teens and their families, and the communities in which they live.

UNDERAGE DRINKING AND SUBSTANCE ABUSE

Mrs. Lowey: I am concerned that HHS is blending underage drinking and drug use with other adolescent mental health issues. Teenagers who use alcohol and other drugs do not necessarily have mental health issues, and I believe the best way to combat the problem is to implement alcohol- and drug-specific prevention strategies. What is HHS doing to ensure that programs to address underage drinking and youth substance abuse focus on strategies to decrease access and availability?

Secretary Sebelius: As you know, the Substance Abuse and Mental Health Services Administration (SAMHSA) funds 101 Sober Truth on Preventing Underage Drinking (STOP) grants, which support community coalitions to raise public awareness about underage drinking, to enhance prevention skills of community-based providers who serve youth and their families, and to provide support for alcohol-free activities and alternatives. Underage drinking prevention strategies focus on decreasing access and availability including reducing access to alcohol (e.g. merchant education, parent and third party access awareness); changing consequences (e.g.

individual and business rewards, revocation of licenses for non-compliance); and changing physical design (e.g. location of beer gardens at special events, decrease quantity of alcohol signage).

The majority of the 747 Drug Free Community Support grants (administered in collaboration with the Office of National Drug Control Policy), which serve all 50 states, include an underage drinking prevention focus. *The Surgeon General's Call to Action* emphasizes that preventing underage drinking is a collective responsibility for all members of the community. The strategies implemented through these community grants to decrease access and availability are city curfews, school extracurricular activity policies, positive faith-based and community activities, business/workplace testing, and health care professional advisement.

SAMHSA also funds a number of underage drinking prevention websites to respond to public demand for information:

- Building Blocks for a Healthy Future is designed for the parents and educators of children aged 3 to 6. Access and availability are addressed indirectly with parents by focusing on parenting skills (e.g., role modeling around the use of alcohol and drugs, problem-solving, dealing with stress, and modeling positive traits and behaviors). For more information see http://www.bblocks.samhsa.gov/
- Too Smart to Start addresses the information needs of youth aged 11 to 18 and their parents, educators and communities. Tailored strategies for parents, educators, and communities to reduce youth access and alcohol availability are provided. For more information see http://toosmarttostart.samhsa.gov/
- www.stopalcoholabuse.gov is a Federal portal of resources related to underage alcohol use prevention and serves the needs of national prevention coalitions. How-to guides and public education resources regarding access and availability are available for parents, community/faith-based organizations, business, educators, youth, enforcement/adjudication, and prevention/treatment providers.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) also supports research on preventing underage drinking. Given that alcohol use is pervasive among adolescents and the association between early initiation and future alcohol problems, NIAAA is developing empirically-based guidelines and recommendations for screening children and adolescents to identify risk, especially in younger children, for alcohol use and alcohol use disorders.

NIAAA will also solicit studies that evaluate the use and effectiveness of the guidelines in various settings. In FY 2009, NIAAA solicited applications to study decision-making processes in adolescents as they relate to drinking behavior, and the role of neural circuitry development in adolescent decision-making and alcohol abuse and dependence. NIAAA is also planning a new research initiative on pharmacotherapy for adolescents and young adults with severe alcohol use disorders and major comorbidities, as well as behavioral interventions that target young individuals along the continuum of mild to severe alcohol-related behaviors.

GLOMERULAR DISEASES

Mrs. Lowey: Many glomerular diseases, such as focal segmental glomerulosclerosis (FSGS) cause severe damage to the filter mechanisms of the kidney and must often be treated by a kidney transplant: as of January of this year 759 of 4,123 FSGS patients awaiting kidney transplants had already received at least one transplant that failed. What progress is NIH making to ascertain the reasons for the resurgence of FSGS in some patients who have received kidney transplants?

Secretary Sebelius: The NIH has a robust and diverse portfolio of research into the causes of and treatments for FSGS and the problem of transplant failure in some patients. Basic science studies into the causes of transplant failure in FSGS patients include a collaborative set of studies between researchers at two academic institutions and scientists within the National Institute of Diabetes and Digestive and Kidney Diseases that is investigating a possible role for a recently-discovered protein—cardiotrophin-like cytokine 1 (CLC-1)—in the recurrence of FSGS. This protein may act as a "permeability factor" that allows protein to leak into the urine. This protein is found at high levels in the blood of some FSGS patients. Attempts to generate a mouse model in which this protein is expressed at high levels are underway. Another protein, called soluble urine plasminogen activator receptor, is also being studied as a possible cause of recurrent FSGS, at least in a subset of patients.

In the clinical research arena, NIDDK scientists are investigating whether variations in the *MYH9* genetic locus—some of which are associated with increased risk of non-diabetic kidney disease such as FSGS—play a role in adverse outcomes following kidney transplantation. The NIDDK-supported *FSGS Clinical Trial* a collaborative network of U.S. research centers has now completed a test of the effectiveness of two different treatment regimens in children and young adults who have steroid-resistant FSGS of unknown origin (http://www.fsgstrial.org/). This is the largest randomized trial of FSGS ever conducted, and the results should be published soon. An ancillary study, the *Novel Therapies for Resistant FSGS Clinical Trial (FONT),* has successfully completed its first phase, testing the safety, tolerance, and pharmacokinetic profile of two novel therapies for FSGS that is not responsive to current treatment. The second phase will test these two therapies and a third agent, the milk sugar galactose, which has shown some promise as a therapy for recurrent FSGS following kidney transplantation.

HEALTH CARE REFORM AND PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Mrs. Lowey: The recently enacted health care reform legislation created a Patient-Centered Outcomes Research Institute, which will serve as a home for comparative effectiveness research (CER). During the reform debate, the clinical and translational research community voiced concern over potential conflicts of interest within the governance structure of this new Institute, as pharmaceutical and medical device industry stakeholders will have representation on its Board of Governors and advisory committees. Can you share your thoughts on this issue, and whether or not you share these concerns?

Secretary Sebelius: The Patient-Centered Outcomes Research provision of the Affordable Care Act requires that the Comptroller General appoint a Board of Governors to carry out the

duties of the Institute. As you point out, pharmaceutical and device manufacturers are to be represented on the Board. Additionally, the provision requires that members representing patients, physicians and providers, payers, and Federal and State governments also be represented to provide a broad range of perspectives and various areas of expertise. In an effort to ensure transparency of the Board's deliberations, meetings not concerned solely with personnel matters shall be advertised at least seven days in advance and open to the public. In addition, the GAO is required to review what the PCORI has accomplished not less frequently than every five years and report annually to the Congress on its activities.

COMMUNITY HEALTH CENTERS AND POST REFORM FUNDING

Mrs. Roybal-Allard: With the passage of health care reform and the addition of millions of newly insured people in the United States, many Americans who have gone without care will soon be seeking a health care home through which they can access care. Our nation's Community Health Centers already serve as a health care home for nearly 20 million patients, and with the implementation of the new Community Health Centers trust fund, they stand to double the number of patients they serve over the next five years.

I'd like to ask you two questions: First, can you speak to the critical role that you envision for health centers in meeting our nation's primary care needs in a reformed health system?

Secretary Sebelius: For more than 40 years, health centers have delivered comprehensive, high-quality primary health care to patients regardless of their ability to pay. During that time health centers have become an essential primary care provider for America's most vulnerable populations: the poor, uninsured, and homeless; minorities; migrant and seasonal farm workers; public housing residents; geographically isolated; and people with limited English proficiency. With a proven track record of success, health centers are a key component to health care reform.

The Affordable Care Act provides $11 billion in funding for the operation, expansion, and construction of health centers throughout the Nation. This increased funding will double the number of patients seen by health centers over the next 5 years, making primary health care available for an additional 20 million people.

Mrs. Roybal-Allard: Secondly, in order for the full $11 billion investment supported through health reform by Congress and the Administration in health centers to be realized, is it your opinion that this committee should provide no less than the existing level of discretionary funding for the program- currently equal to $2.19 billion?

Secretary Sebelius: The President's FY 2011 budget includes an increase of approximately $290 million over the FY 2010 level of $2.19 billion. This increase will continue support for the American Recovery and Reinvestment Act investment in 127 Health Center New Access Points as well as the services initiated under the Increased Demand for Services (IDS) grants to health centers nationwide, providing care to approximately 2.85 million medically underserved people. This funding level will also support the development of approximately 25 new access points, increasing access to comprehensive primary health care services to an estimated 150,000 additional health center patients. Additionally, this level will support an estimated 125 service expansion grants to expand the integration of behavioral health into existing primary health care systems, enhancing the availability and quality of addiction care at existing health centers.

MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT

Mrs. Roybal-Allard: The United States spends more on maternity care than any other country in the world, however we rank 41st in the world in maternal mortality and 30th in infant mortality. Despite these dismal rankings funding for the Title V Maternal and Child Health Services Block Grant dropped from $731 million in FY 2003 to $662 million last year. Can you

discuss the Administration's plans to reinvigorate investments to improve maternity care? What coordination is there within your Department to develop strategies that will help improve our standing among these dismal rankings?

Secretary Sebelius: The mission of the Maternal and Child Health (MCH) Block Grant Program is to improve the health of all mothers, children, and their families. Specifically the program seeks to: (1) assure access to quality care, especially for those with low-incomes or limited availability of care; (2) reduce infant mortality; (3) provide and ensure access to comprehensive prenatal and postnatal care to women (especially low-income and at risk pregnant women); (4) increase the number of children receiving health assessments and follow-up diagnostic and treatment services; (5) provide and ensure access to preventive and child care services as well as rehabilitative services for certain children; (6) implement family-centered, community-based, systems of coordinated care for children with special healthcare needs (CSHCN); and (7) provide toll-free hotlines and assistance in applying for services to pregnant women with infants and children who are eligible for Title XIX (Medicaid).

A program assessment of the Title V MCH Block Grant in 2008 determined that the program has had a positive impact, with strong and effective collaborations established between Federal, State, local and private-sector entities concerned with MCH. To this end, the Title V program plays an important role in the delivery of appropriate and effective care for high-risk pregnant women and infants. The Title V MCH Block Grant monitors and works closely with States to decrease the national rate of maternal and infant deaths. It should be noted that one factor contributing to the increase in the reporting of maternal mortality rates is due to changes in the classification and measurement of maternal mortality since the introduction of the revised Birth Certificate in 2003. This increase will likely continue as additional States adopt the new Birth Certificate and its classification of maternal mortality. However, these reporting changes do not fully explain the lack of progress in this area. Other factors include the increasing age of mothers at delivery and the increased prevalence of risk conditions, such as obesity, hypertension and diabetes, in this population.

Efforts to reduce the overall infant mortality rate continue, with the rate having decreased from 9.2 per 1,000 live births in 1990 to 7.0 per 1,000 births in 2002. However since 2002, the rate has remained essentially unchanged, with a range between 6.7 per 1,000 live births and 6.9 per 1,000 live births. A subsequent analysis concluded that multiple factors are contributing to the recent lack of progress. These factors include, but are not limited to, an increase in the number of very small infants (less than 750 grams), the rise in multiple birth rates, and increases in maternal age at childbearing.

Prenatal care is one of the most important interventions for ensuring the health of pregnant women and their infants. Overall, the proportion of pregnant women entering prenatal care in the first trimester increased from 76 percent in 1990 to 84 percent in 2005. While there has been progress in the timely initiation of prenatal care for all population groups, the rate of increase has been slow in recent years. Given the increasing prevalence of diabetes, obesity and pregnancy-induced hypertension during pregnancy, there is a need for such risk factors to be monitored and for timely and appropriate prenatal care to be provided.

As part of their partnership and collaborative relationship with MCHB, State and jurisdictional MCH grantees participate in extensive planning, reporting and evaluation processes. Beginning with a comprehensive statewide needs assessment every five years, with the next Needs Assessment being submitted in 2010, States evaluate the needs of their MCH populations, assess State resources and capacity, identify priority needs, develop program plans to address identified needs and establish performance targets for measuring progress. Specifically related to prenatal care and maternal/infant mortality, two of the 18 National Performance Measures in the State Title V MCH Block Grant program address the percentage of women who smoke in the last three months of pregnancy and the percent of women born to pregnant women receiving prenatal care beginning in the first trimester. The six National Outcome Measures require States to report on their infant mortality rates, neonatal mortality rates, perinatal mortality rates and the ratio of the black infant mortality rate to the white infant mortality rate. These Performance and Outcome Measures and the effective collaborations established between Federal, State, local and private-sector entities are sentinel for progress.

The Maternal and Child Health Bureau (MCHB) works with the State MCH programs in continuing to build the data capacity to better understand the issues which impact maternal and infant mortality and to design interventions that can create positive change. Efforts have centered on the development of client-based data systems that more accurately capture the direct, enabling and population-based services provided. MCHB regularly provides technical support to the States around the priorities identified in their comprehensive five-year needs assessments and the areas of needed technical assistance outlined in their annual applications.

EXTENSIVELY DRUG RESISTANT TUBERCULOSIS

Mrs. Roybal-Allard: As you know Extensively Drug Resistant Tuberculosis (XDR-TB) is a very severe form of TB that is extremely difficult and costly to treat, costing as much $1 million per case, and is often fatal. This issue is of particular importance to border states, like California, which has a disproportionately high burden of TB.

DHHS is to be commended for its ongoing efforts to respond to drug-resistant strains of tuberculosis, including the partnership between National Institutes of Health and Centers for Disease Control and Prevention on the development of the Federal TB Task Force Action Plan on XDR-TB. However I am concerned that the FY11 budget request includes a decrease in funding for the CDC Division of Tuberculosis Elimination. What impact will these cuts have on the cooperative agreements that exist between states and jurisdictions such as California and Los Angeles?

Secretary Sebelius: State TB control programs are integral to the nation's capability to eliminate TB. CDC provides leadership, advice, and assistance to these State programs and develops guidance and national policy for TB control. The FY 2011 Budget includes $143 million for TB, which is $1 million below FY 2010. This reduction is part of a CDC-wide effort to achieve efficiencies in travel and contracting and to maintain the programmatic impact of TB prevention. Consequently, these reductions will not have a negative impact on the cooperative agreements that exist between States and jurisdictions, such as California and Los Angeles. Rather, these savings will improve the effectiveness of this program and other CDC programs agency-wide. FY 2011 funds will sustain and enhance work to reduce incidence of TB among U.S.-born persons in the United States. CDC will also continue to provide domestic and

international leadership and assistance to prevent, control, and eliminate TB.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Mrs. Roybal-Allard: Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in America, afflicting an estimated 10-12 million Americans, with another 10-12 million undiagnosed cases. In last year's Committee report, the COC was asked to develop a national plan to respond to COPD. Additionally, several members of this Subcommittee wrote a letter to COC in support of this initiative. Can you tell me the status of the development of this plan?

Secretary Sebelius: CDC supports the initial assessment and planning for public health in this important area. CDC is interested in consulting with experts to develop a national roadmap to explore the public health issues related to COPD, which would include addressing the public health role in prevention, treatment, and management. This would include the examination of the best strategies to address surveillance of COPD.

HHS RESPONSE TO VIRAL REPATITIS

Mrs. Roybal-Allard: A report released in January by the Institute of Medicine (IOM) cites the dearth of federal resources to address viral hepatitis. This is causing many Americans to go unaware that they are infected with hepatitis B or hepatitis C until their disease has progressed to significant liver damage or liver cancer. Close to one in thirty "Baby Boomers" is living with hepatitis B or C and hepatitis is the cause of health disparities for blacks, Hispanics, and Asian Americans. In addition, viral hepatitis is the most common cause of chronic liver disease and liver cancer. Each year mortality associate with viral hepatitis is equal to that from AIDS; Yet at CDC, Viral hepatitis prevention receives only about 2% of funding that HIV/AIDS prevention receives.

The IOM identified hepatitis as an underappreciated health threat reflected by studies which show that most persons living with hepatitis are unaware of their infection and cited the lack of national coordination as hampering efforts to prevent and control this disease. The IOM recommended increased commitments to surveillance, education, vaccination and screening, and health services to reduce viral hepatitis associated liver disease and cancer. How is HHS responding to this call for action by IOM? Specifically, how will HHS help Federally Qualified Health Centers to improve their ability to care for patients affected by viral hepatitis?

Secretary Sebelius: The Health Resources and Services Administration (HRSA) supports Federally Qualified Health Centers (FQHCs) services for viral hepatitis treatment and prevention in several ways. HRSA requires, as a condition of health center funding and the FQHC "Look-Alike" designation, the provision of diagnostic lab services, screenings for communicable diseases, and immunizations against vaccine-preventable diseases, including hepatitis B virus. They also require that grantees provide health education to patients and the general community, including patient education on diseases including viral hepatitis. They promote screening and treatment of viral hepatitis through a national cooperative agreement, which among other things includes raising awareness of viral hepatitis among health center providers and patients, and provides technical assistance on strategies to treat and prevent patients with viral hepatitis.

As part of this effort, HRSA recently met with the National Alliance of State and Territorial AIDS Directors and the Northeast Hepatitis Coordinators' Alliance to strategize on hepatitis prevention and treatment in FQHCs. In an effort to better monitor hepatitis incidence in health center patients, HRSA has also revised its grantee reporting mechanism to better track patient hepatitis rates. Within HRSA, the HIV/AIDS Bureau and the Bureau of Primary Health Care (BPHC) are collaborating on ways to increase screening and referral to treatment for FQHC patients who are infected with Hepatitis C and those who are dually infected with HIV and hepatitis. In addition to workgroups within the Department on Viral Hepatitis, within HRSA, BPHC is working with the Association of Asian Pacific Community Health Organizations and the White House Initiative on Asian American and Pacific Islanders to develop strategies for improving prevention and treatment of viral hepatitis among Asian and Pacific Islander Americans.

Mrs. Roybal-Allard: Given the high number of people in drug treatment who also have hepatitis B or C, how can HHS help to increase hepatitis testing and hepatitis A/B immunizations in drug treatment centers?

Secretary Sebelius: For the past several years, the Substance Abuse and Mental Health Services Administration (SAMHSA) has included a requirement that entities applying for Drug Courts and HIV Treatment and Outreach funding develop a relationship with local departments of health to ensure access and referral to sexually transmitted infections, hepatitis B and C, and TB testing. These linkages have been successful in facilitating screening, immunization, and treatment for viral hepatitis. The experience of these programs has been very positive, with patients accessing the screening and immunizations and ongoing treatment. SAMHSA is working with States, providers, and grantees to establish and maintain relationships with primary care settings and to effectively integrate substance abuse specialty care with general health care. These relationships will advance the identification and treatment opportunities for individuals living with viral hepatitis.

SAMHSA is also demonstrating the cost-effective delivery of enhanced health services to an ethnic minority population receiving interventions for opioid dependence within a treatment setting, which has the potential to increase recommended vaccination and hepatitis testing services. The program has established a shipping strategy for vaccine and test products to minimize onsite storage and waste problems while reaching the maximum number of patients that can benefit from hepatitis vaccination or testing services. It has also established the true cost of implementing this service, with improvement opportunities for achieving greater efficiency through a quality assurance/improvement program.

Mrs. Roybal-Allard: Why hasn't HHS directed the CDC to implement a comprehensive screening program to identify the 78% (HCV) and 65% (HBV) of people that do not know their status?

Secretary Sebelius: The FY 2011 President's Budget includes $21 million for Viral Hepatitis Prevention, which is +$2 million above FY 2010, to prevent disease and death from chronic hepatitis infections, such as Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). To improve the screening and clinical management of persons with chronic HBV infection, CDC released new recommendations for chronic HBV screening that defined target populations for

screening, and the prevention and care services needed by persons found to be infected with HBV. Research is underway to identify and disseminate best practices to implement CDC HBV testing recommendations and counseling messages best suited for primary care and immigrant health settings. Research is also underway that will inform updates to CDC's hepatitis C screening recommendations.

In addition, HHS has formed a workgroup with representatives across HHS offices and agencies to develop a coordinated departmental response to viral hepatitis. The workgroup will promote program action and investments that foster health system interventions to ensure Americans with chronic viral hepatitis become aware of their infection early and slow their progression to liver disease, cirrhosis, and cancer. CDC is playing a key role in the workgroup and the group's findings and recommendations will be essential for planning and helpful in determining priorities for moving forward to meet the challenges that viral hepatitis presents to our Nation.

Mrs. Roybal-Allard: Where and how much funding to address chronic hepatitis has been allocated with the ARRA wellness and prevention funds?

Secretary Sebelius: Congress appropriated $1 billion in the FY 2009 Recovery Act for Prevention and Wellness. Specifically, $300 million was appropriated for CDC's Section 317 Immunization Program, $50 million was appropriated for healthcare-associated infections, and $650 million was appropriated to implement evidence-based prevention and wellness strategies to address the rates of chronic disease. The program HHS is executing to implement evidence-based prevention and wellness strategies is the Communities Putting Prevention to Work Program, which addresses obesity and tobacco prevention. Thus, none of the funding directly addresses chronic hepatitis.

MENTAL HEALTH FUNDING REDUCTIONS

Mrs. Roybal-Allard: The current fiscal crisis in our states is having a very negative effect on our nation's public mental health system. Specifically, the National Association of State Mental Health Program Directors (NASMHPD) released a survey in December showing that - for the last three fiscal years - state governments have been forced to cut mental health spending by a combined total of $1.8 billion. In many states, the fiscal crisis is so severe that proposals to cut mental health funding by as much as 30 to 40% across-the-board are receiving very serious attention.

My understanding is that states are being forced to close public psychiatric hospitals, reduce access to crisis centers, and cut funding for front line Community Mental Health Centers. While these funding reductions unfold, more low income and recently uninsured people are seeking out services through the public mental health system. Does the President's FY11 budget contain provisions that can help states avert drastic mental health funding reductions?

Secretary Sebelius: Yes, the FY 2011 President's Budget includes an increase of $23 million for mental health programs administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). In addition, the Budget includes an increase of $25 million to expand behavioral health services in community health centers that receive funding from the

Health Resources and Services Administration (HRSA). The Budget also maintains funding for the Mental Health Block Grant, which is a stable funding source that gives States flexibility to address their emerging needs.

Mrs. Roybal-Allard: Do you think that reality justifies the continuation of the Mental Health and Substance Abuse Block Grants?

Secretary Sebelius: The Mental Health Block Grant (MHBG) is the largest source of Federal support for mental health services with the exception of the Medicaid program. States and territories use MHBG funds to support mental health services included in their comprehensive community-based mental health service systems plans that provide services to 6.3 million adults with serious mental illness and children with serious emotional disturbances every year. The MHBG funds many initiatives crucial to these individuals that are difficult or impossible to pay for through more traditional clinic-based payment systems such as Medicaid, private insurance plans, or the Veterans Administration.

Funding provided through the Substance Abuse Prevention and Treatment Block Grant supports eligible individuals with a substance use disorder who meet need criteria as established by each State (e.g. 200% of poverty). This funding stream serves as the foundation for substance abuse treatment and prevention services in the States. While health reform will expand access to these services, there will continue to be a need for continued support from SAMHSA.

Mrs. Roybal-Allard: What kind of Medicaid and state exchange enrollment efforts will HHS mount specifically targeting people with cognitive disabilities of all kinds (e.g., intellectual disabilities, Down syndrome, autism, mental illnesses, Alzheimer's disease) and individuals with low health literacy?

Secretary Sebelius: The Department is currently in the process of implementing several new Medicaid policies enacted by the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act) that specifically target individuals with cognitive disabilities. For example, the Affordable Care Act requires the Secretary to establish a 3-year demonstration project under which States may provide Medicaid payment to non-publicly owned and operated institutions for mental disease (IMDs) for purposes of treating Medicaid beneficiaries ages 21-64 who are experiencing a mental health emergency. The provision appropriates $75 million in FY2011, which will remain available for obligation through December 31, 2015.

Another Affordable Care Act provision that will benefit individuals with cognitive disabilities is a Medicaid State plan option to permit coverage of any medical or remedial service recommended to reduce physical or mental disability and restore functionality. The Affordable Care Act also provides several new improvements to Medicaid long term services and supports that we believe will also greatly benefit individuals with cognitive disabilities. Major provisions in the law we are implementing include:

- the Community First Choice Option to expand home and community-based attendant services and supports;
- a $3 billion grant program for states to shift Medicaid beneficiaries into home and community-based (HCBS) settings beginning October 1, 2011;

- an extension of the Money Follows the Person demonstration through FY 2016; and
- a new option in the Medicaid State plan under which States can pay providers or teams of health care professionals for furnishing health home services, including care management, transitional care, patient and family support, referrals to community and social support services, and use of health information technology, for care given to individuals with chronic conditions including persistent mental health conditions.

PREVENTION AND PUBLIC HEALTH FUND

Mrs. Roybal-Allard: The Prevention and Public Health Fund created through health reform provides us with an unprecedented opportunity to begin to transform our public health system to prioritize prevention programs and could also serve as a way to address health disparities. What is the Department's process for allocating this funding?

Secretary Sebelius: HHS is reviewing options for allocating funds in FY 2010 and FY 2011. The Prevention and Public Health Fund provides HHS an opportunity to expand and sustain an investment in prevention, wellness, and public health programs to improve the health of the nation and help restrain health care costs

Mrs. Roybal-Allard: For FY 2010 and FY 2011 how are you prioritizing spending - is there an overall framework you are using to ensure that we are maximizing our use of this funding?

Secretary Sebelius: HHS is examining section 4002 of ACA, which establishes the Prevention and Public Health Fund, to inform its allocation of these funds. In FY 2010, HHS is prioritizing allocation options in which funds can be obligated by the end of the fiscal year.

Mrs. Roybal-Allard: Once the National Prevention Strategy has been announced, will the Strategy guide funding allocations from the Prevention and Public Health Fund?

Secretary Sebelius: Once drafted, the National Prevention and Health Promotion Strategy, required in section 4001 of ACA, will inform, along with other considerations, future HHS allocations for the Prevention and Public Health Fund.

Mrs. Roybal-Allard: As you know, the House bill included categories of funding, including community prevention, prevention and wellness research, and core public health. Is the Department using similar categories to ensure that we are making progress in enhancing community prevention, bolstering capacity at health departments, and enhancing prevention and public health research?

Secretary Sebelius: HHS is evaluating all options for allocating resources from the Prevention and Public Health Fund consistent with ACA's use of the Fund for "prevention, wellness, and public health activities." To the extent that the House bill's Prevention and Wellness Trust would have authorized funds to be appropriated for "prevention, wellness, and public health activities" consistent with ACA, those activities would be an eligible option for HHS to consider. The community transformation grants authorized in health reform legislation are specifically designed to reduce chronic disease rates, prevent the development of secondary conditions, and address health disparities.

Mrs. Roybal-Allard: Do you envision that the Prevention and Public Health Fund will provide funding for community transformation grants in the coming years, and how will you assure that they are effectively used to address health disparities?

Secretary Sebelius: HHS is reviewing options for allocating funds in FY 2010 and FY 2011 and has not made decisions regarding an allocation for any fiscal year. HHS is evaluating options consistent with ACA's use of the Fund, as stated in section 4002 of ACA, for "prevention, wellness, and public health activities." The Prevention and Public Health Fund cites the Community Transformation Grant Program as an example of an eligible use of Fund resources. Thus, HHS will consider this program as one eligible for an allocation of Fund resources.

The authorization for the Community Transformation Grant Program, in section 4201 of ACA, provides that addressing health disparities is an authorized purpose for these grants. In addition, the authorization states that grantees must submit detailed plans to promote healthy living and reduce disparities.

OBESITY AND CHRONIC DISEASE PREVENTION

Mrs. Roybal-Allard: I'm very pleased to see that obesity prevention has been an important priority for this Administration and particularly the First Lady. Within the Department's budget, how can we continue to emphasize obesity prevention? Are there particular programs or accounts that you think are most important to advancing this goal?

Secretary Sebelius: The FY 2011 President's Budget supports obesity-related activities across HHS agencies as part of the Department's obesity related efforts. For instance, the budget includes $58 million, in CDC to fund 25 States to implement State-wide programs to prevent obesity through activities such as population-based interventions, evaluation, surveillance, policy and environmental change, and translation of research to practice. Of the $58 million, $20 million is for CDC's new Big Cities Initiative, which will reduce rates of morbidity, disability, and premature mortality due to chronic diseases in up to ten of the largest U.S. cities.

In addition, the budget includes $5 million in FDA, $784 million in NIH, and $26 million in AHRQ for obesity-related research that will inform obesity prevention and control efforts across all ages, including children. NIH, CDC, and the Robert Wood Johnson Foundation together launched the National Collaborative on Childhood Obesity Research in February 2009. In FY 2011, this collaborative will continue to focus on efforts that have the potential to benefit children, teens and their families, and the communities in which they live. Finally, Healthy People, a set of health objectives for the nation to achieve over the next decade, is produced by HHS and is utilized by the Federal government to help develop programs and policies and establish priorities to improve the health of the population. Healthy People 2020, scheduled to launch later this year, includes many objectives related to obesity prevention and can be used to guide obesity efforts.

Mrs. Roybal-Allard: What can be done in the childcare environment and/or Head Start to help give kids a healthier start? Is there anything HHS can do to address obesity in the childcare setting, and how is that incorporated into the FY 2011 budget?

Secretary Sebelius: Child care, Head Start, and other early childhood settings can play a key role in obesity prevention efforts by promoting improved nutrition and increased physical activity for children. The Administration is committed to improving the quality of child care, including health and safety standards and improved monitoring to ensure that children are in safe environments. As part of our commitment we are looking at ways that we can work with States and grantees to promote expert-recommended standards related to nutrition and physical activity.

We are also developing technical assistance to promote effective practices in early learning settings, such as extending the Head Start's *I Am Moving, I Am Learning* (IMIL) initiative to child care and other settings. IMIL is a proactive approach to childhood obesity that promotes healthy food choices and seeks to increase the amount and quality of physical activity that children receive. Head Start is planning to expand this initiative to grantees that have not yet participated and, where possible, will make the training available to child care agencies. The training will be revised to include children from birth to age five and include age appropriate physical development activities, structured and unstructured play with 30-60 minutes of moderate to vigorous physical activity, and teaching about making good nutrition choices. It is integrated throughout a program's existing curriculum and, along with health, supports children's progress in the social-emotional and cognitive domains of the Head Start Child Outcomes Framework.

In addition to these efforts in the classroom, it is essential to provide educational materials on nutrition and physical activity to parents and other caregivers of young children. The President's FY 2011 budget request would provide a significant increase for the Child Care and Development Block Grant—making additional quality and technical assistance dollars available for these critical activities.

Mrs. Roybal-Allard: Has the Department begun implementation of the CHIPRA childhood obesity demonstration project that was authorized in CHIPRA and funded through health reform? How will the Department evaluate the demonstration project, and if successful, does the Department plan to expand it?

Secretary Sebelius: CDC, in collaboration with CMS, will implement the CHIPRA childhood obesity demonstration project funded in health reform. CDC and CMS are working on implementation plans, including the evaluation plans. Evaluation measures likely will correspond to the grantees' activities, such as the health outcomes resulting from the grantees'

ARRA PREVENTION AND WELLNESS FUNDING

Mrs. Roybal-Allard: What is the Department doing to ensure coordination between chronic disease prevention funding that is awarded through the ARRA Prevention and Wellness Initiative and the annualized chronic disease prevention programs at CDC supported through the discretionary appropriations process?

Secretary Sebelius: Congress appropriated $1 billion in the FY 2009 Recovery Act for Prevention and Wellness. Specifically, $300 million was appropriated for CDC's Section 317 Immunization Program, $50 million was appropriated for healthcare-associated infections, and $650 million was appropriated to implement evidence-based prevention and wellness strategies to address the rates of chronic disease. The program HHS is executing to implement evidence-based

prevention and wellness strategies is the Communities Putting Prevention to Work Program, which addresses obesity and tobacco prevention. The Recovery Act provided the $1 billion as a one-time appropriation. Consequently, although the chronic disease funding requested in CDC in the FY 2011 President's Budget does not overlap with the one-time funds Congress appropriated in the Recovery Act in FY 2009, HHS expects that any lessons learned from the Recovery Act will inform chronic disease programs supported by CDC's annual appropriation.

Mrs. Roybal-Allard: How will lessons learned from the ARRA investment be incorporated into the existing CDC chronic disease prevention programs?

Secretary Sebelius: The Recovery Act Communities Putting Prevention to Work Program provides a platform for the wide-scale application of a focused set of evidence-based policy, environmental, and systems change strategies. CDC will incorporate lessons learned from this program in its chronic disease prevention programs, such as the Big Cities Initiative, for which the FY 2011 President's Budget requests $20 million. Funded cities of the Big Cities Initiative will implement evidence-based programs to reduce the risk factors that lead to chronic disease and will incorporate lessons learned from the Recovery Act program.

HEALTH DISPARITIES

Mrs. Roybal-Allard: As you know, AHRQ recently released the National Healthcare Disparities Report, which found that disparities related to race, ethnicity, and socioeconomic status still pervade the American healthcare system. In African Americans communities, 48 percent of adults suffer from chronic disease, compared with 39 percent of the general population. Studies have found that forty-four percent of Hispanics receive obesity counseling, and were one-third times less likely to be counseled than whites. Less than one-third of low-income individuals receive diabetes care to prevent progression of the disease, while more than half of people with high incomes receive proper care. What particular programs in the HHS budget would you prioritize in order to address health disparities?

Secretary Sebelius: Health disparities faced by racial, ethnic, and underserved communities are the manifestation and interplay of complex factors and evidence suggests that solutions for reducing health disparities must address those complex factors. It will take many different programs, working in collaboration, to effectively address health disparities. In this regard there are a number of programs in the FY 2011 HHS request that are intended to collectively contribute to improved outcomes for racial, ethnic, and underserved communities.

These programs focus on ensuring access to quality, culturally competent, and patient-centered care; promoting prevention and wellness; increasing access to early learning programs and supporting healthy environments; promoting community empowerment and community-driven interventions; ensuring the collection, reporting, and access to data on all populations; increasing the supply, diversity, and cultural competence of the health-related workforce, particularly within underserved communities; supporting research that specifically adds to the knowledge base on health concerns faced by communities of color; and, increasing coordination and partnerships among organizations, within and outside of the Department, whose programs and activities address factors that influence outcomes for minority communities.

Mrs. Roybal-Allard: CDC's REACH program focuses on eliminating health disparities. How do you assess that program, and do you think it should be expanded in the future?

Secretary Sebelius: The FY 2011 President's Budget requests $39 million for REACH, -$1 million below FY 2010 for CDC-wide contract and travel savings, and will support 50 communities. The REACH program supports communities to implement strategies and interventions to advance the reduction and elimination of racial and ethnic health disparities. The program has been successful in addressing health disparities. For instance, the Chicago Department of Public Health REACH program used a multi-faceted community approach to improve access to diabetes and cardiovascular care and services. The percentage of program participants with diabetes who received annual hemoglobin A1C tests increased from 21 to 96 percent, the percentage who received annual eye exams increased from 22 to 72 percent, and the percentage who received annual foot exams increased from 42 to 72 percent.

Mrs. Roybal-Allard: One factor that contributes to health disparities is lack of access to nutritious foods. As you know, the President's budget has proposed a $400 million joint USDA-HHS-Treasury initiative to address the issue of food deserts. Can you tell me a little more about this Initiative and the HHS piece of it?

Secretary Sebelius: Each of the three agencies supporting the Healthy Foods Financing Initiative brings with it a particular expertise and a set of resources that complement one another. HHS specializes in community-based efforts to improve the economic and physical health of people in distressed areas. We will dedicate up to $20 million in Community Economic Development program funds to the Healthy Food Financing Initiative. Through the Community Economic Development program, we will award competitive grants to Community Development Corporations to support projects that finance grocery stores, farmers markets, and other sources of fresh and nutritious food. Targeting financial assistance to food deserts will not only increase the supply of healthy foods and create new markets for farmers, but also create jobs and support broader development efforts to revitalize distressed communities. HHS has supported fresh food projects in the past, like the Plaza del Valle in Panorama City, CA, a family-oriented public market. This project facilitated the creation of 22 new businesses and the expansion of 28 businesses.

The Department of Agriculture specializes in improving access to healthy foods through nutrition assistance programs, creating business opportunities for America's farmers, and promoting economic development in rural areas. USDA's proposed funding level of $50 million will support more than $150 million in public and private investments in the form of loans, grants, promotion, and other programs that can provide financial and technical assistance to enhance access to healthy foods in under served communities, expand demand and retail outlets for farm products, and increase the availability of locally and regionally produced foods. USDA has a solid track record of supporting successful farmers markets, and has also invested in grocery stores and creating agricultural supply chains for them such as in the People's Grocery project in Oakland, CA.

The Treasury Department will support private sector financing of healthy food options in distressed urban and rural communities. Through the New Markets Tax Credit (NMTC) and financial assistance to Treasury-certified community development financial institutions (CDFIs), Treasury has a proven track record in expanding access to nutritious foods by catalyzing private

sector investment. The Healthy Foods Financing Initiative builds on that track record, with $250 million in authority for the NMTC and $25 million for financial assistance to CDFIs devoted to helping finance healthy food options.

Mrs. Roybal-Allard: What are the most promising provisions in health reform to help address these disparities?

Secretary Sebelius: In addition to provisions that improve and expand access to quality, affordable, patient-centered health care, other important provisions include:

- Establishing a clear and definitive operational structure for coordinating and evaluating health disparities policies, programs, and activities within the Department of Health and Human Services and its partners. The Patient Protection and Affordable Care Act of 2010, reauthorizes the Federal Office of Minority Health, creates offices within the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, and Substance Abuse and Mental Health Services Administration that will improve our policies and programs related to minority communities. The Act also elevates the National Center on Minority Health and Health Disparities to an Institute.

- Improving data collection and reporting requirements for federally conducted or supported health care and public health programs based on existing standards for race and ethnicity and that accounts for the needs of sub-populations.

- Enhancing education and training opportunities to increase the supply, diversity, and cultural competence of the health-related workforce. The Act will address the low numbers of health professionals from minority communities through additional scholarship and loan repayment opportunities for disadvantaged students who commit to work in medically underserved areas and who serve as faculty in participating institutions. It also expands the allowable uses of the nurse diversity program.

- Promoting positive health behaviors and collaborative community-based prevention efforts focused on the social determinants of health.

- Developing and expanding the medical home model for Medicare and Medicaid patients through the new Center for Medicare and Medicaid Innovations. Medical homes are associated with a reduction in health care disparities for adults and better access to prevention services.

- Grants to states, public health departments, clinics and hospitals to promote the use of community health workers in medically underserved areas.

- Reauthorization and expansion of programs to support the development, evaluation and dissemination of model curricula for cultural competency at health professions schools and in continuing education programs.

- Funding for a home visiting program to at risk families and young children, based on the Nurse-Family Partnership program. This nurse home visiting program improves the health, well-being and self sufficiency of low income, minority, first time mothers and their children.

- Funding to establish more community health centers to provide comprehensive, affordable care to low income, racial and ethnic minority communities.

HEALTH REFORM IMPLEMENTATION

Mrs. Roybal-Allard: Health reform will provide greater access to coverage. But the increased coverage rates will also amplify the current primary care shortages. How will the Department work with health departments and providers to assist the newly insured in accessing care?

Secretary Sebelius: The Act includes several provisions to ensure access to health care for all Americans. Specifically, the Act invests in the National Health Service Corps, reauthorizes and improves scholarship and loan repayment programs, increases workforce diversity, develops workforce planning and analysis and incentivizes primary care and practice in underserved areas.

Mrs. Roybal-Allard: How will the Department ensure that as we address the primary care shortages, we are at the same time creating a culturally competent workforce?

Secretary Sebelius: We view having a diverse, culturally competent health professions workforce as integral to ensuring access to health care. We support grant programs that focus on supporting curricula and training that will prepare a workforce. Many of the health professions grant programs – ranging from primary care, nursing, public health and geriatrics -- emphasize teaching cultural competence to new providers and as part of continuing education.

Mrs. Roybal-Allard: What initiatives does HHS have to increase the number of nurse practitioners, who are highly qualified primary care providers, in the health care workforce?

Secretary Sebelius: HHS has several programs whose goal is to increase the number of nurse practitioners qualified to provide primary care. These programs include Advanced Nursing Education, Advanced Education Nursing Traineeship and Nurse Faculty Loan Programs.

The Advanced Nursing Education Program provides infrastructure grants to schools of nursing to develop, implement and evaluate educational programs at the master's, post master's, and practice doctoral level to prepare primary care nurse practitioners. These grants provide financial support to the schools for faculty, faculty development for purposes of the project, teaching/learning resources, clinical site development for student primary care learning experiences, equipment and supplies, travel, and data collection. They prepare nurses for advanced practice across the life span and have linkages with federally funded community based primary care practice sites such as Federally Qualified Health Centers, Nurse Managed and Rural Health Centers.

The Advanced Education Nursing Traineeship program provides grants to schools for award to students who are enrolled in primary care nurse practitioner programs to cover the costs of tuition, fees, books, and reasonable living expenses. Many of the students who are recipients of the traineeships are preparing to be primary care nurse practitioners.

The Nurse Faculty Loan Program provides grants to schools to establish a discrete revolving loan program that provides loans for students enrolled in masters and doctoral programs. The student is able to qualify for cancellation of 85 percent of the loan in exchange for working as nurse faculty over a four year period. Many of the recipients of these loans are preparing to be faculty for primary care nurse practitioner program, enabling the programs to increase the capacity of trained primary care nurse practitioners.

The Nurse Education Practice and Quality Program provides grants to schools of nursing to establish or expand non-institutional nursing practice arrangements (NPAs), also known as nurse managed health centers (NMHCs). The NMHC are innovative health care delivery systems that improve access to primary health care in medically underserved areas and provide nursing practice for nurse practitioners and structured clinical experiences undergraduate and graduate nursing students. The NMHCs are considered safety-net providers of care that are owned and operated by schools of nursing and their primary care nurse practitioners.

Mrs. Roybal-Allard: Additionally, will HHS be looking more closely at decreasing the barriers to nurse practitioner practice in Medicare and Medicaid?

Secretary Sebelius: Under current law, Medicare will pay for services furnished by nurse practitioners if the Medicare benefit permits them to bill for such services. Medicare rules require that the services provided must be medically necessary and within the scope of practice in the State in which the nurse practitioner practices. Medicare payment for such services is generally 85 percent of the physician fee schedule rate.

A provision in the Accountable Care Act encourages expanded access to primary care services by providing a 10 percent additional payment for primary care services furnished by certain practitioners for 5 years beginning in 2011. Nurse practitioners would be eligible to receive this bonus if primary care services account for at least 60 percent of their allowed charges. Also, under current law, nurse practitioners may participate in the Medicaid program. Reimbursement to Medicaid providers is administered by the States and reimbursement rates for nurse practitioners vary.

PANDEMIC INFLUENZA

Mrs. Roybal-Allard: As we have seen with H1 N1, new strains of flu can quickly emerge and spread. It is essential that we are prepared. What is the status of HHS' development of a professional judgment budget for pandemic preparedness, beyond what is in the president's request for FY 2011? When will it be available?

Secretary Sebelius: HHS is in the process of evaluating pandemic influenza needs in light of lessons learned from 2009-H1N1 influenza response. In addition, HHS is conducting a review of the medical countermeasure development process, which includes pandemic influenza. This

review will include recommendations to help ensure the Nation's preparedness for future pandemics and other threats.

Mrs. Roybal-Allard: Has the Department begun to update the National Strategy for Pandemic Influenza or its implementation plan, or do you have plans to do so in the future?

Secretary Sebelius: HHS is currently conducting an After Action Review of the H1N1 pandemic response. Following completion of that review, HHS will update the National Strategy for Pandemic Influenza to reflect successes and lessons learned from H1N1.

Mrs. Roybal-Allard: It is our understanding that the department is preparing an after action report on the H1 N1 response. When will the findings from this report be available to the committee?

Secretary Sebelius: It is anticipated that results from the HHS After Action Review of the H1N1 pandemic response will be available in the fall of 2010.

Mrs. Roybal-Allard: How much supplemental funding remains unexpended? When will the Department update the Committee on its plans for the remainder of the funds?

Secretary Sebelius: As of March 2010, $3.6 billion of the $7.65 billion in FY 2009 supplemental funding remains unobligated. Original plans for this funding assumed that two doses of H1N1 vaccine would be needed in order to provide protection against the virus. Since the H1N1 vaccine is well-matched to the virus and highly immunogenic, less FY 2009 supplemental funding was needed to purchase doses for Americans than originally projected. HHS is in the process of revising plans for this funding in light of lessons learned from 2009-H1N1 influenza response and the medical countermeasure review that is currently underway.

Mrs. Roybal-Allard: As you know, the Department has awarded emergency funding to state and local health departments for pandemic preparedness. When these funds run out, do you have plans to provide ongoing funding for state and local pandemic preparedness activities? Do you believe this funding stream should be combined with the Public Health Emergency Preparedness funding?

Secretary Sebelius: Emergency pandemic influenza funding was provided to 62 grantees, including all 50 states, four cities, and eight territories, for pandemic preparedness and response during the H1N1 pandemic. These grantees are the same as those receiving annual Public Health Emergency Preparedness (PHEP) funding. The FY 2011 President's Budget includes $715 million for PHEP cooperative agreements to support preparedness in public health departments nationwide, including pandemic preparedness.

Mrs. Roybal-Allard: Does the Department have plans to review and evaluate state pandemic influenza response capacity, in light of the H1 N1 outbreak?

Secretary Sebelius: Yes. Recipients of emergency pandemic influenza funding for pandemic preparedness and response during the H1N1 pandemic are required to submit an H1N1 After Action Report and Improvement Plan (AAR/IP) to CDC by July 31, 2010. The AAR/IPs

will identify important issues from the H1N1 pandemic that States plan to address as part of their own process improvement plans with respect to pandemic preparedness and response activities. In addition, Public Health Emergency Preparedness (PHEP) grantees, are required by the Pandemic and All-Hazards Preparedness Act (PAHPA) to submit a plan for responding to pandemic influenza each year. CDC will develop revised guidance for States to use as they update their plans based on lessons learned from the 2009 H1N1 pandemic.

Mrs. Roybal-Allard: How will the Department replenish supplies from the Strategic National Stockpile that have been used during the H1 N1 outbreak?

Secretary Sebelius: The antiviral drugs dispensed from the Strategic National Stockpile (SNS) during the response to H1N1 were replenished in 2009. HHS is currently evaluating the need for acquisition of additional vaccines, personal protective equipment, drugs, devices, and medical equipment following the 2009 H1N1 pandemic.

NEWBORN SCREENING AND PRIMARY IMMUNE DEFICIENCY

Mrs. Roybal-Allard: As you know the Secretary's Advisory Committee on Heritable Disorders in Children voted in January to recommend to you that a newly-developed test for the most severe forms of primary immune deficiencies be added to the core panel of conditions recommended to be tested by the states. Because this is the first new test recommended since the core panel was created, it generates important questions about implementation.

What plans does the Department have, for this test or for others that maybe approved in the future, to educate the public (particularly new parents) about newborn screening and the critical role it plays in early diagnosis, containing healthcare costs and vastly improving the quality of life for children and their families?

Secretary Sebelius: The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (Committee) made recommendations to the Secretary on February 25, 2010 to lay the groundwork for an iterative implemental development of infrastructure needed for: 1) ongoing research, 2) evaluation, 3) surveillance, 4) education, and 5) training for screening for Severe Combined Immunodeficiencies (SCID) and related T-cell lymphocyte deficiencies. The Committee's recommendations are currently under review.

The Health Resources and Services Administration has created a Clearinghouse for Newborn Screening Information (authorized under the Newborn Screening Saves Lives Act 2008) to establish and maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening.

RACIAL AND ETHNIC HEALTH DISPARITIES

Ms. Lee: As Chair of the Congressional Black Caucus I have been working with my colleagues to address racial and ethnic health disparities as part of the health reform law. I'd like you to elaborate if you can on what the Department is currently doing and what new initiatives you will be undertaking to address this important issue. How does the FY 11 budget request support the goals of increasing diversity in the health professions through recruitment and training?

Secretary Sebelius: HRSA administers several health workforce programs with a primary focus of increasing the diversity of the health professions workforce. The Centers of Excellence (COE) Program funds grants to recruit, train, and retain underrepresented minority (URM) students and faculty at health professions schools. COEs carry out activities to improve information resources, clinical education, curricula and cultural competence as they relate to minority health issues and facilitate faculty and student research on health issues particularly affecting URM groups. In FY 2011, an estimated 17 grant awards will provide training to approximately 257 faculty and 2,000 students from URM backgrounds.

The Health Careers Opportunity Program (HCOP) funds health professions schools to provide students from disadvantaged backgrounds, including students from URM backgrounds, with the necessary skills to enter into and successfully complete a health professions education. In FY 2011, an estimated 33 awards will afford approximately 2,700 students the opportunity to be exposed to and pursue careers in the health professions.

The Nursing Workforce Diversity program provides support for infrastructure grants aimed at increasing nursing education opportunities for individuals who are from disadvantaged backgrounds (including racial and ethnic minorities underrepresented among registered nurses) by providing scholarships or stipends, pre-entry preparation and retention activities. The program targets minority and disadvantaged students in nursing schools, pre-nursing programs, and students in secondary schools. In FY 2011, the President's Budget includes approximately 47 grants to support the training of approximately 8,600 minority students/participants.

The Scholarships for Disadvantaged Students program provides grants to eligible entities to provide scholarships to students from disadvantaged backgrounds, many of whom are URMs. This program tackles a major barrier for disadvantaged and minority students' access to a health professions education because of high tuition costs. In FY 2011 an estimated 18,000 disadvantaged students, including 11,200 URM students will receive scholarship support.

Ms. Lee: How does the FY11 budget request support the goal of increasing diversity in NIH institutions and researchers?

Secretary Sebelius: Promoting and increasing diversity of the NIH workforce, and particularly of tenured and tenure track scientists in NIH's intramural research programs, is a priority for the agency. In particular, the NIH is placing special emphasis on recruiting and hiring all under-represented minority scientists in tenure and tenure track positions (Black, Hispanic and American Indian/Alaska Native). NIH has developed a plan to enhance diversity and promote the inclusion of under-represented scientists within these ranks.

Elements of this plan include: a) reaching a diverse pool of applicants by notifying the diversity specialists at Association of American Medical Colleges accredited medical schools, and program directors at NIGMS Minority Opportunities in Research Programs of all tenured and tenure track vacancies and soliciting their assistance in reaching prospective applicants; b) reaching a diverse pool of applicants by conducting targeted outreach to individuals as well as organizations known to have diverse individuals with the requisite skills; c) preparing NCMHD loan repayment recipients to compete for NIH tenured and tenure track positions by providing the Disparities Research Education Advancing our Mission intramural postdoctoral training program; and d) conducting focus groups to learn about any barriers that may inhibit the employment and retention of diverse groups, and developing strategies to remove any identified barriers.

In addition, for the entire NIH workforce, not just the intramural research programs, there is strategy to recruit and retain Hispanic employees. Elements include: a) targeting outreach to the University of Texas, Texas A&M University, the University of New Mexico, and the University of Puerto Rico; b) NIH institutes participating in conferences which target Hispanic audiences; and c) NIH conducting focus groups to learn more about the workforce's perceptions of the reasons for the limited numbers of Hispanics in the workforce.

Similarly, for all positions at NIH, there is a plan to recruit individuals with targeted disabilities. Elements include: a) the Disability Program Manager providing training sessions on special hiring authorities, reasonable accommodations, and the Americans with Disabilities Act Amendments to educate managers and supervisors; and b) NIH conducting focus groups to learn more about the workforce's perceptions of the reasons for the limited numbers of individuals with targeted disabilities in the workforce.

Ms. Lee: How does the FY 11 budget request support the goal of ensuring racial and ethnic minorities benefit from new and innovative health research at the NIH?

Secretary Sebelius: Over the years, NIH research has helped to enhance our understanding of the complexity of health disparities. Most of our research efforts have been focused primarily on the biological pathway of health disparities through the study of diseases and conditions that disproportionately affect health disparity populations such as heart disease, diabetes, obesity, stroke, cancer, HIV/AIDS and infant mortality.

We have witnessed growing research interest and attention to minority health and health disparities since the establishment of the National Center on Minority Health and Health Disparities, now the National Institute on Minority Health and Health Disparities, which has been leading NIH efforts to address minority health and health disparities and to coordinate NIH research activities conducted and supported by ICs in these areas.

In recent years, the scientific knowledge base about health disparities has increased, and research findings point to social, economic, behavioral, and access to care factors as some of the significant contributors to health disparities, leading to increased research focus at NIH in these non-biological areas, as well as on poor and rural populations who also experience disparities in health.

NIH is engaging communities in its research activities as equal partners; multidisciplinary and specialized Centers of Excellence on health disparities are being supported around the country; and research capacity building to facilitate the conduct of scientific research, training, and career development is taking place at institutions around the country due to NIH funding. Innovative outreach, information dissemination and research translation activities are being funded in communities nationwide. The NIH Health Disparities Strategic Plan and Budget provides a roadmap for how the NIH will approach the improvement of health and elimination of health disparities among the nation's most vulnerable populations.

Ms. Lee: How does the FY11 budget request provide direct support for the nation's minority medical colleges and institutions?

Secretary Sebelius: The Department of Health and Human Services supports many programs that assist Historically Black Colleges and Universities, Tribal Colleges and Universities, Historically Black Medical Schools, and other institutions. For example, the FY 2011 request for the Office of Minority Health includes support for Central State University, Stone Child College, Tennessee State University, Morehouse College, and other institutions. The Office of Minority Health also provides support in collaboration with the National Institute on Minority Health and Health Disparities, to Charles Drew University of Medicine and Science, Meharry Medical College, and Morehouse School of Medicine.

Ms. Lee: How does the FY11 budget request provide targeted support to help reduce and eliminate these disparities while addressing communities with the greatest need?

Secretary Sebelius: The Office of Minority Health supports a number of programs that focus on communities of greatest need. For example, the Bilingual/Bicultural Demonstration Program, Curbing HIV/AIDS Transmission Among High Risk Minority Youth and Adolescents by Utilizing a Peer-to-Peer Outreach Model and New Application Technologies (CHAT), Youth Empowerment Program (YEP), Partnerships Active in Communities to Achieve Health Equity (PACT), and Linkage to Life Program (L2L) focus on targeted, hard-to-reach, high risk populations.

Ms. Lee: I understand that earlier this year the Office of Minority Health, through its National Partnership for Action to End Health Disparities, has produced a draft "National Plan for Action" on disparities. What resources will HHS will be devoting to implementing the plan - particularly in circumstances where OMH/HHS may have little direct control over implementation without additional budgetary incentives?

Secretary Sebelius: We appreciate your interest and support for the *National Plan for Action*. In the Department's FY10 appropriation, members shared their concerns regarding racial and ethnic disparities in this country and the need for a national strategy that would be developed and implemented with partners to effectively and cohesively address this national problem. The *National Plan for Action* responds to the Congressional language and advances a coordinated approach. The Department is mindful of the importance of implementing incentives to ensure all sectors address actions that are part of their respective responsibilities and is assessing opportunities as part of the rollout of the *National Plan for Action* in the near future. The implementation of the National Plan for Action will be accomplished in phases. Funds for initial

implementation phase of the *National Plan for Action* are included in the FY 2011 request for the Office of Minority Health. These implementation activities will address the following:

- Supporting the information, capacity building, and technical assistance needs of stakeholders within the public and private sectors who are preparing to undertake strategies of the *National Plan for Action* that correlate with their work.

- Ensuring that Federal programs that address the social determinants of health and that can contribute to achieving health equity are coordinated and incorporate appropriate strategies of the *National Plan for Action* into their supported activities.

- Completing implementation of Health Equity Boards that will coordinate activities across sectors and organizations.

- Contributing to completion of data collection and reporting requirements mandated by the Patient Protection and Affordable Care Act and that also serves as a key strategy for eliminating health disparities under the *National Plan for Action*.

NATIONAL AIDS STRATEGY

Ms. Lee: I'm pleased that the Administration is moving forward in developing a truly comprehensive and collaborative National AIDS Strategy to guide our response to this epidemic. I'm worried however that the funding allocated to implementation of the strategy within your department for the coming fiscal year will be inadequate to truly meet the needs that have been identified.

What part of the current budget allocation - including the proposed $70 million increase in new funding at HRSA and CDC - will go towards implementation of the National AIDS Strategy? Do you need a separate increase in funding to address some of the coordination and implementation issues that will inevitably arise in moving forward with the Strategy?

Secretary Sebelius: The final National HIV/AIDS Strategy is still under development and is expected to be completed this summer in time for the FY 2011 Budget. All of the Department's $17.6 billion requested to be devoted to HIV/AIDS in the FY 2011 Budget are expected to play a part in implementing the National AIDS Strategy.

Ms. Lee: Who will ultimately lead implementation of the National AIDS Strategy? Will this continue to be an initiative within the White House - and who within HHS will be the point person for ensuring that Agencies within the Department are following through on their responsibilities?

Secretary Sebelius: The final National HIV/AIDS Strategy is still under development and is expected to be completed this summer. Consequently, decisions about organizational leads both across the Federal government and within the Department have not yet been finalized.

HHS'S ROLE IN THE PRESDIENT"S GLOBAL INITIATIVE

Ms. Lee: In April of 2009, the President announced a 6 year - $63 billion initiative to strengthen and improve the work of US global health programs in developing countries including to better integrate and coordinate US programs, encourage country ownership - including through building health systems and strengthening health capacity - encourage a women's centered approach to health, and to generally improve the effectiveness of these programs.

Although it was only launched last year - the FY11 Budget technically represents the 3rd year of funding for this initiative. Given the inherent expertise of HHS and specifically CDC in building and supporting public health systems - and the clear intent of the Administration in scaling up funding for global health programs it's a little perplexing why the budget includes so little funding for HHS to help carry out the Global Health Initiative. Indeed the Secretary's testimony only notes a $16 million increase for CDC's global health programs.

What exactly is HHS's role in implementing the global health initiative? Why is HHS's budget for global health not increasing commensurate to the role that CDC currently plays in our global health programs? How much funding does HHS/CDC receive each year in transfer authority from the State Department/USAID? Wouldn't these funds be better utilized and spent if they were provided directly to HHS/CDC in the President's budget?

Secretary Sebelius: All of NIH's $3.2 billion HIV/AIDS research portfolio and the $300 million requested in the NIH budget for use by the Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria, as well as CDC's $118 million Global AIDS Program and its $9 million Global Malaria Program are counted by the Administration as components of the President's $9.6 billion Global Health Initiative (GHI) in FY 2011.

In addition to these resources from its own budget, CDC administers through interagency agreements about $1.4 billion a year of USAID's PEPFAR funds. These funds are used to strengthen the capacity of PEPFAR countries to carry out laboratory, epidemiology, surveillance, and public health evaluation and workforce activities, which are essential components for strong sustainable public health systems. CDC strives to ensure that all of the funds it administers are spent well, regardless of whether the source is direct appropriations or interagency agreements. We are also working with the State Department and USAID to improve the coordination and efficiency of its joint arrangements.

HEALTH WORKFORCE ISSUES AND HEALTH REFORM

Ms. Lee: By all accounts the nation is already facing a huge workforce shortage just to meet the current demand for health services. Whether it's in the number of skilled nurses, physician's assistants, or doctor's we have a clear need for smart, educated, and highly skilled health professionals in this country. The fact is that our current education and clinical training system does not produce enough health professionals to meet the current demand for skilled labor - and as a result our nation is forced to recruit health professionals from abroad to help fill the gap.

At the same time - and because of the current economic downturn I'm hearing reports that graduating health professionals are finding it difficult to get a job even in the midst of a health workforce shortage.

I spoke recently to a dean of one of the nursing schools in my district - at the Samuel Merritt School of Nursing in Oakland- and she indicated that just in the Bay Area alone 40 percent of all new nursing graduates since November 2008 have yet to find a job. Normally every nursing school graduate in the Bay Area would find a job within 6 months. Its not because their skills aren't needed, its because hospitals and clinics can't afford to bring on new staff while dealing with massive budget cuts at the local and state level s they are instituting hiring freezes. In some cases hospitals are cutting back hours for existing staff due to a drop in demand for health services as people lose their job and their coverage.

What are we doing to ensure that we don't lose the current crop of graduating nurses and other health professionals to other fields due to the economic downturn? Can we provide any immediate incentives to employers to ensure that they don't turn away qualified job applicants in the middle of a workforce shortage?

Secretary Sebelius: According to the Department of Labor, the health sector is among the fastest growing sectors in the economy. Pursuing a health professions education in virtually any discipline is likely to provide a stable career with opportunities for advancement in the long run. While regional issues and the current economy may prevent some individuals from finding employment immediately upon graduation, it is expected that more jobs will become available as the economy improves.

In addition, individuals who are willing to relocate can also increase their opportunities for employment. HRSA does not have legislative authority to provide employers with incentives to hire new graduates. Using Recovery Act funding, HHS supported 427 nurses in obtaining loan repayment and scholarship support. Loan Repayment support places nurses into underserved areas and scholarship support also places nurses into underserved areas as well as provides funding so that nurses can complete their education. Recovery Act funding also supported 1,200 nursing students to receive loans so that they could complete their education.

Ms. Lee: It's both a positive and a negative then that the new health reform law - while broadening access to health insurance for an additional 30 million people - will also require us to educate, train, and recruit a whole new generation of public health professionals to help provide health care to these new patients. Frankly its one of the reasons why I believe that health reform - in addition to improving health outcomes - will also help stimulate our economy and create millions of new jobs in the United States. At the same time I'm worried that we are already far behind in training new health professionals, and we've got to play alot of catch up if we are going to truly meet the demand for more skilled labor.

How will the Department's FY11 budget help address the current health workforce shortage including for doctors and nurses - and what are we doing to put the nation on a path to graduating more health professionals over the next five years to take advantage of the new jobs that will be waiting in 2014 and beyond?

Secretary Sebelius: The FY 2011 President's Budget provides continued support for programs that address workforce shortages. To expand the nation's capacity to train more health professionals, the Health Resources and Services Administration (HRSA) takes deliberate steps to address shortages in faculty and clinical training sites, two key limitations on the number of health professionals trained. HRSA's training programs support the development of faculty in primary care, geriatrics, and nursing, as well as supporting a diverse faculty through the Centers of Excellence Program.

HRSA also funds programs that help health professions students find clinical training experiences in underserved areas. Through the Recovery Act, HRSA will fund approximately $50 million in grants for equipment to directly support training. It is expected that this equipment will not only improve the quality of training, but in many cases expand the capacity of training programs. HRSA also invests in several programs that work to increase interest in health professions and support individuals from disadvantaged backgrounds who hope to pursue health professions education.

Ms. Lee: I'm also concerned that in seeking to meet the demand for new health professionals we will be forced to rely even more on other countries to fill these jobs - including in some cases recruiting foreign trained health professionals from countries who are experiencing their own health worker shortage.

Is the Department taking any steps to help mitigate or reduce the prevalence of "brain drain" in developing countries where we might be recruiting these health professionals from? Is your Department aware of and active in any voluntary efforts to encourage responsible recruitment practices and reduce the impact of our need to import labor to the US?

Secretary Sebelius: In 2003, in response to the Department of Agriculture's announcement that it would no longer accept applications for J-1 Visa waivers for physicians, the Department of Health and Human Services reversed its long-standing refusal to request waivers for clinical care in underserved areas. In the first year the HHS J-1 Visa Waiver activity processed 43 applications with no restrictions on the type of outpatient facility or Health Professional Shortage Area (HPSA) score. For the last several years, applications have been limited to those J-1 physicians who will work in a HRSA grant-supported health center, a certified rural health clinic, or a 638-Compacted tribal facility in a HPSA with a score of seven or higher. From 2007 through 2009, with these guidelines in place, the HHS J-1 Visa waiver activity has processed roughly 10 waiver applications per year.

MULTIPLE SCLEROSIS AND SUPPORT FOR ADULT DAY PROGRAMS

Ms. Lee: As you may know, multiple sclerosis is a chronic unpredictable disease of the central nervous system. It's thought to be an auto-immune disorder where the immune system incorrectly attacks healthy nerve fibers of the central nervous system, interfering with transmission of nerve signals throughout the body. It can actually be diagnosed among relatively young people and as a result can lead to chronic unpredictable disability throughout life.

One of the interventions identified by the MS community that could be really helpful to people living with the disease is support for adult day programs. Unfortunately most of these

programs are geared toward an elderly adult population and in some cases may not be the best fit for people living with MS who have different needs.

I'd like to get your thoughts on the possibility of the department collecting some best practice I'd like to get your thoughts on the possibility of the department collecting some best practice information on ongoing adult day programs that serve a younger disabled population, so we can better standardize and replicate these sorts of services across the country. Can resources we provide the FY11 budget of the Administration on Aging help to do some of this work?

Secretary Sebelius: The Administration on Aging currently has two efforts to provide adult day care programs and other services to younger disabled individuals. The first is the Veterans Directed Home and Community Based Services Program, which is designed to serve veterans of any age who are at risk of admission to a nursing home by providing them the opportunity to self-direct their care and access services to help them remain in the community. The second is the Lifespan Respite Care program, which supports the delivery of planned and emergency respite services while also providing for the recruitment and training of respite workers and caregiver training and empowerment. Our FY 2011 budget request proposes doubling this program from $2.5 million to $5 million. We expect these efforts to generate knowledge regarding best practices related to serving younger adults in adult day care settings.

ADMINISTRATIVE COSTS OF IMPLEMENTING HEALTH REFORM

Ms. Lee: The new health reform law requires the development, implementation and enforcement of a range of new regulations and programs to ensure that our constituents are able to utilize the benefits of health reform - ranging from ensuring that insurance companies can no longer discriminate based on pre-existing conditions, to greatly expanding support for community health centers and workforce training programs, to establishing health insurance exchanges similar to what Members of Congress can access. Clearly HHS will playa huge role in setting up this new system.

To what extent was the FY 2011 Budget prepared with the understanding of the Administrative burdens that HHS will likely face in the coming year? Has your department conducting an initial needs assessment to anticipate what the real administrative costs of implementing health reform will be in 2011 - including in terms of how many new full time employees the Department will need to hire? Can you provide the subcommittee with more details on the administrative burdens that we will be expected to help fund over the next year?

Secretary Sebelius: The FY 2011 Budget was developed while the legislation was still being negotiated and the final policies and funding levels included in the bill had not yet been determined, so it does not include the final needs of implementing the health reform legislation. ACA included $1 billion for implementation costs, and HHS is assessing the scope of work required and is determining the most appropriate steps to take as we begin to implement the provisions of the Act. We do not know the full resource needs yet, but we will be closely monitoring agency needs throughout the implementation process. HHS is strongly committed to the successful implementation of health reform. Health reform implementation is one of the highest domestic priorities of the Administration and we will work with you to ensure that we get it right.

Ms. Lee: Do you need any additional resources now to help implement the portions of the law that take effect immediately?

Secretary Sebelius: Since the Affordable Care Act includes $1 billion for a Health Insurance Reform Implementation Fund; HHS is using those resources to implement immediate provisions.

INFERTILITY

Ms. Lee: Secretary Sebelius, last year the Committee requested that the CDC report on the development of a national public health plan for the prevention, detection and management of infertility. I understand that the plan is not completed yet. Can you share with the Committee what the status is of the report?

Secretary Sebelius: CDC is drafting this report, and HHS expects to transmit it to the Committee very soon.

Ms. Lee: In the report language to last year's appropriations bill, the Committee included funding within Safe Motherhood/Infant Health for the development of a national public plan for the prevention, detection and management of infertility. This plan is critical to the efforts of the more than 2 million women who battle this medical condition in the U.S. Can you tell me what the Department's priorities are regarding this infertility plan?

Secretary Sebelius: CDC's report addressed above will include information on the priorities for this plan, such as how to reduce the burden of infertility

TEEN PREGNANCY PREVENTION PROGRAM

Ms. Lee: The $114.5 million teen pregnancy prevention initiative signed into law in December 2009 and championed by this Committee--marks an important victory for evidence-based policymaking and it could hardly be getting off the ground at a better time. However, unintended teen pregnancy is not the only negative sexual health outcome facing America's young people. One young person every hour is infected with HIV and young people ages 15-25 contract about half of the 19 million sexually transmitted diseases (STDs) annually, even though they make up only one-quarter of the sexually active population. By focusing the funding only on teen pregnancy prevention, and not including the equally important health issues of STDs and HIV, it seems that an opportunity has been missed to provide true, comprehensive sex education that promotes healthy behaviors and relationships for all young people, including lesbian, gay, bisexual, and transgender youth. So many negative health outcomes are inter-related and educators on the ground know that they best serve young people when they address the inter-related health needs of young people.

Is the administration open to making this a comprehensive prevention initiative that addresses the inter-related health needs of adolescents, including unintended pregnancy, STD, and HIV prevention?

Secretary Sebelius: The Department conducted a comprehensive review of the evidence base relating to teen pregnancy prevention and related risk behaviors through a contract with. Mathematica Policy Research. This review defined the criteria for the quality of an evaluation study and the strength of evidence for a particular intervention. Based on these criteria, the Department has defined a set of rigorous standards an evaluation must meet in order for a program to be considered effective and therefore eligible for funding as an evidence-based program. As the review of the over 1,000 potentially relevant studies revealed, 28 programs met the evaluation criteria, reflecting a range of program models and target populations. And the results of this review of the evidence-base also support the inter-related health needs of adolescents. Of those 28 programs, 20 had evidence of impacts on sexual activity (for example, sexual initiation, number of partners, or frequency of sexual activity), 9 on contraceptive use, 4 on STIs, and 5 on pregnancy or births.

I have made reducing teen and unintended pregnancies one of my areas for key interagency collaborations at HHS and identified the set of strategies indicated below to reduce teen and unintended pregnancy. As you will note, these strategies include related risk behaviors, which include those contributing to STIs. In working to implement these strategies, HHS will draw upon both the public health and human services expertise in the Department, including the Administration for Children and Families (ACF), the Office of the Assistant Secretary for Planning and Evaluation, the Centers for Disease Control and Prevention, the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), the newly created Office of Adolescent Health (OAH) and the Office of Population Affairs (OPA) within the Office of Public Health and Science. The strategies include the following:

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

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

- Increase Access to Clinical Services -- HHS will ensure access to a broad range of family planning and related preventive health services, including patient education and

counseling; sexually transmitted infection (STI) and human immunodeficiency virus (HIV) prevention education, testing, and referral. Services can be provided through community health centers, Title X family planning clinics, and public programs. HHS-funded health services under the Title X family planning program will encourage family participation in the decision of minors to seek family planning services and provide counseling to minors on ways to resist attempts to coerce them into engaging in sexual activity.

Ms. Lee: In light of the evidence and recognizing that most young people are at risk of both unintended pregnancy and STIs, would the administration support the committee directing the Office of Adolescent Health to prioritize funds to those programs that are more comprehensive in scope in so far as they encourage abstinence and also encourage young people to always use condoms or other contraceptives when they are sexually active?

Secretary Sebelius: I believe it is important for communities to be able to choose evidence-based models that work for their specific needs. Under a contract with HHS, Mathematica Policy Research (MPR) conducted an independent, systematic review of the evidence base. This review defined the criteria for the quality of an evaluation study and the strength of evidence for a particular program or intervention. Based on these criteria, the Department has defined a set of rigorous standards an evaluation must meet in order for a program to be considered effective. As the review of the over 1,000 potentially relevant studies revealed, 28 programs met the evaluation criteria, reflecting a range of program models and target populations. Of those programs, 20 had evidence of impacts on sexual activity (for example, sexual initiation, number of partners, or frequency of sexual activity), 9 on contraceptive use, 4 on STIs, and 5 on pregnancy or births.

Applicants were requested to review the list of evidence-based curriculum and youth development programs which the Department identified as having met these standards. A summary listing of these interventions was published in Appendix A of the FOA. Program models listed in Appendix A are eligible for replication under the teen pregnancy prevention funding announcement issued by OAH on April 2, 2010. Applicants that wish to replicate a program that is not on the list in Appendix A, may apply to do so, but a set of stringent criteria must be met.

Based on the initial receipt of Letters of Intent for the replication grants, we strongly believe that communities have options for choosing models that will work for them. We expect additional communities will combine models or otherwise modify them to meet their needs and apply as demonstration projects under the second funding announcement issued by OAH on April 9, 2010. As demonstration projects are implemented over the coming years, we believe that additional models and approaches will be added to the evidence base, giving communities additional choices to address the specific, unmet needs in their communities.

Ms. Lee: What is your plan for hiring a permanent director of the Office of Adolescent Health and by when do you hope to have a permanent director in place? What are your goals for the Office of Adolescent Health beyond this new prevention initiative and what role do you see sexual health playing in these efforts?

Secretary Sebelius: The Office of Public Health and Science (OPHS) has initiated a competitive process for hiring a permanent director for the Office of Adolescent Health. OPHS anticipates that we will have a permanent director in place before the end of FY 2010.

I have made reducing teen and unintended pregnancies one of my areas for key interagency collaborations at HHS. We expect this to be one of several areas on which the Office of Adolescent Health will focus as it grows to full operational status. The OAH is leading an internal Adolescent Health work group that is currently developing recommendations in several areas. We are also exploring ways to tap the youth of America for their input on OAH, and HHS-wide, adolescent health issues. We expect additional strategies will focus on implementing the Patient Protection and Affordable Care Act, especially enrollment of eligible adolescents in Medicaid and CHIP, preventing and addressing mental disorders and promoting mental wellness among adolescents. OAH will also play a key role in continuing efforts to support pregnant and parenting adolescents through the implementation and administration of the new Pregnancy Assistance Fund and coordination with existing Title XX Adolescent Family Life Care grants, as well as with the Department of Education.

TITLE X- FAMILY PLANNING PROGRAMS

Ms. Lee: Title X family planning providers are often the sole preventive/primary care providers for low-income women and men. In a report released last year by the National Academy of Sciences Institute of Medicine, family planning was described as "one of the most significant public health achievements of the 20th century." The report goes on to say, "The Title X federal family planning program provides these critical services to those who have the most difficulty obtaining them," but it also cites the program's chronic underfunding, which prevents providers from meeting the current demands of operating a comprehensive family planning program. Would you agree that Title X funding should be expanded to meet the current needs of a comprehensive Title X family planning program?

Secretary Sebelius: Yes, I agree that funding for the Title X family planning program should be expanded. Toward this end, the FY 2011 President's Budget requests an additional $10 million to support family planning services. Title X-funded family planning centers provide services to more than 5 million individuals annually, 70% of whom have family incomes at or below the Federal poverty level (FPL), meaning that services are provided to clients at no charge.

HIV TESTING INITIATIVE

Ms. Lee: Secretary Sebelius, I was pleased to see that CDC is planning on expanding its enhanced HIV testing initiative into additional jurisdictions and targeting additional populations, I think this will do a great deal to help identify those infected and get them into treatment as quickly as possible. Can you explain the planned reduction in funding for HIV testing at a time when CDC seems poised to expand this critical program?

Secretary Sebelius: The FY 2011 Budget requests $64 million for HIV testing, which is approximately $2 million below FY 2010. This reduction is part of a CDC-wide effort to achieve efficiencies in travel and contracting and to maintain the programmatic impact of HIV testing.

NATIONAL PUBLIC HEALTH PLAN ON INFERTILITY

Mr. Honda: Secretary Sebelius, last year the Committee requested that the CDC report on the development of a national public health plan for the prevention, detection and management of infertility. I understand the plan is not completed yet. Can you share with the Committee what the status is of the report?

Secretary Sebelius: CDC is drafting this report, and HHS expects to transmit it to the Committee very soon. In the report language to last year's appropriations bill, the Committee included funding within Safe Motherhood/Infant Health for the development of a national public plan for the prevention, detection and management of infertility. This plan is critical to the efforts of the more than 2 million women who battle this medical condition in the US.

Mr. Honda: Can you tell me what the Department's priorities are regarding this infertility plan?

Secretary Sebelius: CDC is drafting this report, and HHS expects to transmit it to the Committee very soon. The final report will include information on the priorities for this plan, such as how to reduce the burden of infertility.

MARCH 20TH LETTER TO THE MEMBERS OF THE QUALITY CARE COALITION

Ms. McCollum: On March 20, 2010, the Secretary of Health and Human Services sent a letter to the Members of the Quality Care Coalition with a commitment and plan to address the current geographic variation in Medicare reimbursement and advance health care quality and value to bend the cost curve that meets the goals outlined in Section 1157 and 1158 of the *Affordable Health Care for America Act* (H.R. 3962), which passed on November 7, 2009

Your commitments to execute studies at the Institute of Medicine to improve geographic adjustment factors and implement the findings, and to make recommendations on changing the payment system to reward value and quality are critically important to bending the cost curve. In addition, I also look forward to working with you as you convene a National Summit on Geographic Variation, Cost, Access, and Value in health care this year. Could you inform the Committee as to the status of the efforts and the timeline outlined in your March 20th letter?

Secretary Sebelius: I am deeply committed to developing and implementing policies that advance health care quality and value, reduce unnecessary utilization, address geographic variation in reimbursement rates, and bend the cost-growth curve. The Department continues to take a number of steps to address these challenges.

In the March 20, 2010 letter, I committed to commissioning two studies on Medicare's geographic payment adjustments for hospitals and physicians and geographic variations in the volume and intensity of Medicare services. I am pleased that Department staff are making progress on contract language to direct the Institute of Medicine's work. Second, planning has begun to convene a National Summit on Geographic Variation, Cost, Access, and Value in Health Care later this year to further examine these issues and consider ways to adjust our payment systems so they better account for geographic variation, while maintaining access and quality of care in all areas. Finally, once both the studies and the summit are done, I am confident that the results will be considered by both the new Center for Medicare and Medicaid Innovation and the Independent Payment Advisory Board.

MINDFULNESS-BASED STRESS REDUCTION

Mr. Ryan: Mindfulness-based stress reduction (MBSR) is the most commonly used meditation-based intervention in medical settings in the U.S. There is a growing body of scientific literature that has examined the impact of MBSR on pain, brain function, immune function, and on the symptoms and underlying biological mediators of some diseases, such as cardiovascular disease, psoriasis, and cancer. However, the extent to which MBSR might affect health care utilization has never been systemically studied. Even modest reductions in health care utilization could translate into significant dollar savings cumulatively throughout the nation and may have implications for health care policy. The Committee urges AHRQ to support research to determine whether MBSR impacts health care utilization.

Madam Secretary, the above report language was included in the FY2010 Labor-HHS Appropriations Report. What is HHS/AHRQ's plan for following through on the Committee's recommendation?

Secretary Sebelius: AHRQ aims to improve the quality, safety, efficiency, and effectiveness of the delivery of evidence-based preventive services, chronic care management in ambulatory care settings, and inpatient care. The relationship among psychological well-being, physical health, and the impact of stress reduction interventions on health care utilization are within AHRQ's Prevention/ Care Management Portfolio's scope and interest. AHRQ would be interested in receiving, reviewing, and potentially funding grant applications for research projects that focus on the impact of mindfulness-basses stress reduction on health care utilization. AHRQ would also consider funding conferences that address this important topic.

ELECTRONIC HEALTH RECORDS (EHR)

Mr. Ryan: A significant amount of private and federal dollars has been spent over the years to address the need to establish nationwide electronic health records. According to the Office of the National Coordinator for Health Information Technology the reason behind the Health Information Technology movement is:

> "To improve health care quality, prevent medical errors, increase the efficiency of care provision and reduce unnecessary health care costs, increase administrative efficiencies, decrease paperwork, expand access to affordable care, and improve population health."

To realize the full potential of the billions of dollars we have already spent on establishing EHRs, we need to make health information accessible and easy to review in a secured fashion to allow physicians and researchers to study the comparative effectiveness of treatments not just in their own health systems, but in patient settings throughout the nation. In mid-March I met with a company in Northeast Ohio, Explorys, which is creating a unique grid of medical data gleaned from millions of EHRs from the leading hospital systems across the country. This unique data grid will serve as a clearinghouse for anonymous health data across patient populations, with Defense-grade privacy protections in accordance with the HIPPA law, allowing researchers to conduct real-time comparative effectiveness analyses with a Google-like search engine and build cohorts to improve treatment outcomes while saving millions of dollars. This seems to me to be the vital next step in our HIT efforts.

With that in mind: What programs or projects are being funded in this current budget request to enable this kind of nationwide comparative effectiveness research and to expand the secondary use of health data from the EHRs we have implemented? Also, do any of these efforts involve public-private collaborations to accelerate this kind of system, taking all our work with HIT and EHRs to the next level and improving the quality of health care?

Secretary Sebelius: We agree that electronic health records (EHRs) hold great potential for facilitating the study of the effectiveness of different medical treatments. In FY 2010, HHS plans to spend $25 million appropriated under the Recovery Act to fund EHR-driven distributed research networks that link clinical and administrative data to allow for the investigation of the effectiveness of different medications, treatments, and strategies to improve health outcomes. The ability to analyze clinical data from EHR systems will allow research to occur on large numbers of patients in a variety of different health care settings and will increase the likelihood of being able to answer critical questions about the treatments for rarer conditions and for patients not currently included in clinical studies. This will certainly involve public-private partnerships and will lead to innovation in both the public and private sectors on the use and protection of clinical data from EHR systems.

In addition, the FY 2011 Budget includes $286 million within AHRQ to build on Recovery Act investments in comparative effectiveness research. Research funded in FY 2011 will include identification of new and emerging issues; evidence synthesis, gap identification, and generation; translation and dissemination of findings, training and career development; and stake holder engagement. The Department, in close coordination with the individual operating divisions and the ONC, are making and proposing further investments in the HIT infrastructure needed to make our health care system a "learning health care system."

ACCOUNTABLE CARE ORGANIZATIONS

Mr. Ryan: With healthcare reform now law, the Obama Administration committed to create Accountable Care Organizations across the country to make healthcare providers more accountable and efficient through value-based purchasing, and improve quality and patient safety, including reducing preventable readmissions. Given that 80 percent of children with chronic illness become adults with chronic illness, it would benefit us not just to focus on improving adult care but also pediatric care.

Since pediatric care deals with Medicaid, and since Medicaid is administered by the states, we already have some accountable care models in place for Medicaid. The National Association for Children's Hospitals said that one of the best models in America is located in your (and my) home state of Ohio. Nationwide Children's Hospital has a partnership with the state in which they are paid a capitated model right now to manage a Medicaid population of 280,000 children, which is by far the largest in America. The Hospital has high immunization rates, a fully integrated IT system with telemedicine, and has done groundbreaking work on both childhood obesity and prematurity. When are you looking to launch the pilot programs to formally create pediatric Accountable Care Organizations?

Secretary Sebelius: Section 2706 of the Patient Protection and Affordable Care Act of 2010 establishes a pediatric accountable care organization (ACO) demonstration in the Medicaid and CHIP programs. Under this section, the demonstration is set to start on January 1, 2012; however, Congress has not yet appropriated the funds needed to begin implementation.

Mr. Ryan: How do hospitals apply to become an Accountable Care Organization?

Secretary Sebelius: Once funds are appropriated the Secretary will provide guidance and will solicit states for participation in the Medicaid and CHIP demonstration. Under the Affordable Care Act, a pediatric hospital that would like to apply to become an Accountable Care Organization (ACO) under the Medicaid and CHIP pediatric ACO demonstration may apply directly to the state. Medicaid and CHIP pediatric medical providers are recognized as an ACO for purposes of receiving incentive payments in the same manner an ACO would be recognized and eligible to receive payment as an ACO under Medicare (see section 3022 the Affordable Care Act). Under section 2706 of the Affordable Care Act, in consultation with the Department, the state must establish an annual minimal level of savings under Medicaid and CHIP that an ACO must meet in order to be eligible for an incentive payment. Further, the State must be participating in the demonstration under an agreement with the Department and an ACO must enter into an agreement with the State for a period of not less than 3 years.

LIHEAP

Mr. Ryan: I'm concerned about the agency's request for the LIHEAP program. While I believe the Administration deserves credit for what is, historically speaking, a high request for LIHEAP, $3.3 billion is significantly below the enacted levels for the past two fiscal years. I believe it equates to about a 45 percent cut to the block grant Ohio receives to implement the program. And it goes without saying that LIHEAP is a critical, life-saving safety net for my low-income constituents in northeastern Ohio. Such a dramatic decrease is concerning to me, especially now, with unemployment at a high level.

As I mentioned, the Administration's should be applauded for submitting a budget proposal for LIHEAP that is high by historic standards. But it is far below the level of funding that Congress has appropriated for the past two years; and in my view, far below the demonstrated need on the ground in Ohio and elsewhere.

Secretary Sebelius: The Administration proposes a mandatory funding trigger for LIHEAP which will automatically provide additional funding in response to increased need. Under current economic predictions, the trigger proposal would provide $2 billion in mandatory funds in FY 2011. Adding the $3.3 billion discretionary funding request, a total of $5.3 billion is requested for LIHEAP in FY 2011, an increase of $200 million over the amount provided for FY 2010.

NATIONAL INSTITUE FOR OCCUPATIONAL SAFETY (NIOSH)

Mr. Ryan: The NIOSH mining program has developed many solutions to mining safety and health problems; and one of the critical areas of their work addresses the prevention of dust

and gas explosions in mines. However, this work was seriously interrupted two years with the loss of the Lake Lynn Experimental Mine 50 miles southeast of Pittsburgh, PA, which I understand is still unresolved. Two years ago, there was a roof failure at that experimental mine and subsequently, NIOSH, has been trying to get the approval of CDC to rehabilitate the facility so that they can continue to conduct tests. CDC has not given NIOSH the authority or the funds to rehabilitate the facility.

Is the Department of Health and Human Services prepared to do whatever it takes to support critical mining safety research at NIOSH including making a commitment to restore NIOSH's ability to conduct explosion testing in the next 9-12 months?

Secretary Sebelius: Yes, the Department of Health and Human Services recognizes that this critical capability must be restored as quickly as possible to allow continuation of critical research in explosion prevention. CDC is currently implementing an acquisition plan to obtain a long-term lease or purchase agreement, the first step before CDC can restore the Experimental Mine. Reconstruction of an entrance to the mine will be required before underground research can continue. At this time, CDC does not have the authority to make improvements to the mine under the current lease agreement.

TITLE X FAMILY PLANNING:

Mr. Ryan: A 2009 Guttmacher article noted that in after Massachusetts reformed its health care system, "access problems presenting themselves in the state indicate that even after health care reform, [community-based family planning centers] will continue to be needed as a critical source of high quality, low-cost primary and preventive reproductive health care. At the same time, the Massachusetts example suggests that national health care reform opens the possibility for family planning providers to formalize and be compensated for another vital but under-recognized function they have long played-acting as an entry point to care for clients who may have had little or no other interaction with the health care system.")

Do you agree that as we move towards implementation of health care reform and the coverage of approximately 30 million more people, it is important to provide increased resources to support the public health safety net, including the Title X program that provides quality care for millions of low income and underserved people?

Secretary Sebelius: I agree that we need to continue to support the public health safety net, including the Title X family planning program. As one example of such support, in an area that you have expressed interest in, the FY 2011 President's Budget requests an additional $10 million to support family planning services.

Mr. Ryan: Title X family planning providers are often the sole preventive/primary care providers for low-income women and men. In a report released last year by the National Academy of Sciences Institute of Medicine, family planning was described as "one of the most significant public health achievements of the 20th century. The report goes on to say, "The Title X federal family planning program provides these critical services to those who have the most difficulty obtaining them," but it also cites the program's chronic underfunding, which prevents

providers from meeting the current demands of operating a comprehensive family planning program. Would you agree that Title X funding should be expanded to meet the current needs of a comprehensive Title X family planning program?

Secretary Sebelius: Currently, Title X- funded family planning centers provide services to more than 5 million individuals annually, 70% of whom have family incomes at or below 100% of the Federal poverty level (FPL), meaning that services are provided to clients at no charge. Title X providers are required to maximize resources available to provide family planning services through billing third parties that are authorized or legally obligated to pay for services. However, providers are stressed with the high number of clients for whom there is no third party reimbursement source. The Title X Program has an important role to play in preventing teen and unintended pregnancy, since clients are predominately young. According to the 2008 Family Planning Annual Report, prepared by RTI International for HHS' Office of Family Planning, 24 percent of Title X clients were under age 20 and 51 percent were between the ages of 20 and 29.

An expansion in Title X funding will enable the Title X Program to serve additional clients in need of services, and will expand the availability of a broad range of contraceptive methods, as well as enable a more comprehensive set of services, including but not limited to: pre-conception and inter-conception care, HIV and STI/STD testing, cervical and breast cancer screening, and counseling and education on a number of preventive health measures, including nutrition and obesity prevention, smoking cessation, and prevention of intimate partner violence.

VECTER-BORNE DISEASES

Mr. Ryan: Secretary Sebelius, your budget proposes elimination of funding for vector--borne diseases, which includes all federal funding for West Nile Virus surveillance. The Ohio Department of Health tells me they rely on these funds-a little more than $250,000 annually-to monitor viruses carried by mosquitoes, as well as to provide supplies to local health departments, lab tests, and education and awareness efforts. Do you believe it's wise to cut these funds when new viruses are emerging around the world, like Chikungunya virus, Japanese encephalitis and Rift Valley fever?

Secretary Sebelius: Although the FY 2011 budget request does not include specific funding for vector-borne activities, including West Nile Virus (WNV) surveillance, the budget request includes $155.2 million for the emerging infectious disease budget line, which is an increase of $18.9 million above FY 2010. These emerging infectious disease funds can support vector-borne activities in FY 2011, including WNV, if determined a priority by States and the CDC. Moreover, several years of CDC funds have allowed States to develop and enhance their WNV activities.

FEDERAL MEDICAL ASSISTANCE PERCENTAGES (FMAP):

Mr. Ryan: Madam Secretary, as you know, the House has twice acted on the Administration's request to extend the ARRA Enhanced FMAP (EFMAP) by 6 months. According to many economists and independent experts, if EFMAP is not quickly extended, the result will be added uncertainty in the economy, weaker consumer confidence, further job loss, and ultimately a slower economic recovery.

Although my home state is in the middle of a two-year balanced budget, twenty-two states, whose legislative sessions will conclude at the end of April, are proposing deeper cuts and higher tax cuts than would be necessary if EFMAP were extended. First, if FMAP is not quickly extended, what do you believe will be the impact on the economy and the national unemployment rate?

Secretary Sebelius: Given the continuing fiscal pressures States are facing, the Administration believes it is important to provide States with additional relief as the economy moves to recovery, and in keeping with our FY 2011 budget request, we hope Congress will include this necessary help for States in legislation this year. Because of this financial crisis, many States are eliminating jobs and contemplating severe cuts to critical services that struggling families rely upon. We believe this six-month extension of the increased FMAP will ease burdens on States trying to recover and rebuild with fewer resources, provide economic stabilization for the States, and strengthen a critical safety net for children and families.

Mr. Ryan: Second, what will the impact be on state Medicaid programs and health care providers if EFMAP is allowed to expire?

Secretary Sebelius: The increased FMAP has been critical in protecting Medicaid beneficiaries and providing additional fiscal relief to States. Medicaid is, by definition, a countercyclical program -- more people become eligible for Medicaid during a recession but the same economic conditions that give rise to more need also result in lower State tax revenues to finance the program. Although the economy is beginning to improve, States are continuing to experience significant budget problems.

We know this additional funding has helped protect existing coverage for millions of children, parents, and pregnant women and are concerned about the impact on vulnerable populations if the increased FMAP expires in December 2010.

COMPARATIVE EFFECTIVENESS RESEARCH

Mr. Tiahrt: I have repeatedly expressed concerns with the comparative effectiveness research that was included in the so-called stimulus bill last year. After reading the Department's generic implementation plan that was submitted last year, nothing has changed my mind. My specific concern is that funding can be used to conduct research that will be used to justify rationing care. In my view, the only reason to do this research is to deny coverage of a procedure, a medical device or a drug because some bureaucrat out there thinks there's a cheaper alternative. Clinical comparative effectiveness research that will inform patients and doctors what procedures or treatments work best for them is important information to have and we should do it. But we need look no further than Canada, Great Britain or Australia to see how cost decisions have had a negative impact on availability of quality health care.

In Britain, the agency that determines what procedures and treatments will be financed by the National Health Service has tried repeatedly to stop breast cancer patients from receiving a powerful drug called Herceptin; it has tried to deny a drug to Alzheimer's patients; and it stopped MS patients from receiving medicine called Beta Interferon because it was too expensive. A recent study of Australia's cost-effectiveness policy found that if that same policy were implemented in the US, "millions of patients nationwide would face significant new barriers to obtaining medicines that they currently receive to treat serious and life-threatening diseases." The reality is that we all have different physiologies - a drug that works well for one person may not work well for another. This is the basis for the notion of personalized medicine, where doctors can take into account each patient's unique physiology to tailor treatments that will work best for them. Quite frankly, the only way I see cost-effectiveness research coming out in the end is socialized medicine, not personalized medicine.

How much of the $400 million in comparative effectiveness research that was provided to the Office of the Secretary in the American Recovery and Reinvestment Act is being used to support research that focuses on cost-effectiveness? Please provide a list of all grantees conducting cost-effectiveness research and the amount of the award. Are there plans to use a portion of those unspent funds to support cost-effectiveness research? The stimulus bill contains non-binding language that says these funds are not intended to be used as the basis of coverage decisions. If HHS decides to honor that language, what is the expected end use of cost-effectiveness research?

Secretary Sebelius: The American Recovery and Reinvestment Act (ARRA) Office of the Secretary comparative effectiveness research (CER) funds required two reports to Congress: one from the Federal Coordinating Council for Comparative Effectiveness Research (FCC-CER) and one from the Institute of Medicine. In keeping with the recommendations made by these groups in their reports, the funds are targeted toward building an infrastructure to conduct CER and to specifically enhance the research infrastructure to address the needs of priority and under-studied populations, including racial and ethnic minorities, children and the elderly, rural and inner city populations, and patients who have multiple chronic conditions and/or have suffered disproportionately from a particular condition. Additionally, it is anticipated that the infrastructure investments will assist in understanding the individual needs of patients and their caregivers. The emphasis of these investments is on the effectiveness and comparative effectiveness of clinical and health strategies with an overarching goal to learn what works best in

what patients and in what settings of care. None of the $400 million in OS CER ARRA funds is targeted to cost-effectiveness research.

LIHEAP

Mr. Tiahrt: Under the existing LIHEAP authorizing statute families are eligible for federal assistance if their income is at or below 60 percent of state median income (SMI). However, a couple of years ago this committee included a provision that permits states to provide LIHEAP benefits to families who earn as much as 75 percent of SMI.

Some have argued that all the provision did was provide states with additional flexibility in administering these funds. While that may not seem like a big deal, it causes me serious concern - specifically because what the provision does is water down assistance to the poorest of the poor in favor of providing federal subsidies to middle and upper middle class Americans who do not need the help.

For example, according to data provided by ACF, the State of California served less than 5 percent of its eligible population under the 60 percent formula. Yet, the Congress continues to grant states with the authority to increase their eligibility requirements to 75 percent of SMI despite the fact that some states are barely serving the eligible population at the 60 percent threshold. In some states, 75 percent of SMI would exceed $93,000 per year under that formula.

Please provide a list all states that have expanded LIHEAP benefits to greater than 60 percent of SMI, including the new cap those states have adopted and the maximum income level that would qualify a family for benefits in those states.

Secretary Sebelius: At this time, we know of only two States (Maine and Delaware) that have plans to use the new cap of 75 percent of State median income in their programs for FY 2010. The maximum income level would vary by household size. Using a household size of 4, the maximum income level would be $50,211 for Maine and $59,782 for Delaware. We will have actual data once States complete the LIHEAP Grantee Survey later this year.

Mr. Tiahrt: Has HHS conducted an analysis of the impact that increasing eligibility to 75 percent of SM I has had on truly low-income families?

Secretary Sebelius: ACF has not conducted this type of analysis. To date, we know of only two States that have chosen to increase eligibility. More complete data will be available later this year.

Mr. Tiahrt: I was alarmed to learn that LIHEAP has an improper payment rate around nine percent, and that LIHEAP payments were provided to 11,000 people who are deceased. Please outline the steps the Department is taking to correct this situation.

Secretary Sebelius: HHS has no tolerance for fraud or improper payments in the programs we administer We have undertaken a number of initiatives to ensure program integrity across the board. The improper payment rate quoted is incorrect. We would note that GAO found that nine percent of the cases they reviewed contained invalid or incomplete information to confirm

applicant identity. A third of those cases lacked SSNs, which is not surprising since our previous guidance to States was that they could not request them.

To address these kinds of concerns, as a first step, are taking a number of actions to correct this situation. We are issuing guidance strongly encouraging States (who administer this program) to require LIHEAP applicants to provide Social Security Numbers for all members of their households as a condition for receiving benefits. States will be able to use this information to confirm the identity of all household members, confirm income reported for the household, and check that all of the household members listed in the application reside in the household. We also are requiring States to describe their systems for ensuring LIHEAP program integrity and will be working with States to improve these systems.

RECOVERY ACT JOBS SAVED AND CREATED

Mr. Tiahrt: We've heard a lot about "jobs saved," which pre-supposes a host of things that ought not to be taken as a given. For example, on December 15, 2009 the vice president sent a memo related to clean energy that says "a project that employs one person for two years would count as creating two jobs." Has HHS employed this methodology in its calculation of jobs created or saved?

Secretary Sebelius: The Department of Health and Human Services follows OMB's Dec.18, 2010, guidance (http://www.whitehouse.gov/omb/recovery_default/) in calculating the number of jobs created or saved through Recovery Act funds. Accordingly, the number of jobs saved or created is reported specific to the quarterly reporting period and is not cumulative. Per OMB guidance, HHS recipients calculate job estimate totals by dividing the hours worked in the reporting period by the hours in a full-time schedule in that quarter. The Dec. 18 guidance also "defines jobs created or retained as those funded in the quarter by the Recovery Act." The "full-time equivalents" (FTE) are adjusted to count only the portion corresponding to the share of the job funded by Recovery Act dollars. Also following OMB guidance, the number of jobs created and the number of jobs saved are reported as one number: the number of jobs created or saved.

Mr. Tiahrt: Please provide, as of April 21, 2010 the amount of the nearly $22 billion of discretionary funds provided to HHS by the American Recovery and Reinvestment Act that has been spent (outlayed) to stimulate the economy.

Secretary Sebelius: The HHS Financial and Activity Report for the week ending April 16, 2010, is the most recent data that would have been available as of April 21, 2010. As of April 16, HHS has outlaid $3.8 billion and obligated $15.6 billion of the $22.3 billion in discretionary Recovery Act funds available through FY 2010. Taking into account mandatory spending programs as well, HHS has outlaid in total $59.8 billion, or 59 percent of the available funds, and obligated $85.2 billion, or 84 percent of the available funds.

Mr. Tiahrt: How many jobs were "saved" as a result of that spending?

Secretary Sebelius: Recipients do not report jobs saved or created separately, but as one number, per OMB guidance. As of the May 3 HHS analyses of the April 2010 recipient reports, HHS recipients reported creating or retaining 44,265 jobs with Recovery Act funds. Recipients

reported creating or retaining 31,247 jobs in January and 20,000 jobs in October. These numbers are only for the stated reporting periods and are not cumulative (see Dec. 18, 2009, OMB guidance).

Mr. Tiahrt: In February the administration developed a new method of counting the number of jobs created or saved as a result of the "stimulus" bill, which is to count as a job saved any job that was in any way supported by "stimulus" funding - regardless of whether or not the job was in jeopardy. There have been news reports that indicate some Head Start centers gave raises to existing employees whose jobs were not in jeopardy and called those jobs saved. Are those numbers reflected in the Department's estimates of jobs "saved?"

Secretary Sebelius: OMB explained in its Dec. 18, 2009, guidance that it changed the way recipients should calculate saved or retained jobs so that they would "no longer be required to make a subjective judgment on whether jobs were created or retained as a result of the Recovery Act". Instead, recipients will more easily and objectively report on jobs funded with Recovery Act dollars. This update aligns with GAO's recommendation to "[make] more explicit that 'jobs created or retained' are to be reported as hours worked and paid for with Recovery Act funds.' " In addition, OMB stated that COLA payments or retention bonuses are to be excluded from the calculation of jobs created or saved. Head Start recipients were instructed to exclude them from their jobs calculations. For additional information, see http://www.whitehouse.gov/omb/recovery_faqs/

Mr. Tiahrt: Please provide a list of the number of jobs created and the number of jobs saved, by program, as a direct result of spending in the American Recovery and Reinvestment Act.

Secretary Sebelius: According to a preliminary analysis of the April Recovery Act recipient reports, recipients reported the following number of jobs funded by the recovery Act for the second quarter of FY 2010 by HHS Operating Division:

Operating Division	Number of Jobs
Administration for Children & Families	17,794
National Institutes of Health	17,224
Health Resources and Services Admin.	7,511
Centers for Disease Control & Prevention	534
Administration on Aging	515
Indian Health Service	448
Program Support Center	87
Office of the National Coordinator for Health Information Technology	83
Centers for Medicare & Medicaid Services.	36
Agency for Healthcare Research and Quality	33
Total Number of Jobs by OPDIV	**44,265**

MEDCICARE ADVANTAGE

Mr. Tiahrt: In order to finance the health reform bill Medicare Advantage is being cut by more than $130 billion. My understanding is that many seniors - about 11 million of them - choose Medicare Advantage plans because they offer more extensive coverage than the Medicare fee-for-service program. My concern goes to the oft-repeated promise that if people like the insurance plan they have now, they can keep it. But the reality is that cuts to Medicare Advantage are going to force one of two things - either a reduction in available services, the very services that caused seniors to choose Medicare Advantage in the first place, or higher premiums for people with fixed incomes.

What can seniors who chose Medicare Advantage over Medicare expect as a result of this cut? Has the administration given any consideration to the fact that more than 20 percent of seniors choose to participate in Medicare Advantage - and seem to be largely satisfied with their plans?

Secretary Sebelius: Medicare Advantage (MA) is the part of the Medicare program that allows beneficiaries to receive services via private insurance plans. Historically, private plans that participated in MA received significant taxpayer subsidies from the federal government, receiving payments on average 14 percent more than traditional Medicare.

The Administration recognizes that many MA beneficiaries are satisfied with their current coverage and will not implement any changes that result in a reduction in quality of care that these beneficiaries receive. However, the Administration is also required to implement the changes to the law that Congress passed in the Affordable Care Act. The Administration's proposed strategy of a phased-in implementation of the modified MA benchmarks will soften the impact for beneficiaries residing in areas where the payment reductions would result in a significant reduction of extra benefits over a short period of time.

The Administration is also looking at the benefits that will accrue to MA plans under the Affordable Care Act. These benefits include additional incentive payments to high quality plans operating in areas where fee-for-service costs are low and increased beneficiary rebate percentages that reward enrollees who select high-quality and high-efficiency plans. Additionally, the Affordable Care Act includes new beneficiary protections that will improve access to important services for all Medicare beneficiaries such as chemotherapy administrative services, renal dialysis, and skilled nursing care.

BIODEFENSE RESEARCH

Mr. Tiahrt: Last year Congress transferred $304 million from the BioShield Special Reserve Fund (SRF) to the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. Does NIAID intend to issue a Request for Applications to ensure that the SRF funding that was transferred will be used for research related to biodefense, the purpose for which Congress originally provided the funding?

Secretary Sebelius: In the Consolidated Appropriations Act of 2010 (P.L. 111-117), $304 million was transferred from the Project BioShield Special Reserve Fund (SRF) to the

NIAID, the lead Institute of NIH for biodefense research, as an offset for other new budget authority. The total combined appropriation for NIAID in FY 2010 is over $4.8 billion, of which NIAID estimates it will spend nearly $1.7 billion, including the transferred funds, for research on biodefense and other emerging infectious diseases. One of the new activities to be supported in FY 2010 will be projects solicited under a Broad Agency Announcement (BAA) entitled, "Development of Technologies to Facilitate the Use of, and Response to, Biodefense Vaccines." Other new activities to be supported in FY 2010 include research and development of broad spectrum antibiotics and filovirus vaccines.

MEDICALLY UNDERSERVED AREAS (MUA)

Mr. Tiahrt: As a representative of Kansas, I am very concerned that a significant number of the Medically Underserved Areas (MUA) in the states which comprise the Midwest Census Region continues to lack necessary access to community or migrant health center services. A 2008 GAO report found that sixty percent of the Medically Underserved Areas in the Midwest Census Region states are without a federally supported health center site. These states had the highest percentage of MUAs without a health center site in the United States according to the GAO report. The underserved areas within the states of Ohio, Minnesota, Wisconsin, Kansas, Indiana, Missouri, North Dakota, Michigan, Nebraska, South Dakota, Illinois, and Iowa need new and expanded access points to health services.

Secretary Sebelius: The President's Budget includes additional funding to support the development of approximately 25 new access points, increasing access to comprehensive primary health care services to an estimated 150,000 additional health center patients living in medically underserved areas.

Mr. Tiahrt: As the former governor of Kansas, Madame Secretary, you understand the unique needs of the Midwest MUAs. What is the Department doing to make sure the needs of medically underserved are met?

Secretary Sebelius: We are working to ensure that all of our health center grantees are identifying and addressing the existing primary health care needs in their service areas and throughout their target populations. Additionally, we are analyzing our methods of awarding new grant funding so that our competitive processes are equitable across all regions of the nation, including the Midwest region.

Mr. Tiahrt: Have you directed HRSA to identify new access point, service expansion, health center capital and expanded medical capacity proposals from these states?

Secretary Sebelius: HRSA is working to ensure that all opportunities for competitive grant funding equitably consider and address the needs of the medically underserved populations of the nation, including those in the Midwest states.

QUESTIONS FROM TOWN HALL MEETINGS

Mr. Tiahrt: Over the past year, I have held several town halls across the State of Kansas, and met with hundreds of providers. I have heard many concerns about the health care reform

legislation, but the greatest is the frustration that Kansans have with the administration's refusal to listen to them or even to answer their questions. Therefore, Madame Secretary, I ask that you answer these questions our fellow Kansans asked me to ask you:

"Why in the world would President Obama not post the healthcare changes and laws online?" -Shirley Ann (who would like to see a comprehensive list of all the changes in plain English).

Secretary Sebelius: The law, as well as documents describing the provisions of the bill and their effects, is available online at www.healthreform.gov.

Mr. Tiahrt: "How will we stop insurance premiums from being higher based on your credit report?" – Denice

Secretary Sebelius: In 2014, the Affordable Care Act will prohibit insurance companies from denying any individual coverage because of a pre-existing condition, excluding coverage of that condition, or charging more because of health status or gender. Individuals purchasing coverage through State exchanges can only have their premiums vary by a certain set of factors such as age and family size, not credit scores.

Mr. Tiahrt: "When can we expect a tort and litigation cap as part of the reform?" – Gary

Secretary Sebelius: The bill establishes a demonstration grant program for states to develop, implement, and evaluate alternatives to current tort litigation that 1) allow for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and 2) promote a reduction of health care errors.

There is no need to federally override what is already working for states. The bill takes a better approach by giving states the resources they need to test out their reforms, measure the results, and build on what works. In fact, some of the biggest proponents of one of the more aggressive tort reform ideas – health courts – have called for grants to states as a first step.

Mr. Tiahrt: "What is the plan for healthcare for rural areas? Does reform address this disparity?" Sandra

Secretary Sebelius: The legislation helps ensure access to quality, affordable health care in rural areas. The legislation creates state-based health insurance Exchanges to provide the same private insurance choices that the President and members of Congress will have. In addition, each exchange will include at least two multi-state plans to foster competition and increase consumer choice. Seed money is included to create non-profit health plans, like co-ops, to increase choice. The legislation provides for the development of standardized, easy-to-compare information through the Exchanges on different health insurance plans offered in their geographic area so that they can easily compare prices and health plans and decide which quality affordable option is right for them and their families. This will particularly benefit the one-third of farmers who purchase health insurance directly from an insurance company – more than three times the national average.

The new law invests in the health care workforce to ensure that people in rural areas have access to doctors, nurses, and high quality health care. Beginning next year, the Act will provide funding for the National Health Service Corps for scholarships and loan repayment for primary care practitioners, including doctors and nurses, who work in areas with a shortage of health professionals. The legislation provides more resources to medical schools to train physicians to work in rural and underserved areas, and establishes a loan repayment program for pediatric specialists who agree to practice in medically underserved areas such a rural regions. These provisions will help rural Americans who do not have access to primary care.

Finally, the legislation ensures that hospitals and other providers in rural and remote communities receive the reimbursement they need to offer quality care to patients and keep their doors open.

Mr. Tiahrt: "If Sec. Sebelius is going to eliminate $90 billion from pharmaceutical companies, how can she expect people to keep their jobs and the companies to stay solvent?" – Mike

Secretary Sebelius: Health insurance reform will create jobs, vastly improve labor markets and the efficiency of American businesses, and encourage entrepreneurship and small business creation.

The delivery system reforms and revenue provisions in the bill provide incentives and create new measures to contain health care spending, allowing employers to hire more workers rather than spending money on rising health insurance premiums. The President's Council of Economic Advisers (CEA) estimated that by simply slowing the growth of health care costs by 1.0 percent per year, the number of jobs could rise by more than 300,000 by lowering the unemployment rate that is consistent with steady inflation. By slowing the growth of health care costs, health reform will improve our economic security as individuals and our competitiveness as a nation. For pharmaceutical companies specifically, this is a minimal contribution when considering the increased customer base they will experience as 32 million more individuals become insured.

ANTHRAX VACCINE STOCKPILE NEEDS AND ACQUISITION CONTRACT PLANS

Mr. Rehberg: Madame Secretary, it is my understanding that the Department has a requirement and need to contract for additional doses of the FDA licensed anthrax vaccine because the number of the doses in the Strategic National Stockpile currently are well below the total needed to meet the Department's 75 million anthrax vaccine dose requirement and the shelf-life dates for using the earlier stockpiled anthrax vaccine doses have expired and others will continue to expire.

It is also my understanding that with the termination of an earlier contract and delays in the development of new experimental anthrax vaccines, HHS now estimates that it will take at least 8 years before potential development and FDA licensure of new anthrax vaccines.

Given many government and other experts are saying that the number one WMD threat is anthrax and there is a continuing need for protecting 151 responders and citizens from another potential anthrax attack with both vaccines and drugs, what are your plans and timing for contracting for additional doses of the current FDA licensed vaccine to replenish the stockpile and move toward meeting the 75 million dose stockpile requirement?

Secretary Sebelius: CDC is committed to support the research, development, and procurement of the countermeasures contained in the Strategic National Stockpile, including those for Anthrax. CDC has made tremendous progress in stockpiling antibiotics and other countermeasures for use in a public health emergency. CDC currently has a contract in place for procurement of additional FDA licensed anthrax vaccine in order to move toward meeting the 75 million dose stockpile requirement and is receiving the full production capacity of this vaccine. CDC is currently receiving shipments of the anthrax vaccine every four to eight weeks.

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

Secretary Sebelius: CDC currently has a contract, with a multi-year contracting mechanism to ensure preparedness, in place with Emergent for procurement of additional 14.5 million doses of FDA licensed anthrax vaccine in order to move toward meeting the 75 million dose stockpile requirement, and is receiving the full production capacity of this vaccine.

COMPARATIVE EFFECTIVENESS RESEARCH

Mr. Rehberg: Madam Secretary, AHRQ has issued a solicitation for a vendor to undertake a so-called "academic detailing" program, under which the vendor will meet with doctors to "present information on comparative effectiveness" with "the intent of changing behavior in clinical practice." This raises a number of questions I'd like to have answered.

This solicitation is being conducted with stimulus bill funds. In the recently passed health care bill, there are specific standards applied to dissemination of government-funded comparative

effectiveness research by AHRQ. These standards, for example, ensure that differences in patient needs are recognized, and that communication does not take the form of policy requirements or treatment recommendations. Will AHRQ be adhering to these specific standards, or will it be disregarding them because this is being funded with stimulus money, even though Congress has since adopted specific policy about dissemination of comparative effectiveness information in a comprehensive health care law?

Secretary Sebelius: At this time, no contract solicitation on the academic detailing has been issued. AHRQ has announced the availability of the solicitation and expects to release it on or about May 14, 2010. Accordingly, the sensitivities related to the integrity of a competitive procurement apply here. In general, AHRQ's plans for dissemination of research findings on the effectiveness of different medical options are consistent with the tenets laid out in the recently passed health care reform legislation. AHRQ recognizes the importance of individual differences and the flexibility that must be considered when assessing evidence of the effectiveness of different treatment interventions. AHRQ will not be developing treatment recommendations or policy recommendations but will make the evidence available to health care decision makers, including patients and their caregivers for, their use in health care decisions.

Mr. Rehberg: The solicitation states that the program intends to "change behavior in clinical practice". That sounds to me like a government agency telling doctors what care they should deliver to patients. Please explain exactly what the government contractor will be advising physicians to do. For example, will it be to prescribe a particular medicine or treatment rather than an alternative that the physician may determine superior for his or her patient?

Secretary Sebelius: Studies have shown that it can take up to 17 years for evidence about treatment effectiveness to make its way into clinical practice. This effort will support the dissemination of research findings to clinicians so that they can make informed decisions on different treatment options for their patients. It will not mandate any treatment option but will provide unbiased and methodologically strong evidence to help health care decision makers.

Mr. Rehberg: Detailing is extensively regulated by the Food and Drug Administration. For example, FDA has strict requirements on the type of information on safety and comparative claims that manufacturers' representatives can make. The purpose of these requirements is to ensure that information provided to physicians is accurate and reliable and consistent with safe, high quality patient care. Will the government's academic detailing program adhere to these same standards?

Secretary Sebelius: The solicitation will clearly specify that communication to clinicians will be consistent with FDA policies. HHS will not be promoting a specific drug in a proprietary way but will be providing research evidence on an array of treatment alternatives. In many instances, options for treatment may include a medication, a medical procedure, or specific health behaviors such as exercise, or even what is sometimes called 'watchful waiting'. This is in contrast to traditional pharmaceutical detailing that promotes a particular product. HHS takes very seriously the importance of objective unbiased dissemination of research results.

Mr. Rehberg: The solicitation states that the vendor will conduct follow-up activities and document successful implementation. Please explain specifically what that means. Does it mean

that doctors will be reported to HHS based on whether or not they follow the government detailers' recommendations? Will physicians' treatment patterns be tracked by HHS to determine whether they are following the detailing recommendations? Will there be any database or other tracking of whether particular, identifiable physicians or physician practices adhere to the detailing program's views or choose to treat patients differently than specified by the detailing program?

Secretary Sebelius: There has been no solicitation released. In general, HHS simply wishes to assess the successfulness and impact on clinical decision making of the dissemination of CER findings. It is solely intended as a measure of whether or not this method of dissemination is successful in meeting the needs of health care decision makers.

Mr. Rehberg: What standards will apply to the information disseminated by government detailers? What will be the process for reviewing the detailing information; will there be an opportunity for public comment on this information? Will you work with me on defining an appropriate role of the Institute in overseeing these activities?

Secretary Sebelius: All of the research findings disseminated will have undergone extensive public and private peer review. No preliminary or draft results will be disseminated in this activity and only final public and peer reviewed results will be disseminated.

Mr. Rehberg: The new health care bill gives government many new powers in relation to doctors. In this environment, it is very important to protect the physician's ability to use his or her best professional judgment about how to treat his or her patients. With all the power that the government has over doctors, what assurances will be provided to physicians that they will not be penalized or subject to retaliation if they treat a patient differently than the government detailing program wants them to treat their patients? With all the powers that government will have over doctors, when a government-funded contractor comes into a doctor's office and "recommends" to the doctor how he or she should treat a patient, it seems to me that this could easily and appropriately be perceived by the doctor as more than a mere suggestion.

Secretary Sebelius: Research findings are intended to provide physicians with tools, not "rules". This activity in no way is meant to undermine the autonomy of physicians but is intended to assist them by providing the best available unbiased evidence on different treatment options. Each patient is an individual and this activity is not meant to replace clinical judgment but is intended to aid the clinician by providing timely evidence on available treatments.

Mr. Rehberg: What conflict of interest standards will apply to the vendor? And on what basis will the vendor be paid?

Secretary Sebelius: This competitive contract will be very explicit about conflict of interest and its avoidance. The contractor will be reimbursed according to established Federal government procurement standards.

Mr. Rehberg: Currently, about 75% of all prescriptions are filled with generics and that percentage is projected to rise in coming years as major brand drugs go off patent. And pharmacies, PBMs and health plans of course have strong incentives to drive generic use as high

as possible. So is this program designed to increase generic use above the already very high and rising level? If so, please explain what it adds to the strong incentives already in the system to promote generic use, other than spending, more bureaucracy, and government agents visiting doctors? Likewise, assume that a new drug is better for patients than a generic. Will your academic detailers go out and promote use of that new drug to replace use of generics?

Secretary Sebelius: The purpose of this activity is not to increase or decrease the use of generic medications or to promote one drug over another. This activity is intended to supply research findings to health care decision makers so that they can make informed decisions about what treatment options, including but not limited to medications, are best for their patients.

Mr. Rehberg: I'm concerned that government funded programs seeking to change "clinical behavior" inevitably take a "one size fits all" approach that ignores differences in patient needs, especially when one of the goals is cutting costs. This approach ignores, and will discourage, the emerging science of personalized medicine, which gives physicians new genetic and molecular tools to help them tailor treatment to the needs of the individual patient. In the health reform bill, we worked hard to make sure comparative effectiveness research recognizes this emerging science. Will this program take a similar approach, and include discussion of the genetic variations that have a potential to change a patient's response to treatment?

Secretary Sebelius: Individual patient characteristics and genomic information are an important part of health care decision making. This effort will address individual circumstances as well as the use of genomic testing in making treatment decisions.

Mr. Rehberg: I'm very concerned if this new AHRQ initiative is vulnerable to influence by health insurance companies, especially because one of its main goals is to use comparative effectiveness research results to cut costs, not just improve patient care. Can you describe for me what if any role health insurance companies or their affiliated organizations play in AHRQ's current CER stakeholder group, and whether these organizations are eligible to receive CER funds from AHRQ?

Secretary Sebelius: AHRQ traditionally involves stakeholders, including patients and their providers, in its programs to ensure that the information needs of participants in the health care system are effectively met. In its work, AHRQ places special emphasis on preventing undue influence from any sector in conducting its activities. In conducting research that studies the effectiveness of different medical options, AHRQ's main goal is to identify and describe the evidence underlying the effectiveness and safety of different health care interventions so that decision-makers can make informed decisions about the health care they provide and patients receive. AHRQ involves a broad group of stakeholders in its CER activities and stakeholder group, including health care plans, physicians, researchers, industry, employers, and patients and their caregivers but does not encourage or allow one view point to predominate or direct activities. Additionally, AHRQ funds CER contract and grant applications based on scientific and technical merit and rigorous peer review that similarly avoids undue influence from any sector.

INDEPENDENT PAYMENT ADVISORY BOARD

Mr. Rehberg: Madame Secretary, as you know the health reform law establishes a new Independent Payment Advisory Board to make recommendations to Congress for containing Medicare costs. If Congress does not act on these recommendations, they automatically take effect. Under the law, IPAB is prohibited from making recommendations that would "ration health care." This is a very important protection for America's seniors, especially because of the considerable power of this Board and the lack of mechanisms to ensure its accountability. What is your understanding of how IPAB will ensure its recommendations do not constitute rationing? How will this protect patient access to medically appropriate care?

Secretary Sebelius: I share your concerns; however, I believe that the Affordable Care Act includes a number of important mechanisms to ensure the accountability of the Independent Payment Advisory Board. As a State insurance commissioner for eight years, I worked every day to limit the extent to which private insurance companies could ration care based solely on costs. That is why it was so important that the Congress passed health reform legislation to eliminate the denial of coverage or payment for valuable health services. Arbitrary coverage limits reduce quality and shift costs. Low payments or lack of coverage can block access to important life-saving treatments. This situation is economically and morally wrong. The ACA recognizes this and Congress explicitly prohibits the Independent Payment Advisory Board (IPAB) from proposing recommendations that would "ration health care" ensures that the work of health reform will continue to benefit all Americans.

The statute also builds in numerous measures for review and transparency to ensure the Board's accountability. IPAB, by law, is required to consult with the Medicare Payment Advisory Commission (MedPAC), an independent Congressional Agency, and submit all draft proposals for review. IPAB is also required by law to submit all draft proposals to the Secretary of HHS for review and comment and the Secretary is required to submit the results of that review to Congress. The impact of the proposals must be reviewed and estimated by the Office of the Chief Actuary. The Board is also required to consult with the Medicaid and CHIP Payment and Access Commission. The statute establishes a separate Consumer Advisory Council to advise the Board on the impact of policies on consumers. Like MedPAC, the members of this Council are appointed by the Comptroller General of the United States. GAO is also required to report to Congress on the impact of any changes made as a result of IPAB recommendations.

Board members are appointed by the President with the advice and consent of the Senate and in consultation with the majority and minority leadership of both houses. Appointed members are to be selected based on nationally recommended qualifications for their expertise across a range of professions, with a requirement for broad geographic recommendations.

As you know, the Board will not begin to make recommendations until 2014 and the President has not yet begun to make the fifteen board appointments, which will be done with the advice and consent of the Senate. As such, the safeguards that will be put in place by the Board to ensure that their recommendations do not ration care are not yet developed. However, the law is clear and transparent and I have no doubt that any necessary safeguards will be instituted in a timely manner as the Board is developed.

Mr. Rehberg: In a recent column in the Washington Post, Ezra Klein suggested that the Independent Payment Advisory Board will "use a lot of the comparative effectiveness program's data when making its decisions." In the health reform law, we worked hard to include patient protections on how CER is used in Medicare so that it doesn't lead to policies that harm Medicare patients. If this Washington Post article is accurate, I am very concerned that the new IPAB board would effectively eviscerate all of these patient protections we worked so hard to include for Medicare beneficiaries. Is it accurate that IPAB's use of comparative effectiveness result is not subject to these protections? If so, what can we do to remedy this and ensure that CER results are not misused in ways that prevent seniors from gaining access to medically beneficial treatment options?

Secretary Sebelius: There are numerous beneficiary protections included in the Independent Payment Advisory Board provisions in the health reform legislation. The Board is explicitly prohibited from issuing any recommendation that would ration health care, raise Medicare beneficiary premiums, increase Medicare beneficiary cost-sharing, or otherwise restrict benefits or modify eligibility criteria. Research that studies the effectiveness of different medical options is one component of building a high-quality, value-oriented health system and it is about providing consumers with more choices, not less. It is not about government rationing. To improve the effectiveness of our health care system, we need to learn more about the causes of, and cures for, diseases, as well as the strengths and weaknesses of various treatment options. This is what this research can and should provide -- it is a tool for informed decision-making on how best to care for patients. I want to give patients and doctors objective information about which treatments work and which don't -- information that will improve the quality of care given in our country and inform the recommendations of the Board.

There are a number of provisions built into the new law to provide oversight for the Board's actions. Before making recommendations, the Board is required to share draft proposals with MedPAC and the Secretary of HHS. The ACA establishes a separate independent Consumer Advisory Council, with members appointed by the Comptroller General of the United States, to advise IPAB on the impact of policies on consumers. I want to assure you that any use of such research by the Board will be subject to all the beneficiary protections included in the Affordable Care Act.

Mr. Rehberg: A recent article in the New York Times reports that the Administration is considering speeding up the timetable for creations of the Independent Payment Advisory Board. Can you elaborate on this?

Secretary Sebelius: The Administration is committed to implementing the Affordable Care Act in a timely and expeditious manner, which includes the development of the Independent Payment Advisory Board. The law is clear that the first year the Board is required to develop and submit a proposal to Congress in 2014. However, much of the leg work of implementing the Board, including appointments, hiring of staff, and policy considerations must be complete before any work on these reports and recommendations can begin. Therefore, we are taking our work of implementing the legislation very seriously and building implementation plans that are both aggressive and attainable. I look forward to keeping the Congress abreast of our progress.

Mr. Rehberg: Under the health reform law, the Independent Payment Advisory Board is required, "to the extent feasible," to give priority to recommendations that improve the health care

delivery system and health outcomes, including by promoting integrated care, care coordination, prevention and wellness, and quality and efficiency improvement." It is not at all clear to me how this is feasible when the provision exempts large sectors of the health care system, including hospitals, that are essential to improving care delivery, integrating and coordinating care, and improving health care quality and efficiency. In addition, the financial benefits of improving quality and care be met when the IPAB recommendations must cut cuts in a single year. Please explain how IPAB will meet its goals to cut spending on an annual basis with a focus on quality and outcomes, when it's so often the case that the budget scorekeepers simply won't give credit for savings related to quality and outcomes even over longer periods, much less over a single year? And if quality and outcomes improvements don't score, how will IP AB cut spending?"

Secretary Sebelius: High-quality health care is critical to improving patient outcomes and containing rising costs. Yet, nearly 100,000 Americans lose their lives from preventable medical errors in hospitals and, on average Americans receive only 55 percent of recommended care. Experts believe that up to 30 percent of every health care dollar is wasted on inefficient and ineffective care.

Improving quality and reducing costs can be attainable at the same time if we can find ways to target the 30 percent of health care spending that is wasted. The Affordable Care Act anticipates that recommendations from the Independent Payment Advisory Board to promote integrated care, care coordination, prevention and wellness, and quality and efficiency improvement will assist in reducing this unnecessary waste in health care programs. I would also underscore that while IPAB is a critical component in the legislation's effort to improve health care delivery systems and patient outcomes, there are many other changes within the ACA designed to support these efforts including expanded demonstration and pilot authorities and CMS's Center for Medicare and Medicaid Innovations.

SURGICAL QUALITY METRICS

Mr. Bonner: The University of South Alabama Hospital in my district has a Level One trauma center, one of only three in the state of Alabama and one of only a few along the Gulf Coast. The chair of the surgery department there has been involved in looking at metrics for surgical quality improvement. He is concerned that the implementation of surgical quality rules, and the carrots and sticks that may go with them will not be accurate or effective if they do not take into account the multitude of preoperative and interoperative factors that are present in any surgical procedure.

Simply put: how do we adjust for the difference in expected outcomes from surgery between a healthy 25 year old patient and an 85 year old patient with serious health problems? Publication of complication rates at hospitals which take care of disproportionate share of the 85 year old man with health problems may lead the public to the mistaken conclusion that this hospital doesn't deliver good care.

Secretary Sebelius: CMS has adopted three types of surgical care quality measures in its hospital reporting programs: structural measures, process of care measures, and outcome measures. CMS did so in order to provide a more complete picture of the quality of care delivered at a particular hospital. Not all of these types of measures require adjustment for perioperative factors, or patient risk factors, in order to provide useful and accurate information to the public.

Structural measures assess the extent to which the practice environment is conducive to delivery of high quality care and better outcomes. Currently, we have adopted one structural measure for surgical care that we currently display on our consumer-oriented website for hospitals (Hospital Compare). The measure is whether hospitals performing cardiac surgery participate in a systematic clinical registry for cardiac surgery, and the hospital's response to this question should not be contingent upon patient risk factors or perioperative factors.

Process of care measures assess the degree to which clinical guidelines and/or widely accepted clinical best practices are employed. Performance on these measures also in theory and principle should not systematically vary based on patient characteristics as the processes being measured should be occurring in most cases. However, there are some cases for which the process being measured is either unnecessary or contraindicated. Such cases are excluded from the population included in the measure. Doing so alleviates the need to statistically adjust for patient risk factors from a measure that theoretically should apply to all eligible cases. Currently, most of the surgical care measures that we have implemented on Hospital Compare are process of care measures.

We have also adopted and will begin to display outcome measures for surgical procedures on the Hospital Compare website in late 2010, and have expressed our intent to expand the number of outcome measures for reporting in the future through rulemaking. Outcome measures assess the state or health status of patients, i.e., death, survival, infection. The likelihood of outcomes does vary systematically with patient risk factors and co-morbidities. Therefore, risk adjustment for such factors will be employed for surgical outcome measures that we have adopted as well as for future outcome measures that we have proposed to adopt through rulemaking.

We have already successfully employed risk adjustment techniques for condition-specific outcome measures that are displayed on Hospital Compare, including the 30-day mortality and readmission measures for Acute Myocardial Infarction, Heart Failure and Pneumonia. In calculating these outcome measures, we take into account patient demographic characteristics (including age) and patient health problems (or comorbidities).

Mr. Bonner: Can you talk about whether the department is planning on examining the use of *expected outcomes* along with *observed outcomes* as it makes rules to implement programs for surgical quality improvement?

Secretary Sebelius: There are several statistical modeling methods for risk adjustment. One is the Logistic Regression that calculates the observed rate over the expected rate and another is the Hierarchical Modeling method that compares the predicted rate over the expected rate. CMS has considered the relative merits of both methods, and has adopted National Quality Forum (NQF)-endorsed outcome measures for public reporting that employ hierarchical modeling for risk adjustment in order to take into account hospital-specific effects in addition to patient case mix. CMS will continue to risk adjust current and future outcome measures it implements, including those pertaining to surgical procedures and complications, employing recommendations from our broadly representative Technical Expert Panels that guide measure development, and from the NQF.

AREA WAGE INDEX

Mr. Bonner: As you are aware from your service as governor of Kansas, CMS' area wage index (AWI) can pose significant problems for hospitals in multi-state labor markets. Wage indices can vary significantly from city to city, especially where adjacent cities lie in bordering states. In areas like the Gulf Coast, where multiple states - and multiple statistical areas - are part of the same labor markets, hospitals finding themselves in low wage index cities face a very real disadvantage when competing with higher wage index cities.

Obviously, wage index disparities are not unique to Alabama or to the Gulf Coast. Over time, Congressional prerogative and bureaucratic expediency have combined to make a hash of an already confused patchwork of high and low wage indices.

Has HHS studied the budgetary impact of inequalities in the area wage index, including the effect such inequalities may have on nursing shortages? Has the department looked into alternatives to the current metrics which may provide for more consistent wage indices within labor markets, rather than exclusively within states? Thank you.

Secretary Sebelius: I am deeply committed to developing and implementing policies that advance health care quality and value, reduce unnecessary utilization, address geographic variation in provider reimbursement rates, and bend the cost-growth curve. A number of provisions in the Affordable Care Act address these issues, including a quality and value adjustment for physician payments; value-based purchasing for hospitals and other providers;

accountable care organizations that allow providers to share in savings from providing care that improves quality and lowers cost; and policies that address geographic payment differentials.

The Department will continue to take a number of steps to address these challenges. Recently, the Department issued a series of studies on revising the hospital wage index and on developing alternative geographic practice cost index payment locality structures under the physician fee schedule. And, section 3137 of the Affordable Care Act asks for a report on a plan to reform the hospital wage index system. This report should be ready by the end of 2011 and, hopefully, will provide us with more insight into how we proceed in addressing this issue.

In addition, I have committed to commissioning two studies on Medicare's geographic payment adjustments for hospitals and physicians and geographic variations in the volume and intensity of Medicare services. The Department will seriously consider the results of these studies as part of our continuing effort to advance health care quality and value.

I also plan to convene a National Summit on Geographic Variation, Cost, Access, and Value in Health Care later this year to further examine these issues and consider ways to adjust our payment systems so they better account for geographic variation, while maintaining access and quality of care in all areas. While to date we have not done an analysis of the impact of area wage index inequities on nursing shortages specifically, we anticipate that research on Medicare's geographic variation in reimbursement will be relevant to all health care providers.

VACCINE COST AND ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Mr. Cole: Madame Secretary, I understand that at the most recent meeting of the Advisory Committee on Immunization Practices (ACIP) in February, the Committee said that there would be no further additions to the pediatric schedule for infant vaccines - at least in the foreseeable future. Without a routine or permissive recommendation by ACIP, a childhood vaccine will not be covered by either a public program or private insurance, so even parents that want to give their infant a vaccine could be denied that opportunity. To what extent does the cost of a vaccine factor into a decision by ACIP to include or exclude a vaccination in their pediatric schedule?

Secretary Sebelius: Information on cost-effectiveness of vaccines is one of several factors considered by the ACIP when formulating vaccine policy recommendations. In addition to reviewing economic data on vaccines, the ACIP reviews a number of factors in this process, including: 1) morbidity and mortality associated with the disease in the general U.S. population and in specific risk groups; 2) available scientific literature (both published and unpublished) on the safety, efficacy, effectiveness, cost-effectiveness, and acceptability of the immunizing agent, with consideration of the relevant quality and quantity of published and unpublished data; 3) clinical trial results and usage information provided in the manufacturer's labeling/package insert; 4) recommendations of other professional liaison organizations; and 5) the feasibility of incorporating the vaccine into existing domestic immunization programs. The ACIP adopted guidance for the presentation of cost-effectiveness and other types of economic analyses to ensure that economic data presented to the Committee and its Work Groups are uniform in presentation, understandable, and of the highest quality.

Mr. Cole: If the FDA subsequently approves a vaccine for use in infants that is found to be highly effective in preventing a deadly infectious disease, such as meningitis for example - would ACIP reconsider this decision?

Secretary Sebelius: If a new vaccine became available and was approved by FDA, ACIP would consider recommending the vaccine based on the scientific evidence available.

PEDIATRIC CANCER FUNDING

Mr. Cole: Madame Secretary, as you know, about 2,300 children die of cancer each year. Cancer is the number one kills more children than asthma, cystic fibrosis, AIDS, and diabetes combined. Public Law 110-285, the Caroline Pryce Walker Conquer Childhood Cancer Act, was passed unanimously by the House and Senate. We all understand the fiscal constraints of your Department, so please understand that this statement and the following question comes with that knowledge and consideration. It's been said that we are judged by those we help who cannot help themselves. These children cannot take action on their own therefore we elected and appointed officials must take action. So there is the human element of this -- the prevention of the pain and suffering through identifying cures for cancer -- but there is also a fiscal benefit to such funding. The funding generated through the 2,300 lives saved each year - lives of children who turn into productive citizens.

In a recent letter to one of my colleagues from OMB Director Orszag, it is indicated that NIH will provide $215 million for the conditions and needs of children with cancer in FY 2010. However, in a document recently distributed by NCI, only $196.3 million will be provided for such research. Can you clarify how much funding will go specifically to pediatric cancer research and what you anticipate out year funding to be?

Secretary Sebelius: NIH has not set its tracking system on disease spending to be able to capture estimates for childhood cancers or pediatric cancer research funding across all of NIH. However, these estimates are available for research funded by NCI. The estimated funding level in Director Orszag's letter reflects the NCI-projected FY 2010 funding level for pediatric research (approximately $215 million), which is a broader research category than childhood cancer alone, and includes research related to child health, childhood cancers, birth defects, multiple sclerosis, etc. In FY 2011, NCI expects to fund pediatric research at $223.7 million. NCI also projects funding in the category "childhood cancer research", which is a subset of pediatric research and includes only childhood cancer research (such as childhood leukemia and neuroblastoma). The National Cancer Institute (NCI) estimates it will spend $196.3 million in FY 2010 and $202.7 million in FY 2011 on childhood cancer research. This is the funding level that was provided in the recent NCI document. The key difference between these two categories of research is pediatric research is a broader category that includes research related to child health in general, whereas childhood cancer specifically deals with cancers affecting children.

NCI uses this funding to support a comprehensive pediatric cancer research program that extends from basic biology research and preclinical testing to identifying new therapeutic targets and an extensive clinical trials program that determines whether the preclinical discoveries can be translated into clinical benefit. Pediatric research in the laboratory includes studying the genetic and other mechanisms related to tumor formation and metastasis. For example, NCI's Childhood Cancer Therapeutically Applicable Research to Generate Effective Treatment (TARGET) Initiative applies high-throughput genomic analysis methods to identify novel therapeutic targets for childhood cancers. The Pediatric Preclinical Testing Program (PPTP), an NCI-supported research contract begun in 2005, generates preclinical data that informs decisions about prioritizing new agents and combinations of agents for study against specific types of childhood cancers. NCI supports several consortia of institutions to perform clinical trials of novel agents and treatments, thereby allowing preclinical discoveries to rapidly move to the clinic and be studied by experienced pediatric oncology investigators. The Children's Oncology Group (COG) develops and coordinates cancer clinical trials available at over 200 U.S. and international institutions. The clinical trials conducted by COG, NCI, and other NCI-supported consortia play key roles in evaluating new treatment approaches.

Finally, an important feature of the NCI research program is its work addressing the special issues faced by childhood cancer survivors. Initiated in 1993, the NCI-funded Childhood Cancer Survivor Study (CCSS) is a collaboration of 27 institutions which seeks to increase knowledge of the late effects of childhood cancer treatment. With an original cohort of 20,000 childhood cancer survivors diagnosed between 1970 and 1986, the CCSS began recruiting an additional 14,000 individuals treated for cancer as children between 1987 and 1999 to allow for the evaluation of late effects of newer types of cancer treatment.

More than 12 million cancer survivors are alive in the United States, at least 270,000 of whom were originally diagnosed when they were under the age of 21. Although there has been some increase in the incidence of all forms of invasive pediatric cancer over the past 20 years, from 11.5 cases per 100,000 children in 1975 to 14.8 per 100,000 children in 2004, death rates have declined dramatically and five-year survival rates have increased for most childhood cancers during this same time. Advances in cancer treatment have meant that today, over 80 percent of children diagnosed with cancer are alive at least five years after diagnosis, compared to about 58 percent in the 1970s. These advances have averted an estimated 38,000 childhood cancer deaths in the U.S. between 1974 and 2006. This improvement in survival rates is due to significant advances in treatment, resulting in a cure or long-term remission for the majority of children with cancer.

It is important to note that the basic research on cancer mechanisms done by NCI as well as most of the other ICs at NIH also contributes heavily to the understanding of all cancer mechanisms including pediatric cancers. That research and the dollars spent on it are not reflected in the above mentioned programs that are specific to pediatric cancers and are designed to funnel basic research discoveries into specific studies and clinical trials in pediatric cancer.

WEDNESDAY, APRIL 28, 2010.

FY 2011 BUDGET OVERVIEW: NATIONAL INSTITUTES OF HEALTH

WITNESSES

FRANCIS S. COLLINS, M.D., PH.D., DIRECTOR, NATIONAL INSTITUTES OF HEALTH

ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

THOMAS R. INSEL, M.D., DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

GRIFFIN P. RODGERS, M.D., DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

CHAIRMAN OBEY OPENING STATEMENT

Mr. OBEY. Good morning, everybody.

Today we will hear from a variety of witnesses on the President's request for the National Institutes of Health. We will have as a principal witness Dr. Francis Collins, who has been here many times in his former role as the Director of the National Human Genome Research Institute at the National Institutes of Health (NIH). This is his first appearance before the Subcommittee in his new capacity as the Director of NIH.

Accompanying Dr. Collins is Dr. Tony Fauci, Director of the National Institute of Allergy and Infectious Diseases; Dr. Tom Insel, Director of the National Institute of Mental Health; and Dr. Griffin Rodgers, Director of the National Institute of Diabetes and Digestive and Kidney Diseases.

I think it is fair to say that supporting the work of NIH has been a priority of this Subcommittee, certainly for as long as I have been in the Congress, and I am pleased that the President has, in the context of a tight budget situation, still provided a request for a $1,000,000,000 increase proposed for NIH overall.

Depending upon how you measure it, NIH has either had a meaningful increase in spending over the past 30 years or it has had a spectacular increase in funding. NIH was spending $1,800,000,000 when I joined the Subcommittee in 1973. The current fiscal year budget provided NIH with $31,000,000,000, so that is 16 times what it was spending when I joined the Committee, which sounds awfully big except that it is not adjusted for inflation. When you adjust it for inflation, we have not quite doubled in real dollar terms funding for NIH over that period.

We have had, I think it is fair to say, a mixed bag with respect to success against various diseases. With some, childhood leukemia, we have had significant gains. We certainly have had gains in holding at bay, somewhat, AIDS in comparison to what we feared when the Subcommittee first started talking about it. And

yet there are other areas where very little progress has been made; example, pancreatic cancer, esophageal cancer, and a variety of other maladies.

So today we want to hear from these witnesses about not only what they intend to do with their money, but what their observations are in terms of how we can develop a better track record in the future in attacking diseases that have not been the subject of much progress over the past two decades.

And I have to say one thing before I ask Mr. Tiahrt for his comments. I have always been rather disappointed that, in my many conversations with people in the medical field, with providers in the field, that the discussion, when it turns to health care, so often is focused simply on issues such as reimbursement rates, what are hospitals going to get by way of compensation, what are doctors going to get paid.

And that is all very legitimate, but I have personally been struck by the lack of comment or curiosity or, for that matter, the lack of visible political support for added medical research which, after all, lays the foundation for the product that the practitioners in the health care area have to offer their patients and their customers.

So I think while there are many activists who have, for years, been pushing for additional funding for National Institutes of Health, I think in some ways I have been disappointed by the lack of aggressive activism on the part of so many professionals in the field. And I am not quite sure what to do about that, but I know since Dr. Collins is a very smart fellow, he will have an answer to that and everything else.

The other thing I want to say, Doctor, I want to express my personal appreciation for the fact I think you have, by your public statements, made it quite clear that one does not have to believe—I am saying it backwards. You have made it quite clear that there is not necessarily any inconsistency between pursuit of science and the belief in religion. To me, I have never understood why people think that the two are at loggerheads; that has never been my conclusion either intellectually or emotionally. So I appreciate the role that you have played in driving that point home as well.

With that, let me simply turn to Mr. Tiahrt to see what comments he might have.

Mr. TIAHRT. Thank you, Mr. Chairman. It is always a mystery, what I am going to say, is it not?

I am very pleased to see you gentlemen here today. Thank you for coming; appreciate your time. Dr. Collins, I am enjoying the Language of Life. The first chapter caught my attention when you say we are not in Kansas anymore. Being from Kansas, you do not know how many times I have thought that here in the District of Columbia.

I think you do present genetics at a level that can be understood, and I think that is very important for our culture today. But certainly DNA research is proceeding at a very fast pace, and one of the concerns that I have is what we call the valley of death, the gap between our basic research and clinical development.

We seem to have this void in the middle where we cannot get it into action sometimes, and you are coming across very critical research, and we want to find mechanisms to get it into the clinic

and get it into applying; I guess because I feel like basic research will not do us any good unless we get it in a practical application for those of us out here. And that is why we make the investment, so that we can get it into the clinics and into the cures.

I am pleased to see that there are initiatives that are relatively new in your budget request, particularly the Therapeutics for Rare and Neglected Diseases, or TRND. I think that is exactly the type of effort we need to focus NIH's resources so that we can get across this valley of death and start funding cures.

So I look forward to your testimony and I have some questions once we get through it.

Thank you, Mr. Chairman.

Mr. OBEY. Mr. Lewis.

Mr. LEWIS. Thank you very much, Mr. Chairman. I will wait to ask questions after we have heard from the witnesses. I appreciate being recognized.

Mr. OBEY. All right. Dr. Collins, please proceed. Take as much time as you want, within reason. [Laughter.]

DR. COLLINS OPENING STATEMENT

Dr. COLLINS. Well, thank you, and good morning, Mr. Chairman and distinguished members of this Subcommittee. It is a great honor to appear before you for the first time in my role as the Director of the NIH and to present the fiscal year 2011 budget, but especially to discuss my vision for the future of biomedical research.

I would like for my written testimony to be included in the record. I am going to deviate from it quite a bit in my remarks this morning.

So I would like to thank each of you for your steadfast support of NIH's mission, which, as you can see—and I am going to show a few visuals on these screens—is a dual one: to support the discovery of fundamental knowledge about the nature and behavior of living systems, but to be sure that we are then applying that to extend healthy life and reduce the burdens of disability and premature illness and death.

I want to thank the Committee for the support in fiscal year 2010 of $31 billion, as well as the $10.4 billion that was provided through the American Recovery and Reinvestment Act. And I have been very grateful, over 15 years leading the Human Genome Project, for the support of this Committee. As you know, that project finished ahead of schedule and under budget, and was supported strongly by this Congress and by this Committee even at times when there were controversies about it.

But now, as steward of the entire portfolio of NIH, I believe that opportunities to turn discovery into health have never been greater. I am honored to have with me this morning three distinguished leaders from NIH that the Chairman has already introduced, Dr. Rodgers, Dr. Insel, and Dr. Fauci, and I am sure they will be happy to also engage you in the questions.

But I also want to introduce you to some other folks today, just a few of the millions of Americans who have been helped by NIH-funded research. And let us begin with Kate Robbins. So let us hear from Kate.

[Video shown.]

KATE ROBBINS. The message I got is make your plans, get your life in order, and enjoy the next few months; and I was enraged.

[End of videotape.]

Dr. COLLINS. So eight years ago, at the age of 44, this non-smoking mother of two was diagnosed with lung cancer and given a diagnosis essentially of terminal disease. She had non-small cell lung cancer that had already metastasized to her brain. And it continued to spread, after surgery, radiation, and chemotherapy, to her liver, her pancreas. But she enrolled in a clinical trial of a new drug called Iressa, or gefitinib, which is a new genome-based drug for cancer. And after Kate started the drug, dramatic things happened: most of her metastases vanished.

As you can see in these CT scans of her liver before and after Iressa—this is before, six months later, and then today, seven and a half years later, those metastases shrank and disappeared and have not returned. There is no sign of cancer in her liver, her lungs, her pancreas. Her brain metastases are small and manageable; and, as you saw in the video, she is doing extremely well.

So why does not Iressa work in all cases? Well, we understand that. The response depends on whether or not the tumor has a specific mutation in a gene called EGFR. And we now understand that, which demonstrates the potential of personalized medicine. This drug is a god-send for that subset of individuals with those mutations, but it is unlikely to work if that mutation is not present.

We need a lot more stories like Kate's, so NIH-funded researchers are now busy with projects like the Cancer Genome Atlas, mapping genomic changes in many types of cancer, including, Mr. Chairman, pancreatic cancer, which I agree is one where we desperately need new solutions.

Next, I would like you to meet nine-year-old Corey Haas; his parents, Nancy and Ethan, shown up here in this photo. Corey was born with a disease which has quite a mouthful, Leber's congenital amaurosis, and it is a cause of blindness; it gradually robs young people of their sight. It is caused by mutations in a gene called RPE65.

Now, by age seven Corey was legally blind; he needed a cane to get around, had to use a special computer screen. But that all changed in 2008, when Corey enrolled in a gene therapy trial at the University of Pennsylvania, which involved injecting normal copies of this RPE65 gene into his left eye. Researchers shot this video, then, of Corey navigating an obstacle course, and let me explain here. I am going to show you a video that is in the lower left here.

Basically, Corey is being asked to walk a maze pattern. There are arrows painted in the floor. In this image they have covered up his treated eye, so he is only able to navigate based upon the untreated eye; and you will see that he is very, very limited in his eyesight.

[Video shown.]

Unidentified SPEAKER. You do not see any lines on the floor that tell you which direction?

COREY HAAS. No. No, I do not.

Unidentified SPEAKER. Do you want a clue?

COREY HAAS. I cannot even see anything.

Unidentified SPEAKER. Okay.

[Video paused.]

Dr. COLLINS. Now see what happens when they repeated the trial, same day, but now covering up his untreated eye and allowing him to use the eye that has received the gene therapy to find his way around.

[Video resumed.]

Unidentified SPEAKER. Okay, perfect. All right. And you can start whenever you are ready.

Wow. Wow.

[Applause.]

[End of videotape.]

Dr. COLLINS. Pretty amazing, though Corey is probably even more amazed he can ride a bike now and read the chalkboard like any other kid.

Now finally meet Leslie Cook, a wonderful example of prevention-oriented research. Leslie smoked for 25 years, half of her life, a habit that put her at increased risk for heart attack, cancer, and many other diseases.

[Video shown.]

LESLIE COOK. I felt as though the drug nicotine was actually controlling me, I was not controlling it, and I just wanted control over my life again.

[End of videotape.]

Dr. COLLINS. So this high-powered real estate lawyer tried to kick the habit many times; she used the gum, the patch. You name it, she had tried it. Nothing worked. And then in 2006 she enrolled in a phase 2 clinical trial of an anti-nicotine vaccine called NicVAX. This vaccine actually stimulates the immune system to produce antibodies against nicotine. Those antibodies bind to the nicotine and keep it from entering the brain, therefore reducing the pleasure associated with smoking.

NicVAX apparently did the trick for Leslie; she has not smoked in three and a half years.

Now, hopefully her experience will soon be repeated on a much larger scale. A clinical trial of NicVAX involving about 1,000 smokers was recently launched. About $10 million in NIH Recovery Act funds are being used to support that effort, which is rooted in research-funded at NIH, and it is the first ever phase 3 trial of a smoking cessation vaccine.

So I would like to thank Leslie, Corey, and Kate for allowing me to share their stories. I think their experiences show that science is not a 100-yard dash, it is a marathon. Each of those built upon years of research getting to that clinical advance. But thanks to discoveries you have funded through NIH appropriations, we have covered a lot of ground in this marathon.

Let me tell you how NIH plans to meet that continuing challenge, because there is still a ways to go.

So one of my first actions upon being named NIH Director was to scan the landscape of biomedical research for areas that were ripe for major advances that could yield substantial benefits downstream, because this is a unique time. While the list of specific

projects could go on forever, I have identified five areas of exceptional opportunity I want to very briefly tell you about, and they are in a paper that you have at your place published in Science Magazine on January 1st.

The first of those opportunities is to use the high throughput technologies that have recently been invented to understand fundamental biology and how disease occurs. This includes genomics, nanotechnology, imaging approaches, computational biology, and a host of other new technologies that are truly powerful to understand the causes and the means to treat or prevent cancer, autism, infectious diseases, and a long list.

A second opportunity—and this ties very much into what Mr. Tiahrt was asking about—is the effort to take these basic science discoveries that are pouring out of research laboratories and accelerate the translation of this into new and better treatments. This is not an easy process, as the picture shows you; there can be a difficult passageway between basic research and drugs. We need to build a bridge—by the way, that is San Francisco, in case the first picture was not so clear—and we are doing that with programs like TRND, which stands for Therapeutics for Rare and Neglected Diseases.

And in the health care reform bill the cures Acceleration Network, which is a new provision that would give NIH additional flexibility to push this translational agenda even more robustly and in a more innovative way. And this includes cell therapy as well, the effort to use stem cells for therapeutics. If you noticed in this morning's Washington Post, we have now approved another set of stem cell lines, bringing the total to 64 that are available for use by federally funded researchers.

The third opportunity here, shown by these various banners representing programs that NIH has supported particularly to try to get information out there about the public health, is to put science to work for the benefit of health care. We, after all, need evidence to support the transformation of the practice of medicine that we all agree is necessary. Some of that is comparative effectiveness research, personalized medicine, the study and the attempt to solve health disparities, the efforts to focus on behavioral medicine; and even on health care economics, to understand what are the factors that play into better outcomes at lower cost.

The fourth area, global health. Clearly we have a great opportunity now because science has moved forward rapidly in uncovering the nature of many pathogens that we previously did not understand that affect hundreds of millions of people in the developing world. We have the chance to push that agenda forward, building upon what NIH has done already in the past and focusing now not only on infectious diseases, but also on noncommunicable diseases like depression, which also become, in the developing world, major public health problems. It is the noncommunicable diseases that represent the most rapidly growing area of morbidity and mortality.

And, finally, and fifth, we need to reinvigorate and empower our biomedical research community, our most important resource. That means we need to focus on innovation, making sure that we are giving ideas that are a little wacky and out of the box a chance to

get supported. We need to be sure that we are supporting early-stage investigators, giving them the confidence that there is a place for them in our research community, even at times when budgets are tight. And we need to focus on training the next generation, and particularly reaching out to diverse communities that are not adequately represented right now in our workforce.

Those are the five themes that I have focused on. You also have at your place a new document that has just come out from NIH that talks more about these, and also the many advances that have occurred because of NIH research over the last few years.

So, to summarize, if our Nation is bold enough to act today upon these unprecedented opportunities in medical research, I think we will be amazed at what tomorrow can bring. In the world I envision just a few decades from now, the one-size-fits-all approach to medicine will be a thing of the past. We will use genetic information to personalize our health care. We will use stem cells to repair spinal cord injuries; bioengineered bones and cartilage to replace worn out joints; nanotechnology to deliver therapies with exquisite precision. We will preempt heart disease with minimally-invasive image-guided procedures and use an artificial pancreas or other new technologies to manage diabetes better.

As for infectious diseases, I look forward to having a universal vaccine with the power to protect against both seasonal and pandemic flu. I also hope, and that hope is based upon progress, for an AIDS vaccine and a malaria vaccine, which together would save millions of lives around the globe every year.

And I dream of a day where, in ways yet to be discovered, we will be able to prevent Alzheimer's disease, Parkinson's disease, and many others that rob us much too soon of family and friends.

Just imagine what that future could mean for our Nation, our economy, for all humankind. This is what keeps NIH in the research marathon and why we are asking you to go the distance with us. The fiscal year 2011 request for NIH from this Committee is $32 billion, an increase of $1 billion, or 3.2 percent above the fiscal year 2010 level. Those funds will enable the nationwide biomedical research community to pursue a whole number of substantial opportunities for major scientific and health advances.

So thank you, Mr. Chairman and members of the Subcommittee. I would be pleased to respond to any questions you may have.

[Written statement by Francis S. Collins, MD, PhD, follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2011 Budget Request

Witness appearing before the

House Subcommittee on Labor – HHS – Education Appropriations

Francis S.Collins, M.D., Ph.D.
Director, National Institutes of Health

Accompanied by:

Anthony S. Fauci, M.D.
Director, National Institute of Allergy and Infections Diseases

Thomas R. Insel, M.D.
Director, National Institute of Mental Health

Griffin P Rodgers, M.D.
Director, National Institute of Diabetes and Digestive and Kidney Diseases

April 28, 2010

Good morning, Mr. Chairman and distinguished Members of the Subcommittee:

It is a great honor to appear before you today to present the Fiscal Year 2011 budget request for the National Institutes of Health (NIH), and to discuss my vision for the future of biomedical research.

First, I'd like to thank each of you for your steadfast support of NIH's mission: discovering fundamental knowledge about living systems and then applying that knowledge to fight illness, reduce disability, and extend healthy life. In particular, I want to thank the committee for the FY 2010 budget level of $31 billion, and the $10.4 billion provided to NIH through the American Recovery and Reinvestment Act. I was very grateful for the committee's interest and support over the course of my 15 years as Director of the National Human Genome Research Institute, most notably during our successful effort to sequence the human genome. Now, as steward of NIH's entire research portfolio, I truly believe that the opportunities for us to work together to improve America's health have never been greater.

One of my first actions upon being named NIH Director was to scan the vast landscape of biomedical research for areas ripe for major advances that could yield substantial benefits downstream. I found many of the most exciting opportunities could be grouped under five main themes: taking greater advantage of high-throughput technologies; accelerating translational science, that is, turning discovery into health; helping to reinvent health care; focusing more on global health; and reinvigorating the biomedical research community.

The Administration's request of $32.1 billion for NIH's biomedical research efforts in FY 2011 would help more researchers take greater advantage of these unprecedented opportunities, all with the aim of helping people live longer, healthier, more rewarding lives. We at NIH are fortunate to have a very solid foundation upon which to build, established by such extraordinary leaders as James Shannon, Nobel laureate Harold Varmus, Elias Zerhouni, and the late and much missed Ruth Kirschstein.

THE RESEARCH MARATHON

In his FY 2009 budget remarks, Dr. Zerhouni warned that our nation's biomedical research effort is in a race that we cannot afford to lose. I wholeheartedly agree, and want to provide a few more insights about what that race involves.

Science is not a 100-yard dash. It is a marathon – a marathon run by a relay team that includes researchers, patients, industry experts, lawmakers, and the public.

Thanks to discoveries funded through NIH appropriations, we have covered a lot of ground in this marathon. Let us take a moment to look back at a few of the advances made possible by NIH-supported research, and then look ahead to some of our nation's biggest health challenges and how NIH intends to meet them.

HOW FAR WE'VE COME

U.S. life expectancy has increased dramatically over the past century and still continues to improve, gaining about one year of longevity every six years since 1990. A baby born today can look forward to an average life span of 77.7 years, almost three decades longer than a baby born in 1900.

Not only are people living longer, they are staying active longer. From 1982 through 2005, the proportion of older people with chronic disabilities dropped by almost a third, from 27% to 19%.

Some of the most impressive gains have been made in the area of cardiovascular disease. In the mid-20th century, cardiovascular disease caused half of U.S. deaths, claiming the lives of many people still in their 50s or 60s. Today, the death rate for coronary heart disease is more than 60% lower -- and the death rate for stroke, 70% lower – than in the World War II era.

What fueled these improvements? One major contributor has been the insights from the NIH-funded Framingham Heart Study, which began in the late 1940s and is still going strong. This population-based study, which changed the course of public health by defining the concept of disease risk factors, continues to break new ground with its recent move to add a genetic component to its analyses.

Other factors include NIH-supported research that led to minimally invasive techniques to prevent heart attacks and to highly effective drugs to lower cholesterol, control high blood pressure, and break up artery-clogging blood clots. Science also played a crucial role in formulating approaches to help people make lifestyle changes that promote cardiovascular health, such as eating less fat, exercising more, and quitting smoking.

Many chronic conditions have their roots in the aging process. One such disease, osteoporosis, can lead to life-threatening bone fractures among older people. NIH-funded research has led to new medications and management strategies for osteoporosis that have reduced the hospitalization rate for hip fractures by 16% since 1993. Science has also transformed the outlook for people with age-related macular degeneration, a major cause of vision loss among the elderly. Twenty years ago, little could be done to prevent or treat this disorder. Today, because of new treatments and procedures based on NIH research, 750,000 people who would have gone blind over the next five years will continue to have useful vision.

Biomedical research also has benefitted those at the other end of the age spectrum. NIH-funded research has given hearing to thousands of children who were born profoundly deaf. This hearing is made possible through a cochlear implant, an electronic device that mimics the function of cells in the inner ear. Since the Food and Drug Administration (FDA) approved cochlear implants for pediatric use in 2000, more than

25,000 children have received the devices, enabling many to develop normal language skills and succeed in mainstream classrooms.

Then, there are the infectious diseases – diseases that often know no boundaries when it comes to age, sex, or physical fitness. One of NIH's greatest achievements over the past 30 years has been to lead the global research effort against the human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) pandemic. With discovery building upon discovery, researchers first gained fundamental insights about how HIV works, and then went on to develop rapid HIV tests, identify a new class of HIV-fighting drugs, and, finally, figure out how to combine those drugs in life-saving ways in the clinic. As a result, HIV infection has changed from a virtual death sentence into a manageable, chronic disease. Today, HIV-infected people in their 20s who receive combination therapy may expect to live to age 70 or beyond.

HOW FAR WE HAVE TO GO

Although we have accomplished much, and as tempting as it may be for NIH to rest upon its laurels, we all know that biomedical research still has an enormous amount of ground to cover before discovery is turned into health for all Americans.

Consider the challenge posed by cancer. This disease still claims the lives of more than 500,000 Americans annually – about one every minute. But in 2007, for the first time in our nation's history, the absolute number of cancer deaths in the U.S. went down. And, over the past 15 years, cancer death rates have dropped 11.4% among women and 19.2% among men, which translates into some 650,000 lives saved – more than the population of Washington, D.C. These are very encouraging milestones, but they are not nearly enough.

NIH-funded research has revolutionized how we think about cancer. A decade or two ago, cancer treatment was mostly reactive, diagnosis was based on the organ involved and treatment depended on broadly aimed therapies that often greatly diminished a patient's quality of life. Today, basic research in cancer biology is moving treatment toward more effective and less toxic therapies tailored to the genetic profile of each patient's cancer.

Among the early success stories in this area is the drug trastuzumab (Herceptin) for breast cancer. An NIH-sponsored clinical trial found that when breast cancer patients whose tumors were genetically matched to trastuzumab received the drug, along with standard chemotherapy, their risk of cancer recurrence fell 40%. That improvement is the best ever reported in post-surgical treatment of breast cancer. Studies also have found that the chemotherapy drugs gefitinib (Iressa) and erlotinib (Tarceva) work much better in the subset of lung cancer patients whose tumors have a certain genetic change.

To accelerate the development of more individualized strategies for more types of cancer, NIH has tapped into the promise of high-throughput technologies to launch The Cancer Genome Atlas (TCGA). Over the next few years, TCGA's research team will

build comprehensive maps of the key genomic changes in 20 major types and subtypes of cancer. This information, which is being made rapidly available to the worldwide scientific community, will provide a powerful new tool for all those striving to develop better ways to diagnose, treat, and prevent cancer.

Already, TCGA has produced a comprehensive molecular classification system for ovarian cancer and glioblastoma, the most common form of brain cancer. The survey of glioblastoma recently revealed five new molecular subtypes of the disease. In addition, researchers found that responses to aggressive therapies for glioblastoma varied by subtype. The findings hold promise for matching the most appropriate therapies with brain cancer patients and may also lead to therapies directed at the molecular changes underlying each subtype, as has already happened for some types of breast cancer.

Diabetes is another disease that is inflicting much damage on U.S. health. More than 23 million Americans currently have diabetes – nearly 8% of the population. Another 57 million have blood sugar levels that indicate they are at serious risk of developing the disease, which is a major cause of kidney failure, stroke, heart disease, lower-limb amputations, and blindness.

For type 2 diabetes, prevention appears to be the name of the game. This form of the disease, which accounts for more than 90% of diabetes among adults, often can be averted or delayed by lifestyle factors. The NIH-funded Diabetes Prevention Program (DPP) trial showed that one the most effective ways to lower the risk of type 2 diabetes is through regular exercise and modest weight loss. There is good reason to believe that such efforts may lead to a lifetime of health benefits. A recent follow-up study of DPP participants found the protective effects of weight loss and exercise persist for at least a decade. The United Health Group has recently announced a partnership with Walgreen's and the YMCA to implement the results of this groundbreaking NIH-funded research on a broad scale.

More than one-third of adults in the U.S. are obese, according to the latest data from the National Health and Nutrition Examination Survey which is conducted by the Centers for Disease Control and Prevention (CDC). And there are signs that the next generation may face an even greater struggle. Over the past 30 years, obesity has more than doubled among U.S. children ages 2 through 5 and nearly tripled among young people over the age of 6. Those statistics translate into tens of millions of Americans who face an increased risk of type 2 diabetes, as well as cardiovascular disease, high blood pressure, certain cancers, osteoarthritis, and other serious health problems associated with excess body fat.

To address America's growing problem with obesity, NIH has launched a variety of initiatives aimed at developing innovative approaches for weight control. One such effort, called the National Collaborative on Childhood Obesity Research, has pulled together experts from four NIH institutes, the CDC, and the Robert Wood Johnson Foundation. One example of their work is the Trial of Activity for Adolescent Girls, a national study to develop and test school- and community-based interventions to get

girls more involved in gym class, organized sports, or recreational activities. Another NIH program, called *We Can!*, provides families with practical tools for weight control at more than 1,000 community sites nationwide. How to get more people to lose weight is also among the questions being explored by OppNet, a new trans-NIH initiative for basic behavioral and social sciences research.

Meanwhile, other NIH-funded researchers are busy uncovering information about genes and environment that may pave the way for more personalized, targeted strategies for controlling weight and preventing diabetes. For example, in just the past few years, we have identified more than 30 genetic risk factors for type 2 diabetes.

A better understanding of genetic and environmental factors may also help solve a longstanding medical puzzle: the causes of autism. Children with autism spectrum disorders experience a range of problems with language and social interactions, sometimes accompanied by repetitive behaviors or narrow, obsessive interests. Recent studies funded by NIH have associated autism risk with several genes involved in the formation and maintenance of brain cells, but much more work is needed to follow up on these clues.

In FY 2011, NIH will support comprehensive and innovative approaches to piece together the complex factors that contribute to autism spectrum disorders. One ambitious effort will involve sequencing the complete genomes of 300 people with autism and their parents. Other researchers will examine a mother's exposure during pregnancy to identify possible environmental contributions. NIH hopes to use these insights to develop new molecular and behavioral therapies for such disorders, as well as to identify possible strategies for prevention.

Another brain disorder, depression, presents a different set of challenges. Although researchers have made significant progress in understanding the biology of depression, improving treatment, and lessening the social stigma associated with mental illnesses, suicide still claims the lives of twice as many Americans as homicide. And it does not end there -- untreated depression also increases the risk of heart disease and substance abuse.

How can medical research reduce depression's tragic toll? One way may be getting people into treatment more quickly. Researchers today are using functional magnetic resonance imaging and other innovative technologies to see how the brains of people with depression differ from those without the disorder. Rapid diagnosis is just part of the equation. Finding the right antidepressant drug for any particular patient currently is a lengthy, trial-and-error process that can take weeks before symptoms are relieved. NIH supports laboratory research aimed at developing quicker-acting antidepressants, as well as genetic studies that will help to match individuals with the drugs most likely to work for them.

In 2008, 143 soldiers died by suicide – the highest rate since the Army began keeping records three decades ago. To address this problem, NIH and the U.S. Army recently partnered to launch the largest study ever of suicide and mental health among military personnel. The Army Study to Assess Risk and Resilience in Service Members (Army STARRS) will identify risk factors that may inform efforts to develop more effective approaches to suicide prevention.

TRANSFORMING DISCOVERY INTO HEALTH

Whatever the disease, be it depression, diabetes, or something much rarer, NIH's emphasis in FY 2011 and beyond will be on translating basic discoveries into new diagnostic and treatment advances in the clinic.

In the past, some have complained that NIH has been too slow to convert fundamental observations into better ways to diagnose, treat, and prevent disease. Although some of that criticism may have been deserved, most of the delay has stemmed from the lack of good ideas about how to traverse the long and winding road from molecular insight to therapeutic benefit.

That is now changing. For many disorders, there are new opportunities for NIH to shorten and straighten the pathway from discovery to health. This expectation is grounded in several recent developments: the dramatic acceleration of our basic understanding of hundreds of diseases; the establishment of NIH-supported centers that enable academic researchers to use such understanding to screen thousands of chemicals for potential drug candidates; and the emergence of public-private partnerships to aid the movement of drug candidates identified by academic researchers into the commercial development pipeline.

Let me give you one example of how NIH plans to implement this strategy: the Therapeutics for Rare and Neglected Diseases (TRND) program. This effort will bridge the wide gap in time and resources that often exists between basic research discoveries and the human testing of new drugs.

A rare disease is one that affects fewer than 200,000 Americans. However, if all 6,800 rare diseases are considered together, they afflict more than 25 million Americans. Private companies seldom pursue new therapies for these types of diseases because of the high cost of research and low likelihood of recovering their investments. Effective drugs exist for only about 200, or less than 3%, of rare diseases. Unlike rare diseases, neglected diseases may be quite common in some parts of the world, especially in developing countries. However, there also is a dire shortage of effective, affordable treatments for many of these major causes of death and disability.

Working in an open environment in which all of the world's top experts on a disease can be involved, TRND will enable certain promising compounds to be taken through the preclinical development phase – a time-consuming, high-risk phase often referred to as "the valley of death" by pharmaceutical firms focused on the bottom line.

Besides speeding development of drugs for rare and neglected diseases, TRND will serve as a model for therapeutic development for common diseases, many of which are being resolved into smaller, molecularly distinct subtypes.

NIH will also take other steps to build a more integrated pipeline that connects all of the steps between identification of a potential therapeutic target by a basic researcher and the point when the FDA approves a therapeutic for clinical use. Among the tools at our disposal is the NIH Clinical and Translational Sciences Award program, which currently funds 46 centers and has awardees in 26 states and plans to add even more in FY 2011. This national network is pulling together interdisciplinary clinical research teams to work in unprecedented ways to develop and deliver tangible health benefits. We also need to take advantage of the nation's largest research hospital, the Mark O. Hatfield Clinical Research Center, located on the NIH campus in Bethesda, Md. Just as they blazed a trail for safe and effective human gene therapy, NIH clinical researchers may be well positioned to move the ball forward for other pioneering approaches, such as those using human embryonic stem cells or induced pluripotent stem cells derived from skin cells.

To make the most of these new opportunities, the NIH and FDA recently forged a landmark partnership with the formation of a Joint Leadership Council. Members of this Leadership Council will work together to ensure that regulatory considerations form an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process. Such collaboration will advance the development of products to treat, diagnose and prevent disease, as well as enhance the safety, quality, and efficiency of clinical research and medical product approval.

BIOMEDICAL RESEARCH PROPELS U.S. ECONOMY

It is crucial to keep in mind that investing in NIH not only improves America's health and strengthens our nation's biomedical research potential, it empowers the entire U.S. economy. Consider the following statistics:

- A report issued by Families USA calculated that in 2007, every $1 in NIH funding resulted in an additional $2.11 in economic output in the U.S. [1]
- In FY 2007, a typical NIH grant supported the salaries of about 7 high-tech jobs in full or in part.[2]
- The 351,000 jobs resulting from NIH awards paid an average annual wage of more than $52,000 per annum and account for more than $18 billion in wages for FY 2007.[3]
- Long term, NIH funded R&D sparks U.S. economic innovation in the high-technology and high value-added pharmaceutical and biotechnology industries. For example, between 1982 and 2006, one-third of all drugs and nearly 60 percent of promising new molecular entities approved by the FDA cited either an NIH-funded publication or an NIH patent.[4]
- Gains in average U.S. life expectancy from 1970-2000 were worth an estimated $95 trillion.[5]

IMAGINE THE FUTURE

If our nation is bold enough to act today upon the many unprecedented opportunities now offered by biomedical research, we may be amazed at what tomorrow will bring.

In the world I envision just a few decades from now, we will use stem cells to repair spinal cord injuries; bioengineered tissues to replace worn-out joints; genetic information to tailor health outcomes with individualized prescriptions; and nanotechnology to deliver therapies with exquisite precision. I also dream of a day when, in ways yet to be discovered, we will be able to prevent Alzheimer's, Parkinson's, and other diseases that rob us much too soon of family and friends.

Just imagine what such a future would mean for our nation and all humankind. This is what keeps NIH in the research marathon, and why we ask you to go the distance with us.

Thank you Mr. Chairman. That concludes my formal remarks.

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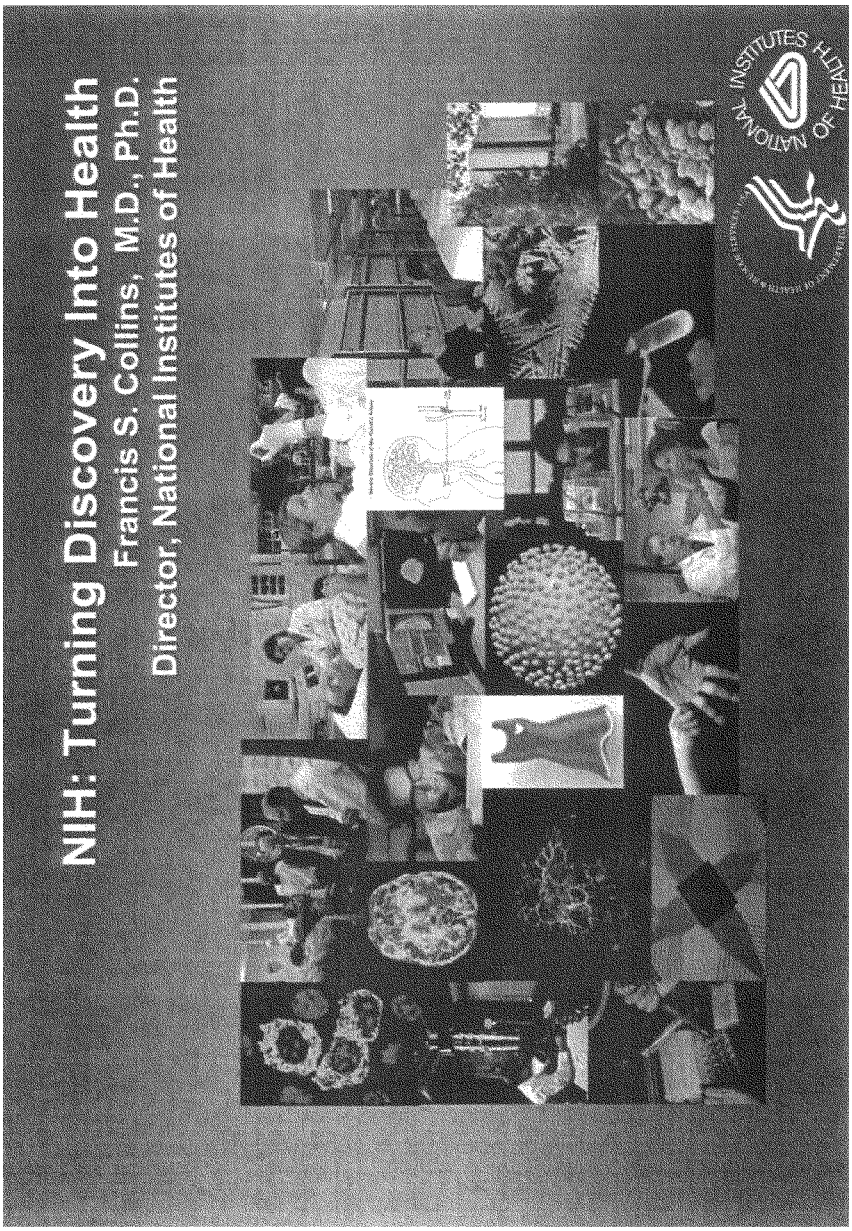
[1] FamiliesUSA (2008). In Your Own Backyard: How NIH Funding Helps Your State's Economy. Washington, DC. http://www.familiesusa.org/issues/global-health/publications/in-your-own-backyard.html

[2] McGarvey, W. E., P. Morris, et al. (2008). How Many Scientists Do the NIH Support? Improving Estimates of the Workforce. http://report.nih.gov/FileLink.aspx?rid=530

[3] FamiliesUSA (2008). In Your Own Backyard: How NIH Funding Helps Your State's Economy. Washington, DC. http://www.familiesusa.org/issues/global-health/publications/in-your-own-backyard.html

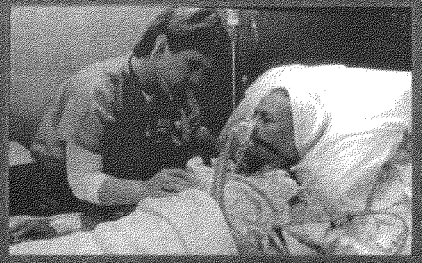
[4] Lichtenberg, F. R. and B. Sampat (2008). The Contribution of NIH-supported research to pharmaceutical-embodied technological progress. OSPA work. Unpublished—paper attached

[5] Murphy, K. M. and R. H. Topel (2006). "The value of health and longevity." Journal of Political Economy **114**(5): 871-904.


NIH: Turning Discovery Into Health
Francis S. Collins, M.D., Ph.D.,
Director, National Institutes of Health
NATIONAL INSTITUTES OF HEALTH

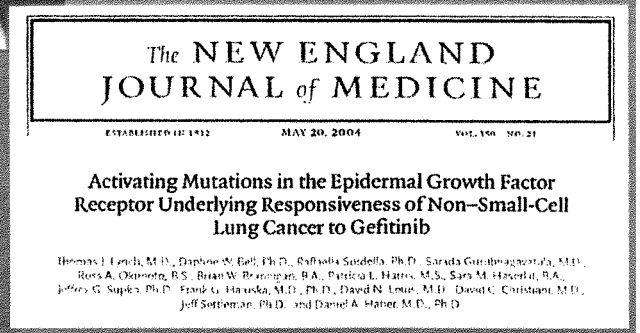
NIH: Steward of Medical and Behavioral Research for the Nation

"Science in pursuit of fundamental knowledge about the nature and behavior of living systems… and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability."



Kate's Story

- Diagnosed at age 44 with metastatic lung cancer
- Cancer spread after surgery, radiation, and chemotherapy
- Participated in a clinical trial testing Iressa™ (gefitinib), a new genome-based drug for cancer



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 20, 2004 VOL. 350 NO. 21

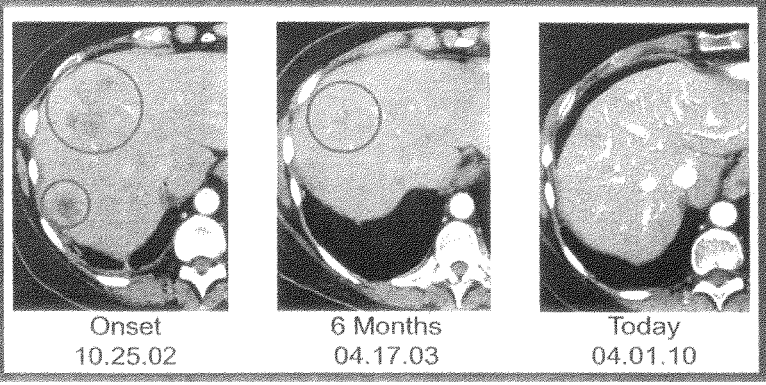
Activating Mutations in the Epidermal Growth Factor Receptor Underlying Responsiveness of Non–Small-Cell Lung Cancer to Gefitinib

Thomas J. Lynch, M.D., Daphne W. Bell, Ph.D., Raffaella Sordella, Ph.D., Sarada Gurubhagavatula, M.D., Ross A. Okimoto, B.S., Brian W. Brannigan, B.A., Patricia L. Harris, M.S., Sara M. Haserlat, B.A., Jeffrey G. Supko, Ph.D., Frank G. Haluska, M.D., Ph.D., David N. Louis, M.D., David C. Christiani, M.D., Jeff Settleman, Ph.D., and Daniel A. Haber, M.D., Ph.D.

Personalized Cancer Treatments

- Kate's metastases shrank; now undetectable in lungs, liver, pancreas
- Why doesn't Iressa work in all cases?
  - Response depends on specific mutation in *EGFR* gene
- Demonstrates the potential of personalized medicine

CT scans showing response of liver metastases to Iressa



Corey's Story

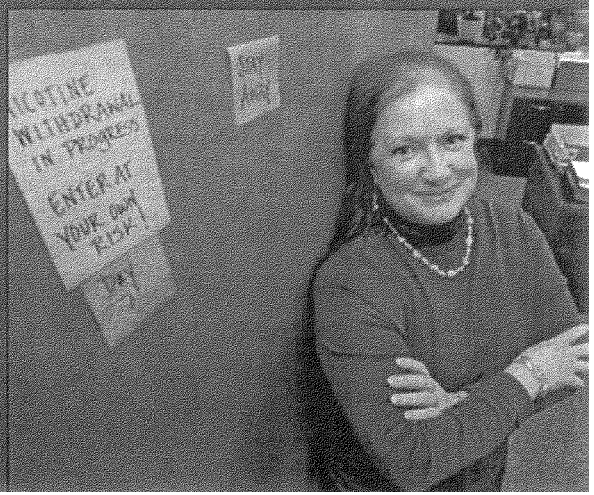
- Leber's congenital amaurosis is caused by a mutation in the *RPE65* gene
- Corey was legally blind by age 7
- Gene therapy procedure was performed in one eye
- Corey's eyesight is returning

Using the untreated eye

Using the treated eye

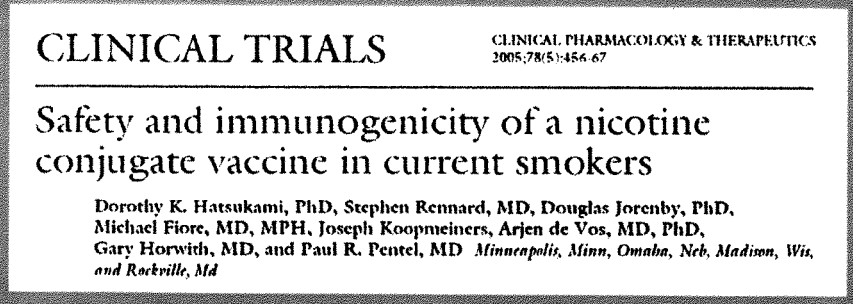
Leslie's Story

- Tried to stop smoking a number of times
- Four years ago, she enrolled in a NicVAX Phase 2 clinical trial …
  - Stimulates production of antibodies to nicotine
  - Bound nicotine cannot enter brain, subverting rewarding effects
- Leslie's results: "To this day, I haven't smoked a cigarette since. I don't want one."



NicVAX Phase III Trial

- Involves 1,000 smokers at 20 centers around the U.S.
- NIH Recovery Act funds ($10 million) are helping pay for the trial
  - Vaccine rooted in NIH-funded basic research
  - First-ever phase III trial of a smoking cessation vaccine



CLINICAL TRIALS

CLINICAL PHARMACOLOGY & THERAPEUTICS
2005;78(5):456-67

Safety and immunogenicity of a nicotine conjugate vaccine in current smokers

Dorothy K. Hatsukami, PhD, Stephen Rennard, MD, Douglas Jorenby, PhD, Michael Fiore, MD, MPH, Joseph Koopmeiners, Arjen de Vos, MD, PhD, Gary Horwith, MD, and Paul R. Pentel, MD *Minneapolis, Minn, Omaha, Neb, Madison, Wis, and Rockville, Md*

POLICYFORUM

1 JANUARY 2010 VOL 327 SCIENCE www.sciencemag.org

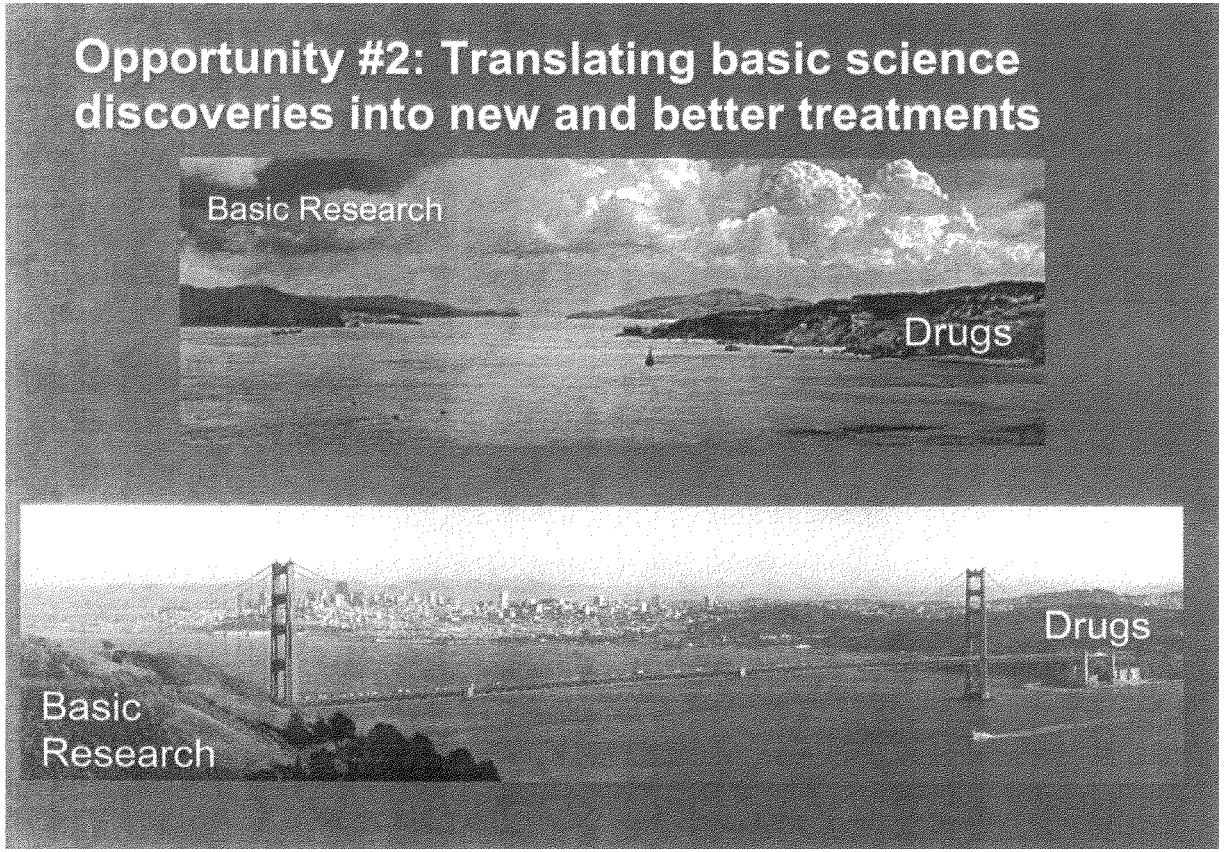
RESEARCH AGENDA

Opportunities for Research and NIH

The promise of fundamental advances in diagnosis, prevention, and treatment of disease has never been greater.

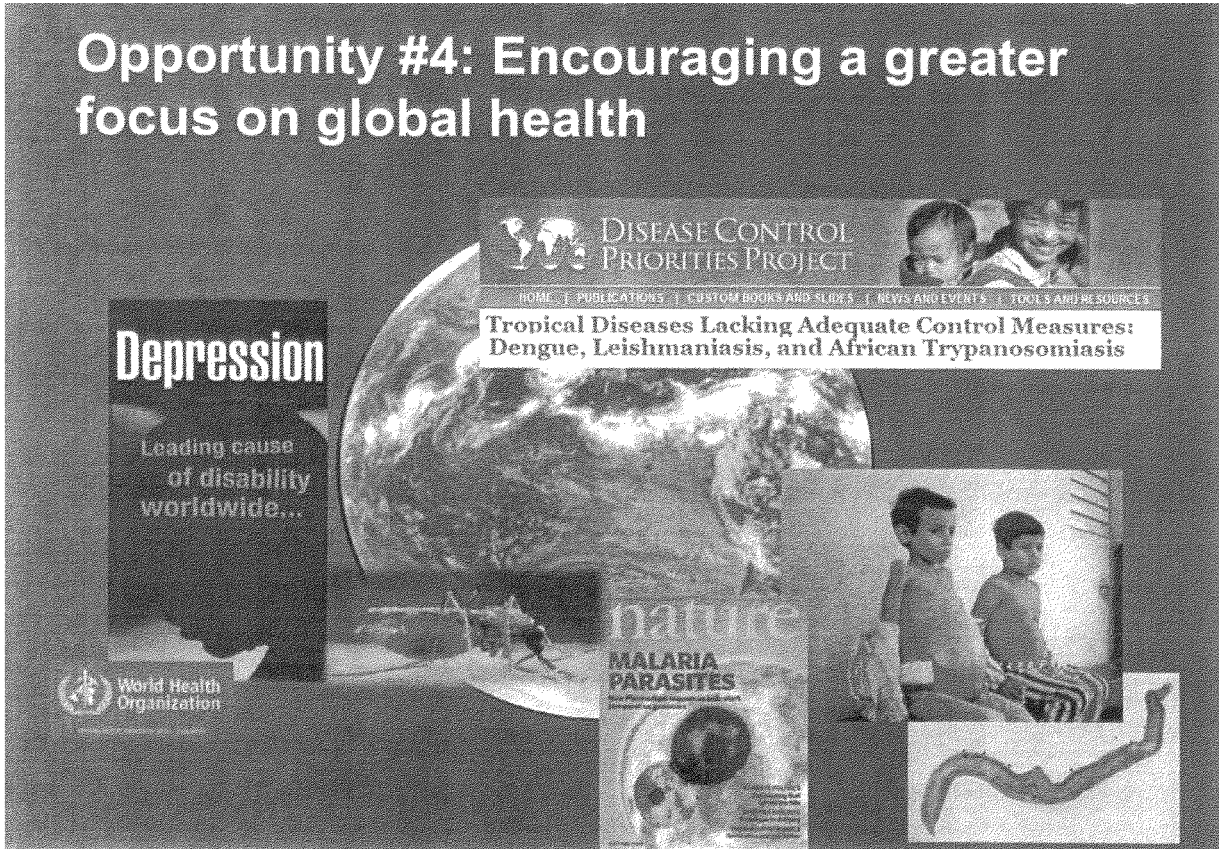
Francis S. Collins

Opportunity 1: Using high throughput technologies to understand fundamental biology, and to uncover the causes of specific diseases

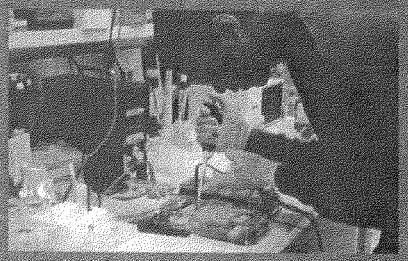

Opportunity #2: Translating basic science discoveries into new and better treatments
Basic Research
Drugs
Drugs
Basic
Research

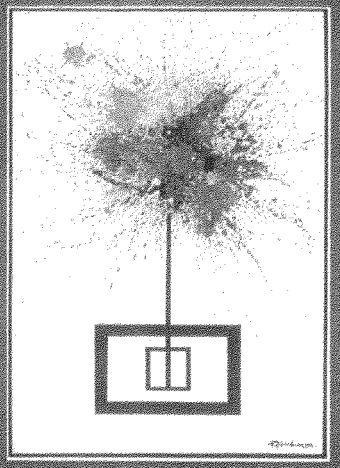
Opportunity #3: Putting science to work for the benefit of health care

Opportunity #4: Encouraging a greater focus on global health

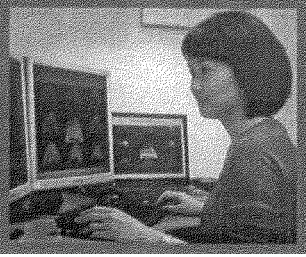


Opportunity #5: Reinvigorating and empowering the biomedical research community



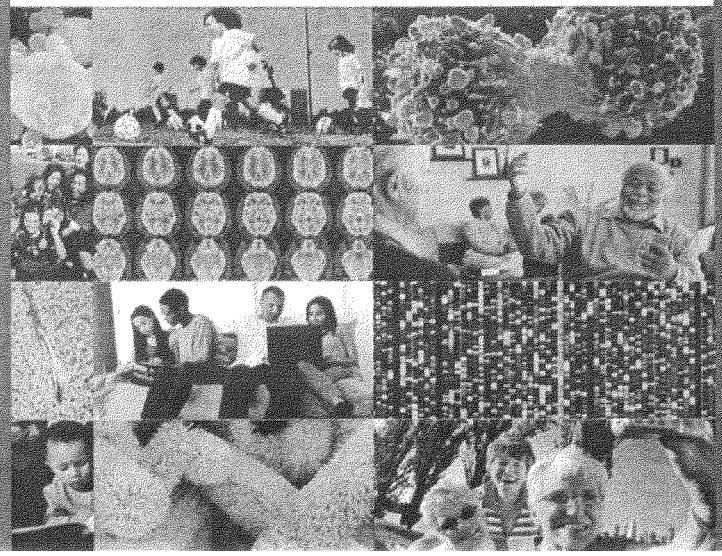


Great projects
outside the box



NIH...
Turning Discovery Into Health

U.S. Department of Health & Human Services
National Institutes of Health



Mr. OBEY. Thank you.
Mr. Tiahrt.

COMPARATIVE EFFECTIVENESS RESEARCH

Mr. TIAHRT. Thank you, Mr. Chairman.

Just reading on personalized medicine in this new publication here. I think one of the concerns I have had with the comparative effectiveness money that we have invested is that the good side of comparative effectiveness is we see what works and we communicate it well to physicians and clinics and hospitals and treatment centers. The part that concerns me is that when we start placing a dollar value on comparative effectiveness, that at some point we start making decisions based on costs that start rationing some care, rationing some treatments.

And I think, during this health care debate that we have had over this past year and a half, that that has been part of the topic. Can you kind of give me some confidence that what we are doing at NIH now through comparative effectiveness research is not going to lead to rationing in the future.

Dr. COLLINS. So, Mr. Tiahrt, I understand the concern. I think when we look at the kinds of research that NIH has done in the past and are planning to do now, the goal really is here to identify interventions that may be more effective and others that are less so, because evidence has to be valuable in making decisions about how we are going to put together a health care system that actually works.

I might even ask my colleague, Dr. Rodgers, to tell you briefly about the Diabetes Prevention Program, the DPP, as an example of a comparative effectiveness research study that taught us something really important about how to prevent diabetes and which is now being implemented across the Country in a new and exciting way by United Healthcare.

So, Griff, do you want to say a word about the DPP?

Dr. RODGERS. Be very happy to.

The Diabetes Prevention Program was a landmark study that was started over 10 years ago involving the NIH, the Centers for Disease Control and Prevention (CDC), and multiple institutes within the NIH, to identify those patients who are at high risk of developing diabetes. In this country, at the moment, there are about 24 million Americans who suffer with diabetes, but there are 57 million Americans who are at high risk of developing diabetes based upon family history, racial and ethnic groups, the fact that they may be overweight or obese. And clearly we are understanding now that a lot of this has to do with the susceptibility genes for diabetes.

This intervention, which was a comparative effectiveness study, involved patients being treated with just general instructions, a so-called placebo group; a second group with a standard therapy for diabetes, Metformin; and a third group with an intensive lifestyle modification. In these over 3,000 patients that were studied, there was about a 58 percent reduction in the risk of patients who are at high risk for developing diabetes who underwent this intensive lifestyle modification over the period of time.

That study was published in 2002, but just last year a follow-up study to that DPP, called the Outcome Study, was published which shows that there is an ongoing effect, even as long as 10 years. Patients who were randomized in this intensive lifestyle still maintain the ability to prevent or delay the onset of diabetes.

Now, in a clinical research study, of course, we required one-on-one counseling with these individuals, but it was clear that in order for this to be effective, we had to figure out a way to make it more reasonable and cost-effective. So we turned to the YMCA to do a translational study to determine whether—because, of course, YMCAs exist in all communities. We have estimated that most individuals in the U.S. live within a five-mile radius of the YMCA, and we wondered whether, rather than doing this on a one-on-one basis, if we do it in a group basis, whether we can cut the cost. In fact, we did. The cost for implementing this intensive lifestyle was reduced from the thousands down to $300 with the same effect.

Mr. TIAHRT. Is that the dues at the YMCA?

Dr. RODGERS. I am sorry? Yes. That is right. I have to say that this study was so effective, our colleagues at CDC got involved, expanded beyond the Indiana center that we initially funded, and just two weeks ago United Healthcare have, for the first time, decided to provide coverage for the use of this intervention at Ys and similar places to all of its members. Initially in six cities around the Country, but in fiscal year 2011 they plan to roll this out nationwide.

Mr. TIAHRT. That is good, because diabetes is one of the leading causes for many things—amputation, blindness, heart disease.

Dr. RODGERS. Absolutely.

ADULT AND EMBRYONIC STEM CELLS

Mr. TIAHRT. One last question here, because my time is short. There are basically two kinds of stem cells—there is the adult and the embryonic—and you have come up with a third from skin cells that you can engineer. Can you tell me what the results have been as far as research? Which category has yielded the most results as far as getting cures available for people?

Dr. COLLINS. Well, we are very interested in the research on stem cells and, of course, that is a very much discussed topic. Adult stem cells, as they are called, have been around longer and certainly bone marrow transplants, for instance, depend upon the idea that there are stem cells in the bone marrow that can expand and repopulate when needed. So we have the greatest clinical experience because that kind of study has been around for quite a while.

Human embryonic stem cells have only been around for about 10 years, and because of the concerns about safety and also some limitations in terms of who had the authority to work with those cells, we are not yet in a position of really knowing what their therapeutic potential might be, although many people are quite excited about that potential based on animal studies. There is so far only one Food and Drug Administration (FDA) approved trial for human embryonic stem cells, and that is for spinal cord injury, and it is too soon, by far, to know how that is going to turn out.

The most recent type, as you mentioned, derive from skin cells, the so called induced pluripotent stem cells, or iPS cells, are even much newer on the scene. Only about three years ago Shinya Yamanaka came up with this amazing observation that with just four genes you could take a skin cell and convince it to be pluripotent.

The potential here is enormous, because that would mean these cells came from the individual, so they could potentially be used therapeutically without rejection by the immune system. But there are many concerns about safety, because pluripotent cells are also capable of growing when you do not want them to, and can even cause tumors. So we have to work that safety issue out very carefully before even beginning to propose a clinical trial. But I think there is a lot of excitement about getting there.

I have just recently initiated an Intramural iPS Cell Center at NIH to try to accelerate our study of these cells and the way in which they could be used in therapeutics.

Mr. TIAHRT. Thank you.

Thank you, Mr. Chairman.

Mr. OBEY. Ms. Lee.

SICKLE CELL

Ms. LEE. Thank you very much, Mr. Chairman.

Let me first thank you all for being here again and just say how important we all recognize and know that your work is at NIH. Following up on the issue that we have discussed, I think most of you were here on the A1C diabetes public awareness campaign. I wanted to see, Dr. Rodgers, if you had any kind of results, feedback from what took place.

Just a bit of background. We learned—and I learned and we brought it to this Committee—and thank you for following up on this—that people who have the sickle cell trait, oftentimes the A1C test for diabetes gives or could give a false result, a false positive, false negative. So we developed a public awareness campaign to let physicians, labs, and what have you, and community clinics know that there are other tests.

So I just want to see how that public awareness campaign developed, what were the results, and also could you clarify the whole issue around sickle cell testing? Is sickle cell testing required at birth? I know it is no longer required when people apply for a marriage license, for what that is worth. So how do we make sure that people are aware that they have the trait or, well, the disease or prone or susceptible to the disease?

Dr. RODGERS. Thank you. Let me answer your second question first, and that is related to is it required to test for sickle cell disease. These are really done on a State-by-State basis, and it is my understanding that most States do now test at birth for the presence of the sickle cell protein. It can be done very easily, using blood samples to detect either sickle cell trait or sickle cell disease. When there are problems, the infant is called back and confirmatory tests are done. It is my understanding that most States currently do testing, but I would have to——

[The information follows:]

SICKLE CELL TESTING

Sickle cell (SC) disease testing is now universally required. Because of the testing used, "carrier status" is determined. While all states do report our carrier status to the responsible physician, where it goes from there (if anywhere) is highly variable, depending upon state and physician practice. In reality, it is likely a relatively small proportion of parents who are actually informed if their child is an SC carrier.

Ms. LEE. And how are adults reminded of that test result when they become adults? How do they know that? How does that follow the adult in terms of their medical records?

Dr. RODGERS. Right. Well, that is something that is certainly, with electronic health records and the ability to follow that as patients move from doctor to doctor and clinic to clinic would be very important. I would have to get information on how that is followed comprehensively. I am sort of aware of this from a limited number of experiences that I have, and I can certainly provide that information to you with our sister organization, the National Heart, Lung, and Blood Institute.

[The information follows:]

SICKLE CELL RESULTS

There is at present no system in place that ensures the orderly transition of health care information for an individual throughout his or her lifespan. Individuals diagnosed with sickle cell disease would ordinarily be aware of their diagnosis and in late adolescence the ongoing care of the child would be transferred from a pediatrician to either an internist or adult hematologist.

The maintenance of information on being a carrier of sickle cell disease is a responsibility shared by an individual, his or her family members, and the team of health care providers.

But back to your first question, and that relates to hemoglobin A1C. That is a very vital test that shows what the average level of blood sugar control is over the preceding three months. When we testified several years ago, you raised our attention to the fact that many patients are receiving this test done in the office and they may have sickle cell trait, and that is a confounding variable, and, as a result of that, we did develop this public awareness campaign, and in no small part due to that most of the tests that are done are now in compliance with the understanding that there is interference of the sickle cell and other genes that can cause a problem.

So essentially all of the commercially available testing for A1C is done using systems that can—that having an abnormal hemoglobin is no longer problematic.

Ms. LEE. Thank you very much.

Mr. Chairman, let me just say to the Committee that this was very important because so many people I know—family members, friends, people in especially communities of color—there were a lot of people who had false positives because of the fact that they had been tested with the wrong test, and did not even know they had the sickle cell trait. So this was a very important effort that started in this Committee, and I just wanted to thank you all for that.

And I am glad to hear now that they have changed the testing now is clear in what to do and look forward to your report back on the sickle cell trait, because I know a lot of people who I just talk to and say, look, do you have the sickle cell trait, and they say we do not know, and will ask their doctor to test them and, lo and behold, they have the trait, which, of course, means certain kinds

of medical tests would not be valid or they need to do certain things in terms of their health.

But unless you follow from birth in the States that do do the testing and somehow people know as an adult they have the trait, they get in a lot of trouble. So we need to really figure out how to make sure that that happens, because most people I know, especially most African-Americans, do not ask their doctor to test them for the sickle cell trait.

Thank you.

Mr. OBEY. Mr. Lewis.

FISCAL YEAR 2011 FUNDING

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

Gentlemen, very much appreciate your presence here today. The Chairman has appropriately outlined the pattern of funding for NIH over time. There is a piece of that that concerns me. You know, beauty lies in the eyes of the genuflector, and with NIH funding we had a very significant increase in the 2009 fiscal year as a result of the stimulus package. I have some questions about that, but, most importantly, I am concerned that even though the President's budget has a $1,000,000,000 adjustment, if you take where we were in 2009 and that dollar amount, one could argue that there is an $8,000,000,000 reduction, if real value came from that stimulus funding.

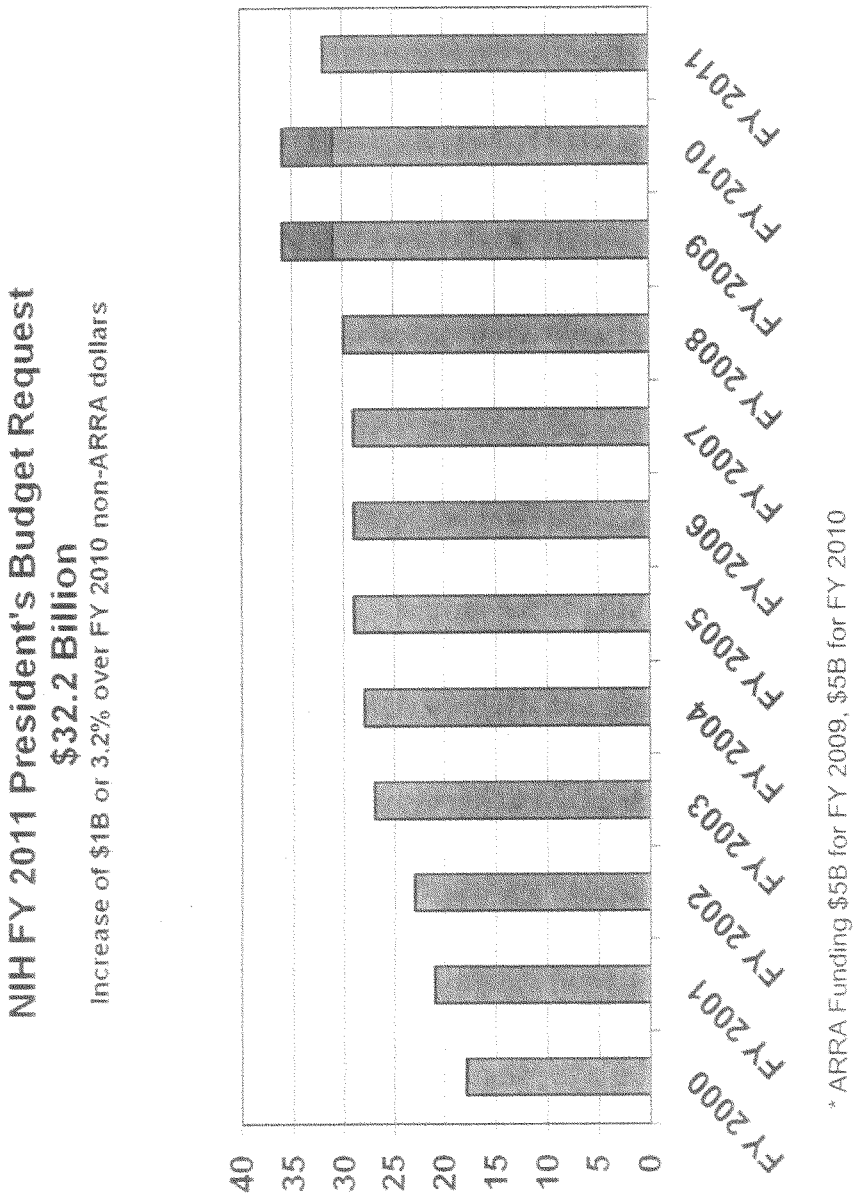
So I would like to have some commentary regarding that and how you have budgeted to try to deal with that adjustment, if it remains as a part of our pattern, and very much be interested in knowing—maybe Dr. Fauci would like to respond to this piece of it.

There has been consistent adjustment also for Labor, Health and Human Services across the board, with a similar big adjustment in 2009. If I were looking at those adjustments and readjusting budgets, I would make sure that continuing funding flowing to NIH would have very high priority in those considerations. There is a broadly based nonpartisan support for research, applied research as well as the basic research. Lots of discussion that is healthy, pushing you to get more in the direction of the applied research, but, nonetheless, we need to preserve this nonpartisan environment in this Committee and otherwise.

So if you would start with that, Dr. Collins, I would appreciate it.

Dr. COLLINS. Mr. Lewis, I appreciate the question and I do appreciate the strong bipartisan support for medical research that has characterized the actions of this Subcommittee for many years. The diagram that you see on the screen there shows you what the total funding allocated for NIH has been over the course of the past decade, and, as you can see, after a period of flat funding from 2003 to 2008, with only modest increases, then, as shown in red, the Recovery Act dollars, $10.4 billion, were given to NIH, but obviously as a two-year enterprise, so roughly $5 billion each year.

[The information follows:]


NIH FY 2011 President's Budget Request
$32.2 Billion
Increase of $1B or 3.2% over FY 2010 non-ARRA dollars
40
35
30
25
20
15
10
5
0
FY 2000
FY 2001
FY 2002
FY 2003
FY 2004
FY 2005
FY 2006
FY 2007
FY 2008
FY 2009
FY 2010
FY 2011
* ARRA Funding $5B for FY 2009, $5B for FY 2010

And the budget is here shown for fiscal year 2011, and I think you can see the delta there, and, in fact, this is the cliff that people are talking about, because effectively in fiscal year 2010, if you include the Recovery Act dollars, the total funding that NIH has had available is $36 billion. What is proposed in the President's budget is $32 billion.

Now, let me say that given the very difficult economic times, the President's support of science and the willingness to put forward a $1 billion increase for NIH is reflective of the Administration's strong support for research and what it can do, and we are deeply grateful for that, because certainly it could have been justified, at a time of growing deficits, to be even more conservative here in terms of providing support for this.

So the $1 billion is certainly something we are delighted to see come forward, although it is a dollar figure which basically matches the inflationary index for biomedical research, just about 3.2 percent.

We were aware that this might be an outcome. What we have tried to do—although I would not tell you that we are going to be completely successful in reducing the consequences of this cliff—certainly some of the money funded by Recovery Act has been for one-time expenditures, special equipment needs, for instance, that universities across this Country have been clamoring for years during the flat funding; construction grants also to help those universities and institutes build up their physical plant or to do some renovations that are badly needed.

We have tried to fund special projects that we thought could get done in two years. The Cancer Genome Atlas, which went from a pilot phase into a full-bore assault on understanding cancer, and which, with that accelerated funding, will tell us in two years the basic landscape of cancer for the 20 most common cancers at the DNA level, a dramatic series of advances.

But we also funded a lot of innovative grants. We invited investigators out there to come forward with their best ideas, and they came forward in great numbers with exciting, innovative stuff. When I arrived at NIH in August, one of my first tasks in those first few weeks was to read a lot of these grants that came forward asking for support from the Recovery Act, and these were really exciting, innovative, many from investigators that had not previously come forward to NIH.

But science is, as I said in my opening statement, not a 100-yard dash, it is a marathon, and two-year cycles are really not the way that advances occur. So we are going to face a crunch in fiscal year 2011. We will be, I think, gracious to investigators who were funded during the Recovery Act for two years and who asked could they please have a no-cost extension for a third year. We will probably, with good justification, be willing to do that in order to try to smooth this out a bit.

But there is no question that if you measure what happens in terms of success rates, that is, what is the chance that an investigator who sends a grant in to NIH is actually going to get funded, that is going to be a tough number in fiscal year 2011. That number used to be, back in the course of the last 30 years, around 25

to 35 percent. That was the success rate for grantees. It has trickled down more recently to 20 percent.

Our predictions are that in fiscal year 2011, with this budget number, it will be more like 15 percent, one grant out of every.

Mr. LEWIS. Dr. Collins, your response has taken up my time, but——

Dr. COLLINS. I am terribly sorry.

Mr. LEWIS [continuing]. In the meantime, I would hope, as you see some of those vacuums or difficulties, that you and your people, Dr. Fauci, would keep very much in touch with this Committee so that we can try to be responsive in ways that will accelerate those opportunities.

Dr. COLLINS. Will do.

Mr. OBEY. Ms. Roybal-Allard.

PANCREATIC CANCER

Ms. ROYBAL-ALLARD. First of all, let me thank you all for being here and for the really important work that you do. However, I have had some concerns with regards to NIH's lack of responsiveness to this Committee on two particular issues.

As you are aware, pancreatic cancer is the fourth most deadly type of cancer, with survival rates that have remained largely unchanged for the last 40 years. Yet, despite its lethal prognosis, only about 2 percent of the Federal cancer research budget continues to be devoted to pancreatic cancer. Recognizing the seriousness of pancreatic cancer, this Subcommittee requested, in fiscal year 2009, in the appropriations report, that the National Cancer Institute give a detailed account of what it would do to increase research and training on pancreatic cancer.

When that request was completely ignored, the Subcommittee, in fiscal year 2010, again made the request for a plan to address pancreatic cancer. The NCI once again ignored the request and has no plan, and we are being told now that there is going to be a meeting held in the future to address pancreatic cancer.

Since the Subcommittee has always chosen to respect the integrity of the scientific community by not directing funds or micromanaging NIH's activities, short of doing that, what does the Subcommittee have to do to get NIH to respect the requests of this Subcommittee and respond to an issue as important as pancreatic cancer?

Dr. COLLINS. Congresswoman, I was unaware, until this moment, of this lack of responsiveness to that specific request about pancreatic cancer, and I would promise to give it my personal attention. Pancreatic cancer is a particularly lethal and very devastating type of cancer about which, as you point out, progress has been rather limited.

We do have some, I think, exciting opportunities on the horizon, particularly trying to understand at the detailed molecular level what are the first steps that cause pancreatic cells to begin to grow into a cancer and what might we do in terms of developing early detection methods based upon that, because that is obviously much of the problem, is not detecting this disease until it is already far advanced; but, most importantly, to develop new treatments that

are targeted towards those specific pathways that seem to drive this cancer.

Again, the Cancer Genome Atlas will provide that kind of information for our 20 most common cancers, and that includes pancreatic. But I am distressed that you feel that this Committee has not been answered in the requests you have made about this, and I will personally look into that. I will tell you that in the relatively near future we anticipate that a new Director of the National Cancer Institute will be named by the President, and I will be certain, if that happens, that this concern of yours is conveyed.

CLASS B DEALERS

Ms. ROYBAL-ALLARD. I would appreciate that. Thank you.

One other area of concern has been the use of Class B random source cats and dogs for NIH-funded research. We were pleased when NIH stopped purchasing dogs from Class B dealers for use in intramural research, but remain concerned that the practice still continues in some of the extramurally funded NIH research. So last year, once again, this Committee, in their report, asked NIH to submit a detailed plan for phasing out random source cats and dogs and extramurally-funded research. Again, NIH has ignored this Subcommittee's request and we have seen no plan.

So my question to you is how much progress has been made towards phasing out this practice and has NIH identified all current NIH-supported extramural projects using Class B dogs and cats? And, if so, how many? Also, does NIH have a plan that we have not seen for implementing a phase-out of the use of dealers by its grant recipients?

Dr. COLLINS. Congresswoman, again, I am sorry that this response has not been forthcoming in a timely fashion. I know it was due on April 1st. I can tell you that it is very close to being finalized; we wanted to be sure that we had answers to all of those questions. I can tell you the substance of the response will be that, yes, NIH is making a plan to phase out the use of Class B dealers for animals.

It is not possible to do that overnight because the needs for animals that currently have been coming from Class B dealers for cardiovascular research and transplant research would be injured rather badly if we did this in a precipitous way. But we will transition over the period of roughly three to four years into a circumstance where we no longer depend upon Class B dealers for animals, and we arrange to have the breeding Class A suppliers fill that need.

Again, that report should be coming forward to you very soon.

Ms. ROYBAL-ALLARD. Thank you. Appreciate that.

Mr. OBEY. Mr. Rehberg.

BREAST CANCER MAMMOGRAPHY GUIDELINES

Mr. REHBERG. Thank you, Mr. Chairman.

Welcome. I always feel like apologizing to somebody with your talent and credentials. And you have entered into the political realm of our world, so I guess my questions probably will be a little more political from the perspective of the comparative effectiveness research that we were talking about before.

While this organization is not necessarily under your purview, the U.S. Preventive Services Task Force, they have certainly created perhaps a firestorm within the breast cancer community, and I would like you to talk a little bit about your own concept of personalized medicine as it relates, then, to some of the comparative analysis that you are going to be doing within your research, because I will just use breast cancer as an example.

This was in the New York Times, an influential group, the one I referred to, provides guidance to doctors, insurance companies, and policy makers, and they have now made the recommendation that mammograms do not need to occur until 50, as opposed to 40; and that was wildly hailed as a step forward by the National Cancer Institute, National Breast Cancer Coalition, Breast Cancer Action, National Women's Health Network welcomed the new guidelines, and, of course, the insurance companies will take that as, well, I guess we do not have to cover that until they are 50. Unfortunately, on the other side are the American Cancer Society and the American College of Radiology.

So a fight has been created that will probably rage on for quite some time. How are you working or how do you intend to keep those kinds of food fights out of NIH? Because it has the potential of creating a lot of politics for you in an arena that research and science should not have politics.

This is just one example, and it is the most recent example of something that is going to occur as a result of something similar to the comparative effectiveness research that is going on.

Dr. COLLINS. Well, Congressman, I appreciate the question and this certainly is an example where those recommendations from the USPSTF on mammography created quite a firestorm of controversy. Specifically, NIH is not in the business of establishing practice guidelines, for the most part, and in that instance the National Cancer Institute stayed out of the fray, basically. Our role is to provide the kind of data that might allow the establishment of guidelines that improve outcomes, and that is something that we are very determined to do.

When it comes to the mammography guidelines, I think you brought up the issue of personalized medicine. Perhaps the path forward here is for us to be more clear about how to utilize individualized information to make better predictions, because while there may be women who are not going to be benefitted by a mammogram in their 40s because they are at very low risk, there are others who are at higher risk for whom that is a highly appropriate procedure.

The Task Force recommendations touched on that, but we did not have enough data to actually be able to say how do you factor that in. That would be one of the things that NIH very much wants to work on.

FUNDING FOR COMPARATIVE EFFECTIVENESS RESEARCH

Mr. REHBERG. I feel very comfortable with your credentials. You are probably the right person at the helm of NIH at a time when we are spending a lot of money on this kind of comparative research. But the problem is—or not necessarily a problem—I do not want to create a problem—have you created an objective conclusion

for the various research? You are spending $400,000,000 on this kind of research, but if it does not come to a conclusion, all it does in this kind of a case is create more confusion in the minds of the patient, the poor 41-year-old woman who does not know what to do now.

And again I go back to this is an influential group that is now making a recommendation that provides guidance to doctors, insurance companies, and policy makers. So are you going to have $400,000,000 worth of confusion created at NIH similar to this, which is what this has done?

Dr. COLLINS. Well, we certainly do not want that outcome, Congressman, and, again, the mammography circumstance had data that fed into it from a variety of perspectives, much of it not supported by NIH.

If you look at our comparative effectiveness research portfolio, what you see are things like the Diabetes Prevention Program that Dr. Rodgers described. Now, there is an example where we learned by rigorous data analysis that in fact an intervention to prevent diabetes—which many people were not that convinced was going to work—worked spectacularly, and it worked better than the alternatives that are commonly used in practice, and that is now——

Mr. REHBERG. Okay, so you will stay out of this controversy and anything else that is controversial?

Dr. COLLINS. No. No, not at all. No, I am not trying to say that.

Mr. REHBERG. Well, then what would be your conclusion here? Are you going to back the——

Dr. COLLINS. My conclusion is that NIH's role is to do research that generates rigorous evidence that can guide conclusions that are based upon data, and we will do everything we can to provide that kind of data to guide those organizations outside of us that are going to try to decide what is right for the individual as far as their health care.

Mr. REHBERG. So you are going to pick a fight.

Dr. COLLINS. We are going to try to——

Mr. REHBERG. Because you are going to provide data to both sides and then step back and watch them duke it out.

Dr. COLLINS. I think we believe that data that is based on evidence and reason is a good thing to add to any discussion, and we hope to be the providers of that.

Mr. REHBERG. Thank you, Mr. Chairman.

Mr. OBEY. Ms. McCollum.

PRIVATE SECTOR INNOVATIONS FROM NIH INVESTMENTS

Ms. MCCOLLUM. Thank you, Mr. Chair.

I think what I heard clearly you said is that more research needed to be done so that people could make a better informed decision between doctor and patient, and that is your goal and your focus.

Dr. COLLINS. Well said.

Ms. MCCOLLUM. Thank you for that.

Mr. Chairman, members of the Committee, I see NIH as a public good. Like highways and clean waters, NIH is a benefit to our entire society. Those benefits are widespread, long lasting, and not always immediately profitable, where we see immediate return. That is why private business does not do and cannot often make the in-

vestments that NIH makes. So funding for the public good is one of the most important functions that the Federal Government has, and I think you gave us some excellent examples in the three patients that you provided, and I know you have hours and thousands, tens of thousands of success stories.

So the investment that this Committee is getting ready to make in the NIH are not only critical to the health of our citizens, but they also contribute to the growth of our economy.

Dr. Collins, I am going to take a little different track in some of the questions I am going to ask you and the panel here today. In your testimony, you state that every $1 of NIH funding directly results in more than $2 in economic output. The indirect and long-term benefits from NIH investments are greater, and I would like you to talk a little bit about that this morning.

So could you please tell us how investments in NIH lead to private sector innovation, both directly and indirectly? Where would the drug industry, the medical device sector, or any of the other major aspects of the U.S. health care sector be without the basic research that is supported by NIH?

Thank you.

Dr. COLLINS. Thank you for the question. And we do believe that by medical research investments at NIH are, besides being a wonderful stimulus of advances in health care, also a wonderful stimulus of the economy, and the evidence is very compelling for that.

Economists agree that American economic growth since World War II, more than half of that has been driven by science and technology. And if we are looking for an occasion to try to get our economy back on track, this sort of economic investment makes a lot of sense.

You quoted the direct effects of NIH investment, this more than twofold multiplier effect in one year. But if you look at the indirect effects in terms of our interactions with the private sector, if you look, for instance, at the development of new drugs, roughly 60 percent of new molecular entities that are put forward by pharmaceutical companies for FDA approval cite an NIH publication or an NIH patent as being fundamental to how that came forward.

And if you look at the jobs in the biopharmaceutical sector that are directly, therefore, related to things that NIH has supported, that is 3.2 million jobs at the present time; and these are high-quality, high-paying jobs that we do not want to see go overseas instead of having them exist here.

If you look at the way in which investments are being made by the pharmaceutical companies in research, again, much of that based upon the foundation that NIH provides, that is $56 billion of research investments done by the private sector exceeding what NIH is putting in at a little bit more than half of that.

The whole landscape, then, I think you can see is very much triggered by this. Let me give you an example of a company called Affymetrix in California, which is the main purveyor now of these DNA chips which have become a revolution in research and in clinical practice. They are the reasons now that people can actually get personalized medicine readouts, as I have done myself. This was started on an NIH grant, as a single investigator with a great idea;

and here we are now with a company that has capitalized in the billions.

I could give you many more examples. But I think your point is extremely well taken. People think of NIH—and we are glad about that—as the place where new cures for diseases are being sought, but it is also a place where our economy is getting one of the best kinds of stimulus it could.

Ms. MCCOLLUM. Thank you, Mr. Chair. And I want to thank past members of this Committee for all the work they did in the genetic research that has led to the gene therapies that are out there now. If people were not willing on this Committee to invest in science, we would not only not have the cures, but we would find other countries getting far ahead of us in this technology and job creation field. So thank you, members.

Mr. OBEY. Thank you.

Mr. Cole.

PRIORITY SETTING FOR RESOURCE ALLOCATIONS

Mr. COLE. Thank you, Mr. Chairman.

Thank you for being here and thank you all very much for the work that you do; it is extraordinary.

A number of years ago our Congress passed the Caroline Price Walker Conquer Childhood Cancer Act and we authorized $150,000,000 a year for pediatric cancer research over a five-year period. We, as a Committee, never chose to fund that, to appropriate money for that purpose.

When you are confronted with a situation like that, where you have sort of congressional authorization on one hand, this Committee does not—because, frankly, I think it is very careful about trying not to interject itself into what are scientific decisions—how do you take something like that and balance it and make basic decisions? Or do you at all?

Dr. COLLINS. Well, it is a daily discussion that goes on amongst the NIH leadership about how to set priorities, Congressman, and it is not an easy task when we have so many opportunities and the resources are not sufficient to chase after all of them. A lot of this depends on scientific opportunity. Simply throwing money at a problem, even if it is a critical problem for public health, is not necessarily going to get you where you need to go; you need to see is there an idea here, is there a research project that could push the ball forward?

So we are always trying to both weigh public health needs, as well as scientific opportunities. We do not want to neglect rare diseases—and many pediatric cancers are rare—just because they do not affect that many people, because if it is your family where a child has been stricken with cancer, it does not matter a whole lot to you that that happens to be a rare disease.

With pediatric cancer, we have certainly adopted that as an area of great priority because of the terrible toll this takes on young people and their families. We have made great strides in many of these cancers that occur in children, but we have many others, particular solid tumors, for which we are not as successful as we would like to be.

The good news here is I think we have the tools—and this was sort of a couple of the themes that I talked about in my opening statement—both in terms of really laying out the landscape of why cancer occurs in children and accelerating the process of going from that understanding to a therapeutic; and that is moving forward at a pace that would not previously have been imaginable, and we are empowering academic investigators to take a larger role in the development of therapies, which, in the past, was largely left to the private sector. And for pediatric cancers that are rare, there is not much of an economic incentive to develop a new therapy if it is going to be risky. If academic investigators could de-risk the project, then it becomes more attractive.

The Cures Acceleration Network is another example of an authorized, but not yet appropriated, effort that I raised briefly in the opening statement that we are quite excited about because it would facilitate this process.

PEDIATRIC CANCER RESEARCH

Mr. COLE. Well, quite often our colleagues count on this Committee to protect them from themselves, so this may be one of those instances, I do not know.

Let me ask you a follow-up question. I have gotten two different sets of responses—and they are not dramatically different—on how much money is actually devoted toward pediatric cancer care. From Director Worzog I think we had a communication that suggested it was something like $215,000,000; from the NIC we got an estimate like it was $195,000,000. Do we have any idea what the range, relatively, of dollars devoted in this effort is?

Dr. COLLINS. I do not have the numbers in front of me, Congressman; I can certainly provide them for the record. We do now have a better method of tracking how NIH is spending its dollars than we have had in the past, something that got unveiled about a year ago. So we are able to tell you, I think, accurate numbers based upon our entire portfolio.

[The information follows:]

PEDIATRIC CANCER RESEARCH

NIH has not set its tracking system on disease spending to be able to capture estimates for childhood cancers or pediatric cancer research funding across all of NIH. However, these estimates are available for research funded by NCI. The estimated funding level in Director Orszag's letter reflects the NCI-projected FY 2010 funding level for pediatric research (approximately $215 million), which is a broader research category than childhood cancer alone, and includes research related to child health, childhood cancers, birth defects, multiple sclerosis, etc. In FY 2011, NCI expects to fund pediatric research at $233.7 million. NCI also projects funding in the category "childhood cancer research", which is a subset of pediatric research and includes only childhood cancer research (such as childhood leukemia and neuroblastoma). The National Cancer Institute (NCI) estimates it will spend $196.3 million in FY 2010 and $202.7 million in FY 2011 on childhood cancer research. This is the funding level that was provided in the recent NCI document. The key difference between these two categories of research is pediatric research is a broader category that includes research related to child health in general, whereas childhood cancer specifically deals with cancers affecting children.

NCI's Pediatric Research and Childhood Cancer Funding, 2007–2010

(dollars in millions)

Year	2007	2008	2009	2010 (estimate)
Pediatric Research	243.2	235.4	240.8	215.0
Childhood Cancer	172.7	189.7	192.9	196.3

Mr. COLE. That would be very helpful. I would really appreciate that. And particularly if you could trend-line is over several years, if that was possible, so we could sort of see relatively where we are headed.

Finally on this topic—and you have answered this partly, but I just want to give you an opportunity to add anything else you would like to—where do you see us going in pediatric cancer research over the next five or ten years?

Dr. COLLINS. I think it is going to be a very exciting time. We will have the ability to identify what are the basic molecular drivers of a cancer that occurs by analyzing hundreds of these tumors and figuring out precisely what has gone wrong; what has made a good cell go bad and have it start growing in this fashion.

I should say, by the way, there is a wonderful new partnership between St. Jude's and the Genome Center at Washington University in St. Louis involving $60 million of private philanthropic donations to make this go forward for pediatric cancers on hundreds of tumors.

We are going to, therefore, be able to say what are the targets for which we need magic bullets, and we should be able, in the next five or ten years, to transform our approach to pediatric cancer from the chemotherapies, which can be successful but which, as you know, are also quite toxic, into compounds that are much more directed, much more rational; more likely to be effective, less likely to be toxic.

Mr. COLE. Terrific. Thank you.

Thank you very much, Mr. Chairman.

Mr. OBEY. Mrs. Lowey.

FOOD ALLERGIES

Mrs. LOWEY. Thank you very much, Dr. Collins, Doctors all. I must say, having served on this Committee for many years, this is one of the most exciting hearings that we have, and I do wish we had hours, but we do not want to take you away from your important work, so let me just thank you for your service to the Country and to the people, and we look forward to continuing to increase the appropriations.

A few particular areas, first with food allergies. It is very frustrating, to those who suffer, that the only advice doctors can give now is do not eat certain foods. And as you probably remember, shockingly, it took me five years, five years to get legislation passed that mandated clear labels on food. But now at least allergy sufferers and celiac disease people call me and tell me how grateful they are that we have those labels on food.

So two questions. Allergies. I never had them until I got here to Washington. What progress are we making in understanding why the same amount of allergens has minimal impact on one person,

lethal to another? And we are any closer, Dr. Rodgers, to understanding why the number of children under the age of five who suffer from peanut allergies has grown so much between 1997 and 2002? Every school has peanut tables; many schools do not allow peanuts to be served. Perhaps you can respond.

Dr. RODGERS. We are going to redirect it.

Mrs. LOWEY. Wrong directions. Dr. Fauci.

Dr. RODGERS. I would be happy to talk about celiac, but let me turn to my colleague.

Dr. FAUCI. Thank you for the question. It is obviously very——

Mrs. LOWEY. How could I forget my good friend Dr. Fauci? I do not know. Yes.

Dr. FAUCI. It is very important, as you well know. Four percent of the people in the United States of America suffer from food allergy, peanut allergy being one of the most severe. Your question about the differences in individuals are clearly related to genetic predispositions. We do not know the exact genetic profile that would pinpoint someone who has a propensity, but clearly these are things that run in families, which strongly point to it being genetic factors, which, as Dr. Collins mentioned in many of his remarks related to other diseases, the more we get a better handle on the genomic basis of disease, the better opportunity we will have to do one of the things that Francis mentioned, more personalized medicine approach. And I think allergies and the response to allergies and the desensitization to allergies are going to very, very much fall into that category of personalized medicine.

The other question you asked is that why does it seem like we have more peanut allergy now than we had before. Well, the honest answer is we do not know. But we do feel that one of the issues that may contribute to it is that, because of the greater sensitivity in the community to the possibility of peanut allergy, more families are withholding peanuts and peanut derivatives from children early on in their lives, which, in our research projects now, we are finding that that might actually, if a person is not allergic to peanuts, have a paradoxical, deleterious effect, because some studies are showing now that when you give children, at a very early age, exposure to peanut, you naturally desensitize them to any allergy they may have. There is a very interesting Israeli study that shows that early exposures to peanuts actually wind up having a lesser incidence of peanut allergy as the child gets older.

So there is a lot of active research going on. We are very excited about it. We are getting new young investigators in the field, and I hope in a year or so we will be able to give you even more encouraging information.

PEDIATRIC DIABETES

Mrs. LOWEY. Thank you very much.

I was looking at you, Dr. Rodgers, because a group of children came to my office just this week who suffer from diabetes, and it is extraordinary to see the advances in treatment. Little children are taking care of themselves. But we are not preventing diabetes and we are not curing diabetes, and perhaps you can—I am not talking about adult onset diabetes; I am talking about those that

are affecting our children. Perhaps you can comment on the research there and what progress are we making.

Dr. RODGERS. Thank you. We are actually making extraordinary progress on the treatments for kids with type 1 diabetes, the type that you are referring to. In fact, just to back up to one of the points that you made. What we are learning a lot about diabetes, actually type 1 diabetes, which is an autoimmune disease in which the body, for unclear reasons, turns against these insulin-producing islet cells in the pancreas, are actually giving us clues to patients with celiac disease. They share many features. So what we are learning in this particular disease may also have implications in a disease that perhaps affects about one percent of the U.S. population, that is, celiac disease.

In diabetes, we are trying to—this is a disease that affects individuals who have a particular genetic susceptibility, and within the last few years the number of genes that account for this susceptibility has greatly increased. Today there are over 40 susceptibility genes, which account for more than half of the predilection for developing the disease, so what that means is that we can identify, early on, which kids are likely to develop type 1 diabetes and when.

Now, it is thought that there are triggers associated with this, and understanding what the environmental triggers are is extremely important. We have almost, very recently, completed a study, a recruitment of about 7,800 infants who have this high type 1 diabetes propensity to follow them for a period of 15 years to understand what it is in the environment that is leading to the disease is it something that they eat, is it something in the environment, et cetera?

And this work is going on with other work that is funded by the NIH in specific areas, for example, the National Institute of Child Health and Human Development (NICHD) is funding a study comparing the effects of hydrolyzed infant formula to that of cow's milk, because there are a number of people who believe potentially that cow's milk may be that trigger. And that work is proceeding quite well.

The NIH, in association with the CDC, has also, for the first time, developed a surveillance program to look for diabetes in youth. This includes both type 1 and type 2. But, importantly, having CDC's involvement, and because of their ability to do surveillance within States, we can better understand the clustering of type 1 diabetes that we are seeing. This may point to specific triggers in certain locales. And this is just in the surveillance. I can provide you more, because I see my time—

[The information follows:]

PEDIATRIC DIABETES

If we find the trigger, we may be able to develop a vaccine or implement a change in diet that can prevent the disease. In addition to research to uncover the genetic and environmental components that contribute to the cause of type 1 diabetes, the NIH is pursuing research to prevent, treat, and one day cure type 1 diabetes. For example, Type 1 Diabetes TrialNet tests strategies for type 1 diabetes prevention and early treatment. TrialNet recently reported that the drug rituximab could preserve the function of the insulin-producing beta cells in people newly diagnosed with type 1 diabetes. Previous clinical trials have suggested that preserving patients' remaining beta cell function can have dramatic, long-term health benefits. TrialNet has also launched a trial testing the ability of another agent, oral insulin, prevent

the disease in people who have high levels of insulin autoantibodies, a pre-clinical marker of the disease. TrialNet also has two other prevention trials that will launch soon or are under development.

An earlier, landmark NIH-supported clinical trial showed that improved control of blood sugar beginning as soon as possible after diagnosis can greatly improve the long-term prognosis of type 1 diabetes and result in reduced rates of life-threatening diabetes complications. This research has contributed to the fact that people with type 1 diabetes are living longer and healthier lives than ever before. However, blood sugar control is not always easy and even the most vigilant patients are at risk for sudden, acute episodes of dangerously low or high blood sugar levels. The NIH is deeply committed to helping patients achieve good blood sugar control and is taking two approaches to realize this goal: beta cell replacement and development of an artificial pancreas. With respect to beta cell replacement, the NIH supports the Beta Cell Biology Consortium (BCBC), which is studying ways to grow beta cells in the laboratory for transplantation into people and examining strategies to promote new beta cell formation in the pancreas. BCBC scientists are gaining key insights about beta cell biology and development, which is paving the way toward new cell-based therapies. The NIH also supports research toward the development of an "artificial pancreas"—a mechanical system that links glucose monitoring to insulin delivery—and has the potential to alleviate an enormous amount of patient burden.

Mrs. LOWEY. Thank you. I see that. But I look forward to it and thank you again, Dr. Collins.

Mr. OBEY. Mr. Moran.

ENVIRONMENTAL CAUSES OF ILLNESS

Mr. MORAN. Thanks very much, Mr. Chairman.

I want to follow up somewhat on the line of inquiry of Mrs. Lowey and Mr. Cole. First of all, NIH, of course, has done wonderful work. The whole Nation is justifiably proud of all you have done. In your opening remarks you cite the extension of life and the progress particularly in cardiovascular disease, the fact that older people with chronic disabilities is down markedly.

But much of the effort, at least in the past—now, I can sense kind of a shift here—has been on those called the dusk of life, and less emphasis on those at the dawn of life. That is why I was particularly impressed by a lot of the questions from the panel.

Something is happening among our children. This past generation, for example, the rate of asthma has tripled. Cancer is now, for the first time, other than accidents, the primary cause of childhood death. One in every six children is born with a developmental disability now; attention deficit disorder, dyslexia, but in many cases significant mental disability. One in 59 children is autistic. And we have talked about obesity, and it is just stunning that one in three children now, we estimate, will suffer from some form of diabetes, we understand.

There was a study commissioned by the Environmental Working Group that looked into umbilical cord blood, and they found that there were 232 industrial compounds in that umbilical cord blood. Many feel that what is happening with this most recent generation is a result of environmental factors; it is something we are breathing, we are eating or drinking. And it could well be the number of chemicals that we now depend upon for our food supply. Cow's milk, I read a number of studies that it may have a direct link to diabetes.

You have the National Institute of Environmental Health Sciences (NIEHS), and it is kind of a new thing. For a while it was sort of marginal in terms of focus.

Well, that is true, Doctor, you know that. You do not need to be defensive about it, but it really was not NIH's focus.

But I think, as we see what is happening in this new generation of young people, these dramatic statistics point to environmental causes that we need to coordinate with our research. The endocrine disruptors is one. In the Potomac River here, that we are all familiar with, every single small mouth bass—and that is a principal fish species—every single one of them is intersexed. Something is wrong.

So I wonder—my first question really would be the extent to which we are integrating some of our findings with what the NIEHS is coming up with.

Dr. COLLINS. I appreciate the question, Congressman, and I agree that studying the environmental impact on diseases of children and of adults is a very high priority. We may be able to understand hereditary implications, but we are not going to change those anyway, so it would be much better if we understood how those interact with the environment.

And this has been one of the challenges, because a compound that in a certain concentration might be entirely safe for one person may actually be quite dangerous for another; and if we do not understand those differences, we have a very hard time identifying what in the environment we should pay attention to, because it all gets sort of blurred out by those individual differences.

With regard to children, the National Children's Study, which is in its pilot phase of enrolling participants—and we are working hard to figure out how to do that in the most effective and cost-effective way—aims to follow 100,000 children preconception, all the way through pregnancy, and then until age 21. And a big part of that study is to collect the most sophisticated data we possibly can on environmental exposures, including in utero exposures, to try to see whether we can draw conclusions that so far have escaped us about what is causing these many different problems that we see in pediatrics.

That is the most ambitious enterprise that has yet been mounted. But, meanwhile, there are specific efforts in specific diseases to try to collect that kind of information, for autism, for instance. Certainly for pediatric cancers, if you see a cluster, what is going on there in terms of environment?

The difficulty we have oftentimes is we can measure the presence of many of these compounds, and we know that in larger concentrations they are not safe because animal studies have told us that. We often do not have the data to know what level would be safe, if any.

So our environment, which is full of the consequences of industrialization, may have things in it that, if we understood them better, we would want to get out of there, but the data is often insufficient to be confident that we know that answer; and what is the safe level is often the question for which there is not a clear response.

Mr. MORAN. Thank you.

Mr. OBEY. Mr. Kennedy.

MENTAL ILLNESS AMONG VETERANS

Mr. KENNEDY. Thank you, Mr. Chairman.

Welcome all of you. Thank you for your service to our Country in a very significant way in reducing the burden of illness for our people. One of the big burdens of illness for our people, and certainly an area where our budgetary dollars are so significant now, more than ever before—and if I could ask you all to comment on that with respect to the recent technology and the opportunities for that technology in the research that we have uncovered so far to make huge advances in this area as it relates to all of your institutes and every institute—is in neuroscience.

And particularly, talking about the burden of illness, my colleague, Mr. Moran, just mentioned autism and the prevalence of autism. Others of my colleagues have mentioned the burden of illness of Alzheimer's with the aging of America. And then, of course, you already have, as Dr. Insel knows, the huge burden of illness of mental illness in this Country, and addiction and substance abuse. And then on top of all of that you have a bow wave of needs coming down the line with our veterans population, and that is what I want to ask you about.

I know that there is greater coordination within the institutes on sharing relevant science amongst yourselves. When you are under a budget that Mr. Obey understands is part of the cap on discretionary funding increases, but Department of Defense and the VA are not, what I would like to know from you is to what extent can you coordinate your neuroscience research and—by the way, they have a big portfolio in areas that you also do research—that affect the veteran.

And I would like to know to what extent do you coordinate your work with perhaps medical research that is designed to help the veteran, because clearly the veteran is going to be—their challenges are going to also be the challenges of America with respect to all of these issues, because in finding out more about Traumatic Brain Injury (TBI) and Post Traumatic Stress Disorder (PTSD) and the complications of those, we are going to also find out the answers to many of these other issues.

And I even point out diabetes because not only do we know the correlation between depression and diabetes, but I know that there has just been a drug approved for type 2 diabetes that relates to neurotransmitters in the brain. And it is ironic because most people think it has to do with the pancreas. Now we know it has to do with the brain, just to show the interconnections in whole health.

So, Dr. Collins, if we could start with you.

Dr. COLLINS. Well, Congressman, you put your finger on a very important issue, and that is the need for us to collaborate across agencies to try to improve health in the area of neuroscience, and I think it is fair to say that that is a topic of great interest. Certainly the topics you mentioned—traumatic brain injury, PTSD, Alzheimer's—have all been areas in which we now have developed partnerships with the Department of Defense and with the Veterans Administration.

I am going to ask Dr. Insel, because he is intimately involved in several of those, to cite a few examples in answer to your question.

Mr. KENNEDY. And, Tom, if you could—by the way, I loved meeting Laura the other day. Anyway, I just want to say do you know if there is the same collaboration within VA and DOD that you have within NIH with respect to the various institutes, in terms of their neuroscience collaboration?

Dr. INSEL. Thanks for the question. I do not actually know what coordination goes on in terms of neuroscience between DOD and VA. It would be a great question to pose to each of them. I can tell you that for the collaboration with DOD, this is very tight and real, and it is a project that really came about because of the DOD's concern, the Pentagon's concern with the rising rate of suicide. As you know, there is a doubling of suicide amongst active duty soldiers. Last year, 160 suicides in the Army. That is actually more than the combat deaths in Iraq.

Mr. KENNEDY. Can I mention something, just if you could comment? Anahedalcystine. Do you know the drug that reduces inflammation in the capillaries, if given, in the brain, because it only goes to those areas where there is blood, so it covers the brain blood barrier? There is Defense Advanced Research Projects Agency (DARPA) research that shows that it can minimize or eliminate mild traumatic brain injury. Do you know about that research?

Dr. INSEL. We have a center that actually—it is a joint center between funded by the Veterans Administration and partly by DOD, but it is a joint center between the Intramural Program at NIH, National Institute of Neurological Disorders and Stroke (NINDS) and National Institute of Mental Health (NIMH), and the Uniformed Services University of the Health Services (USUHS), which is looking precisely at that issue.

I just met with the folks from USUHS about a week ago and heard a little bit about their excitement about this, that this is perhaps a great way for an acute treatment for TBI. And they are also very interested in being able to visualize the changes using new neuroimaging techniques which are just coming online.

So absolutely a very exciting area for science. It is not ready for prime time, but an area where it looks like we are getting some interesting advances.

NATIONAL CANCER INSTITUTE CLINICAL TRIALS

Mr. OBEY. Dr. Collins, as you know, the New York Times published an editorial about a week ago which raised serious questions about waste of time and money with respect to clinical trials, and the editorial indicated that 40 percent of the clinical trials sponsored by NCI are never completed, and it quoted the Institute of Medicine as being quite concerned about the entire situation.

I would like to know what your observations are, what your response would be to that report; where you agree with the concerns they raised, where you might disagree, and what you think ought to happen in order to correct the problem.

Dr. COLLINS. I am very concerned about the outcome of that report. I should tell you that is a report the National Cancer Institute (NCI) asked the Institute of Medicine to conduct and brought in experts to look at the cancer Clinical Trials Network and draw

the conclusion that, as you have said, there are major difficulties in terms of not finishing trials that get started, in terms of trials that take very long to get on the ground after they have initially been designed. And they make a number of recommendations which NIH and NCI are going to now take very seriously.

One of the problems is that the networks are complicated in terms of multiple centers, and that is the nature of phase 3 trials, that they generally involve multiple centers. But there is so much bureaucracy involved in trying to get a trial started, some of that just being the paperwork, some of it being the human subjects effort, where every center has to have its own Institute Review Board (IRB) that reviews the protocol. We clearly need to move in the direction of more centralized IRBs.

It is clear that some of the clinical trials are not necessarily designed in a way that takes advantage of some of the newer discoveries about ways that you could optimize a trial by identifying those most likely to respond and, therefore, making a smaller, more tightly focused trial that would give you a result more quickly; and we need to think about that.

Some of this, though, I think relates to the fact that many of these were for rare diseases, and they simply were not able to enroll enough subjects to get enough power; and perhaps that was an unanticipated problem that should have been anticipated.

So clearly what needs to happen—and I think the IOM recommendations are actually very well put and will be a great starting point for NIH—is to worry more explicitly about efficiencies that could be achieved that are not being achieved. Maybe we do not need to have so many centers if they are only enrolling a few patients each; maybe we could do this more efficiently with a smaller number of centers with larger enrollments.

Maybe we need to prioritize what trials are really critical to do. And maybe we need to come up with a better way to encourage participation by patients, because right now only 3 percent of adult patients with cancer participate in clinical trials, compared to the majority of pediatric patients; and we have to figure out why that is and why we have trials that we cannot manage to fill.

Mr. OBEY. Well, my concern is that one out of every four Americans is expected to die of cancer, so this is not a minor problem.

Dr. COLLINS. No.

Mr. OBEY. And people look at clinical trials as being the gold standard, and when we get a report like this, it raises really significant questions. I would ask that you keep in close touch with the Committee as you review those recommendations and concerns, because we are talking about not just a lot of lives, but a lot of money as well.

But what is the main reason why you think so many of those clinical trials do not finish?

Dr. COLLINS. I think many of them are for conditions where it has just been difficult to find enough patients with the precise conditions that had to be present to be able to enroll in the trial. They cannot find——

Mr. OBEY. Would not that tell us something about what is going on at the front end, before those trials are ever started? How should that process be changed?

Dr. COLLINS. I agree with you, it does tell you something about the inability to plan effectively about whether a trial is likely to be able to meet its enrollment criteria or not; and that is something that has to be looked at very carefully.

Imminently, we will see the appointment of a new Director of the National Cancer Institute. I guarantee you this will be a matter of the highest importance for that individual. And I think, as you have said, we have to get this right, because we are going to see, coming forward, in the next five or ten years, a very exciting list of new cancer therapeutics. But we will only know if they work if we have a clinical trials network that can test them quickly and efficiently. This has to be the highest priority.

Mr. OBEY. My time has expired.

Let me suggest we do a second round of about three minutes apiece.

Mr. Tiahrt.

BIODEFENSE RESEARCH

Mr. TIAHRT. Thank you, Mr. Chairman. This may have been asked by Dr. Fauci than you, Dr. Collins. Last year we ended up transferring $304,000,000 from the Bioshield Reserve Fund to the National Institute of Allergy and Infectious Diseases, and we justified that additional research was needed because, before we can purchase countermeasures for use in the event of a bioterrorism event.

Now, I was opposed to this; I think that it is better spent at the Biomed Advanced Research and Development Authority (BARDA)—in their advanced development program. But if these funds go to NIAID, will NIAID work with BARDA to ensure that the research is supported by those funds that address the issues that we are concerned about, and that is a bioterrorism event? And through these applications can you ensure that the funding will be spent on biodefense research?

Dr. FAUCI. Thank you for that question, Mr. Tiahrt. The answer is we work extraordinarily closely with BARDA. In fact, those very funds that ultimately came to us were spent in coordination with BARDA; they were allocated for the biodefense research and development. As you, I know, well know, we have an issue with regard to the far-end, downstream purchase of something to put into the strategic national stockpile, and what the NIH has been doing for decades, and does very well, is the fundamental basic research, concept development and preclinical development; and then there is a gap in the middle which many people refer to as the valley of death. Not a very good terminology, but it feels that way sometimes.

And that is really what we needed to shore up with the funds that were technically transfers from BioShield, but really went into the research and development in close coordination with BARDA.

So the answer to your question is yes, it will be.

Second question, is it used for biodefense? Absolutely yes.

CURES ACCELERATION NETWORK

Mr. TIAHRT. Okay. Thank you very much.

The valley of death, which we have referred to, I guess it was last authorization we put $500,000,000 in for the Cures Acceleration Network, or CAN, as we refer to it. Is CAN the best way to go about bridging this valley of death that we refer to, or are there other ideas that we should be considering?

Dr. COLLINS. Well, I think CAN is a very exciting idea. The Institute directors will all be gathering for a retreat all day tomorrow to talk about this, because this is an opportunity in a very flexible way to try to push forward new and exciting approaches to therapeutics.

The idea here is, as authorized, but not yet appropriated, is to provide large grants that include participation by public and private sector partners. It includes some flexible research authority to allow us, in a DARPA-like fashion, to move such projects forward rather quickly. And, if appropriated at a reasonable level, would allow multiple projects to go forward simultaneously with project managers that are authorized to both bring in resources when you need it and to kill projects that are failing, which is critical in this high-risk area as well.

The idea here is to develop a new paradigm for how we come up with new therapeutic ideas, partnering in a new way with the private sector, where academics are de-risking projects, which, as soon as they become commercial viable, can then be out-licensed, so the companies can take them and run with them. And I think, from my perspective as a physician who is anxious to see therapeutic successes come forward, this is a mechanism that we very much need and hope to be able to utilize.

Mr. TIAHRT. If I can just finish with a comment, Mr. Chairman. One of the things we saw in the DARPA program is that when we had new ideas that ended up not pursuing, failed, in other words, the people who were managing those programs got a black mark on their resume.

And I hope that when you are pursuing new ideas, that just because the idea does not work out does not mean the person failed; it may have been a very successful way of finding out not to waste more money. So please look at the individual and not put a black mark on their record just because they happen to be managing a program that is not what we want to invest more money in.

Dr. COLLINS. I agree with you, Congressman. Winston Churchill famously said that success is nothing more than going from failure to failure with undiminished enthusiasm. And one needs to keep that in mind. If we are not doing the kind of research that fails on a fairly regular basis, we are not pushing the envelope hard enough.

Mr. OBEY. [Remarks made off microphone.]

Mr. RYAN. Thank you. I have been watching from my office, so do not feel like I have not been paying attention. [Laughter.]

BEHAVIORAL RESEARCH

Mr. RYAN. And I know not to ask about comparative effectiveness research. I know that ground has been covered.

Just briefly, I know Mr. Moran has talked about this, and I heard Congressman Kennedy talk about it a little bit, the issue of behavioral sciences, behavioral research. And last time you were

here I talked to you a little bit about mindfulness and some of the other approaches that I know NIH is looking into doing some research. Can you just kind of update me as far as is there anything that you have been doing over the last year that I should know about?

Dr. COLLINS. So, Congressman, we agree that this is a fruitful area for research. Clearly, the mind-body interaction plays a significant role in lots of illnesses, both in terms of their occurrence and their adaptation to those who are afflicted with them. Certainly, several of the institutes have significant portfolios in this area. I would think the National Center for Complementary and Alternative Medicine particularly comes to mind as a place that is devoted to trying to test out some of these what people might call unconventional therapies, but which clearly many people in the public are convinced are of value, and we need to develop the data to underscore what that is.

Already those kinds of studies, for instance, have shown some value of yoga in terms of helping people cope with chronic disease, and many others are being tested as well.

The National Heart, Lung and Blood Institute is also engaged in a number of these. We have a new program in basic behavioral and social science research called OPPNET, which we think also will provide some of the foundational information to help us understand the correlation between behavior and illness.

And I might ask my colleague, Dr. Insel, at NIMH, if he has other comments he would like to make about the mind-body connection because, of course, that is a topic of great interest in that area of medicine.

Dr. INSEL. Well, I would say it is a topic of great interest across much of NIH in the same way as Mr. Kennedy mentioned the development of the neuroscience effort across institutes so that it is not balkanized in any way. We have a neuroscience blueprint effort across 16 institutes and centers who are now doing this, as Dr. Collins mentions, for behavioral and social science research as well.

So OPPNET is a new project; it is just getting off the ground at this point. It involves all of the institutes and centers at NIH and it will be a new forum, as well, for talking about these kinds of issues and their opportunities for taking those into a translational study of health.

Our own institute has been very interested in the work of people like Richie Davidson in Madison. We fund a center that he runs on the study of mindfulness, not only understanding what its health implications might be, but also looking at the brain and looking at physiology to understand the biology of this process as well as the psychology.

Mr. RYAN. Well, I appreciate that. I went out last year to see Richie's lab, and the work he is doing there is just amazing. And we are talking about adding 30 million people to the health care system, and I think this kind of individual responsibility, where we are actually teaching people how to manage their own levels of stress. We know what stress does to all of us in our daily lives, but over the long term that kind of high stress level leads to a lot of the problems that we are researching and spending a lot of money trying to figure out and then deal with and manage over time.

So I would just encourage you to continue to go down this road. I was at a conference a couple weeks ago at the University of Massachusetts Medical Center was sponsoring, and across the board recidivism, education, health care, prevention, right down the line. There were some cops that were there from Portland, Oregon, talking about being more aware in these kind of intense situations. There were a couple of colonels there. There were military folks talking about building up some resilience in your mind before you even go off to battle so that, when you come back, you are more resilient, you respond better, and over time I think it will prevent a lot of the PTSD that Congressman Kennedy was talking about.

So I just want to encourage you to go down this road. And whether it is health care or education, the idea that we can teach kids to focus—we always tell kids pay attention, but we never teach them how to pay attention. And this is a real way for us to teach kids how to pay attention, how to make better decisions, how to not get caught up in the moment and prevent problems.

So I just want to encourage you, because the science is there. It is there, and I think the more your seal of approval and your street cred is on some of these initiatives, the better off I think we are all going to be.

So I want to thank you for—the last point I wanted to make, too, in the field of education with social and emotional learning. I talked to the Secretary of Education about it when he was before this Committee. They have a metastudy that they did with 300,000 kids. There was an 11 percentile point increase with social and emotional learning, with some mindfulness involved in it as well. Eleven percentile point increase. You are teaching kids how to pay attention.

And we cannot just tell them to pay attention and not teach them how to pay attention; how to deal with their emotions and regulate. When you realize that your emotions are prohibiting your ability to concentrate, then we have to take step one. It does not matter how much money we throw—

And I hope our friends on the Republican side, who do not want us to keep throwing money at problems, will join with us in some of this and realize we are going to teach kids how to concentrate, how to focus, and how to reduce their level of stress and save the health care system a lot of money.

So I am glad I showed up, Mr. Chairman. Thank you.

Mr. OBEY. Mr. Lewis.

COORDINATION OF RESEARCH

Mr. LEWIS. Thank you, Mr. Chairman.

The gentleman's concern about health cost and quality is one I share with you, and it has nothing to do with partisan politics. But let me say this. Years ago a couple of our members suffered from Parkinson's, and that led some of us to organize in a nonpartisan way an environment where people who were doing research and treatment across the country came together, spent like a day and a half together.

The amazing thing to me at the bottom line was that they had never talked to each other in any significant level before, emphasizing that which has been said several ways here today, the need

to have voices within your institution pushing the kind of coordination that allows for us to tap many, many resources.

Years ago we specifically were interested in the proton therapy process. At that time, NIH was not interested in the proton. I do not know if it was based upon cost or what, but they were not interested. So we took that issue to a hearing at the Energy and Commerce Subcommittee of Appropriations, rather than this Subcommittee; and, as a result of that, that subcommittee had about a dozen members on it and ten of them had cancer in their family. They were very interested and initial funding went forward.

Since that time, it has been suggested this might be a great item for rationing because of relative cost for treatment, even though initially we knew there were prospects for small tumors in the brain, great success with prostate cancer; most recently, great success with non-invasive breast cancer treatment. But above and beyond that, NASA is very fascinated with this work because of how it can help them understand better the effects of radiation upon man perhaps in space.

Well, that sort of coordination and communication could cause NIH to help us very much tenor and hold back the tendency of wanting to cut off avenues of research, as well as treatment, because of cost alone. So I would urge that to become a priority.

Mr. KENNEDY. I would hope maybe we could work together on getting DOD and VA to really figure out how they are going to coordinate like the NIH has on their neuroscience, because, really, the biggest amount of additional science in brain research is going to happen on TBI for the veteran, and that is going to accrue to Parkinson's, it is going to accrue to epilepsy, it is going to accrue to Alzheimer's and autism, and everything, because once you start researching the brain—and the VA and DOD are going to be—those veterans are going to be kicking down the door, as they did overseas, to all of these diseases here at home.

Mr. LEWIS. Mr. Chairman, he is referring to a project that Mr. Kennedy and I were going to begin to work on long-range relative to the problems with veterans and specific problems like alcoholism and drugs, et cetera, leading to homelessness. Unfortunately, Mr. Kennedy has made a decision not to run for re-election.

Mr. KENNEDY. That is why I am leaving it all in your hands, Jerry. [Laughter.]

Mr. LEWIS. Thank you, Mr. Chairman.

Mr. RYAN. Mr. Chairman, I would like to intervene. I would love to help and make sure that this project continues.

Mr. OBEY. Mr. Kennedy.

TRAUMATIC BRAIN INJURY

Mr. KENNEDY. I want to go back to this anahedalcystine. From what I understand, the DARPA showed that within the first 24 hours of a veteran suffering a concussion—and they can tell from your rapid eye movement whether you have—and there are objective standards—whether you have suffered this—that that goes right through the blood brain barrier because of the capillaries and it can have long-term impacts in terms of the suffering of the consequences of TBI. And it is sitting right now at the Surgeon Gen-

eral's Office of Review or whatever at I guess it is the Navy, because it is the Marine Corps.

This is something that cannot be sitting around; it has to get out there. We already have FDA approval for this. This would be off-label use of it. So I am just asking, with your basis of science at NIMH and coordination within your group, if you can offer research and support to whatever that surgeon general is going to have to review in terms of that DARPA research, please, as soon as possible, because this is going to help avoid a lot of that downward consequences as a result of TBI.

Dr. INSEL. We are on it.

ELECTRONIC HEALTH RECORDS

Mr. KENNEDY. And they show literally if you do not give it within the first 24 hours, you give it 72 hours later, the effectiveness diminishes dramatically.

To go to David Obey's question about the registries and clinical studies, tell us about how the new health bill and IT with the health bill offers us an opportunity, Dr. Collins, to have gene banks and registries of identify data to essentially do a lot of this that we are currently doing through clinical studies, but to really do it through the new health system.

Dr. COLLINS. Well, we desperately need better systems to do those kinds of large-scale research projects and, frankly, in this Country, we have been significantly impeded by the lack of electronic health records. It is very difficult to do thorough, accurate, efficient, cost-effective studies when everything is scribbled on bits of paper and it is very hard to sort out exactly what is in the medical record at all, if you can even find it. So having the opportunity to see our health care system evolve into an electronic framework is going to help enormously.

But there are a number of issues that we are engaged in here to make sure that we get the most out of this. There is whole term called meaningful use——

Mr. KENNEDY. Are you consulting with those IT folks on this?

Dr. COLLINS. Yes, we are. Yes, we are. Obviously, one of the hopes is that that meaningful use will be defined for the standard medical record so that it is optimized for research questions to be posed. Obviously, this needs to be done, and shall be done, in a fashion that protects privacy and adheres to standards of informed consent, but I believe that those are pathways that can be negotiated. And we are really looking forward to the chance to greatly enlarge the ability to survey exactly what are the causes of illness by potentially having a much more robust system for doing so with the electronic record.

Mr. OBEY. Mr. Cole.

BIOMEDICAL RESEARCH IN THE UNITED STATES

Mr. COLE. Thank you, Mr. Chairman.

Thank you, Dr. Collins. I want to ask you a series of questions just, frankly, will be easier if I just sort of laid it out, and then maybe you could educate me a little bit, since I am new to this Committee and certainly new to this topic, but very interested.

If you could, could you compare our national effort with other countries? Where would you rank us, obviously? Second, what percent of biomedical research done in the United States is actually done by NIH or something you fund? And, again, what percentage would that be nationally, if you know? And, finally, is there some realistic way—you implied in an earlier question that obviously you are at the foundation of a lot of very profitable research for people—that some of the money, some of the profits generated down the line in the private sector could, in some realistic way, flow back to you for the continuation and the augmentation of basic research? Not eliminating our role, but generating additional resources for you to do what you obviously do very well at NIH?

Dr. COLLINS. Those are great questions, Congressman, and I would be happy to quickly go through them.

As far as the national effort of the United States in biomedical research, I think it is fair to say we continue to lead the world, but that leadership is certainly being challenged substantially now by other countries—Europe, Japan, and increasingly China and India. And our trajectory in terms of the support and the numbers of individuals working in the field has tended to be fairly flat, while those are going up rapidly.

We were grateful to hear the President announce a year ago an intention to raise the U.S. investment in research and development to 3 percent of GDP, which would be a big shot in the arm, but no timetable has been set for that. The time is right, certainly, in terms of taking advantage of opportunity and of investigators who are ready to come forward with their best ideas and pursue them.

In terms of research that goes on in this Country, if it is research done in academia, that is, in our great universities and institutes all over the Country, and it is biomedical research, almost all of that is supported by the National Institutes of Health, with a healthy contribution also from philanthropy. Certainly, the private sector—I think I mentioned numbers a little bit ago—invests about $56 billion a year in biomedical research; NIH, at $31 billion is about 40 percent of the total, but in a good partnership.

And your third question about profits that might actually be able to feed back in some way to support the research that goes on at NIH is something we have thought about. In this new model, where we might have a partnership where academic investigators get more involved in the front-end of developing new therapeutics, that will result in some identification of intellectual property.

That intellectual property can then be licensed to a private company that is interested in taking it to the next step and all the way to FDA approval. And if a drug then actually gets approved and for which profits are made, some royalties stream back to the NIH would be highly appropriate, and most companies I have talked to are comfortable with that model as a good way to get the job done.

Mr. COLE. Thank you.

Thank you very much, Mr. Chairman.

Mr. OBEY. Mr. Ryan.

RECOVERY ACT INVESTMENTS

Mr. RYAN. Thank you, Mr. Chairman.

I just wanted to see if you can kind of outline—we put a lot of money into the Recovery Act, and I think you touched upon it a few times here. Can you just talk about, in your estimation, I know a lot of that money was needed to be spent years ago, and we were playing a lot of catch-up here in good measure to the leadership from Mr. Obey, but can you talk a little bit about how you feel the most impactful investments through the Recovery Act, where that went, what it is doing, and how we can—like you said, it is a marathon, not a sprint, and how we can continue to build on it over the years?

Dr. COLLINS. Well, because this was such a significant investment, the list of projects that were possible because of it is much longer than I can fit into this three minutes, but let me give you a couple of highlights of maybe signature initiatives——

Mr. COLE. I mean, things like we want to go out and there is a bid across the Country. Stimulus bill is not working, some people say. Well, all the metrics show otherwise. But if you could give us some tangible information on what would resonate with people, what they would grasp onto.

Dr. COLLINS. So Recovery Act dollars from NIH in fact went out to all 50 States, and we are in the process—quite clear we are creating or retaining 50,000 high-quality jobs in the biomedical research enterprise, which is a significant contribution.

In terms of science that this supports that is going to have a large impact on health, I have mentioned the Cancer Genome Atlas as a rapid acceleration in the ability to understand exactly at the molecular level what is going on in cancer. Similarly, with heart disease. We have the Framingham study, which has been going on for three generations, which now, because of these dollars, is possible to move into a phase of getting even more detailed information about the environmental and genetic risk factors for cardiovascular disease.

In the area of HIV/AIDS—and Dr. Fauci could tell you more details about this—this money has made it possible to tackle a couple of very novel and potentially very valuable ways to reduce the incidence of new cases of HIV/AIDS by identifying individuals who are infected and do not even know they are, and starting them on treatment which will reduce the likelihood that they can transmit the virus to others.

Autism. The effort now is funded by the Recovery Act to obtain the complete DNA sequence of 300 cases of autism and their parents to finally really understand what are the genetic contributions to a disease which clearly can run in families, so there must be something going on there.

All of those are things that we could not have done without Recovery Act dollars to provide that real opportunity to tackle things that are risky and expensive, but are potentially groundbreaking.

Mr. RYAN. I appreciate it. Kent State University, I was there a couple weeks ago. They got a significant amount of money from the stimulus bill from NIH, and I just want to say thank you, because there were a lot of folks there who were working in hiring people in Portage County, Ohio, because of what we did through the stimulus bill and what your work is. So I want to thank you for that as well. Thank you.

Dr. COLLINS. And I could have mentioned the pandemic flu effort, which also was greatly benefitted by the Recovery Act dollars.

Mr. OBEY. Mr. Kennedy, you had one question?

HEALTH CARE REFORM AND RESEARCH

Mr. KENNEDY. Yes.

Dr. Collins, you mentioned a new paradigm in terms of translational medicine perhaps working with the private sector. I would like to ask you, with this new health bill, the elimination of preexisting condition, the elimination of lifetime and annual caps puts a big onus on insurance companies now to come forward and develop models of care for different disease groups. How they put that together will ride on what the evidence-base is on how to best treat and care for groups. That is going to involve you talking to the President's assembled people who are going to roll this out, but also to insurers and, like is said, that public-private partnership as to how they best meet their obligations in the most efficacious way.

And, Tom, how do you think to do that, when it is not necessarily medical and clinical for autism, Alzheimer's, you know, cognitive disorders, but functional? And how do you have a reimbursement system that is not based on the old model? And what are you doing now to help instruct them so they are not just blocking—which they are doing now—and suing against the system? But how do you help them meet their obligations by showing them what the evidence-base is?

If you read this Sunday's New York Times about the veteran, we are not even getting it right in the DOD and VA, and we are supposed to have the best in cutting edge of treating cognitive disorders as a result of TBI and PTSD, and it is a disaster if you read or take anything from that New York Times cover story on returning warriors.

So I am wondering—hopefully, that is not the model, and I do not even know whether you guys are consulting with the VA or DOD.

Dr. COLLINS. We are. But I think your question is even broader in terms of the health care of the Nation, and how are we going to come up with systems that work in the new health care reform environment.

One of the things we are doing in that regard that might be worth mentioning is to try to work with HMOs that already have electronic medical record and are effectively well set up for experiments that we might be able to run in a research way to try to understand how could you provide different kinds of incentives to providers to be able to improve outcomes. Because that is the big sort of missing piece in much of where we hope to go.

It is great to have all the data, and we generate a lot of that data to tell you what works and what does not. But how do you get it implemented and how do you implement it in a way where you have a health care system that actually responds to the right incentives instead of the wrong ones?

Mr. KENNEDY. [Remarks made off microphone.] Are outcomes quality of life or outcomes blood pressure?

Dr. COLLINS. Oh, I would think quality of life and blood pressure, because they are connected.

Mr. KENNEDY. Yes, but HMOs do not measure—or insurance do not measure quality of life.

Dr. COLLINS. And you are right that we need better measures of whether quality of life is actually considered, and how would you define that in a rigorous way. Actually, we have a Common Fund Roadmap project on that, where patients actually are able to define, from their perspective, whether they are being benefitted by an intervention or not, which is often left out of the equation.

Mr. KENNEDY. Tom.

Dr. INSEL. If I may. I think you put your finger on what is going to be a very important challenge over the next couple of years. We are in a very interesting point in time for at least those with serious mental illness. We have the advent of parity for the first time as it rolls out—in spite of some suits, I think it is rolling out—and we have health care reform, which is going to have a tremendous impact for those with mental illness because of parity.

What has been such a struggle for us is so much of the cost and so much of the challenge for those with serious mental illness is outside of the health care system. They are incarcerated, they are homeless, or there are problems that play out in the school system, where we just do not see them in the health care system and we do not think about them through health care dollars.

And one of the challenges will be to figure out how do you throw that net so that all of those needs, as well as the needs of caretakers, get taken into account. We are in discussions with people and it has been a very interesting process, partly because of the parity in health care reform advances that we now are in discussions with payors, as well as everyone else, to think about what is the evidence that you need to make that extension? What would it take?

So I think you know about our Recovery After an Initial Schizophrenia Episode (RAISE) effort, which was really developed almost in the reverse; started with the payors and said what would you need for someone with an acute psychotic break to cover everything, to cover all the things that we know are necessary for recovery? And what kind of evidence could we provide to you that would make you come to the table and say this is a good buy for us, this is worth supporting?

And we are rolling this out; it is a large $25 million effort done with the Recovery Act funds, and we think this is actually going to be transformative for those people who end up being huge costs if we do not get it right on the front end.

Mr. KENNEDY. Thank you very much.

Mr. OBEY. Mr. Tiahrt.

Mr. TIAHRT. Mr. Chairman, I ask unanimous consent to submit some questions for the record.

Mr. OBEY. Sure.

Mr. TIAHRT. Thank you.

Mr. OBEY. Let me ask just two questions. Do not worry, you are not missing much. [Laughter.]

NEW STEM CELL LINES

Mr. OBEY. First of all, would you explain the significance of the story that appeared in the Post this morning with respect to stem cell?

Dr. COLLINS. Yes, I would be happy to. As you know, President Obama, a little more than a year ago, issued an Executive Order indicating that stem cell lines—we are talking about human embryonic stem cell lines—that have been derived since August 2001—which is when the Bush Executive Order took effect—ought to now be considered for Federal funding if they met certain standards as far as the way in which those lines were developed in terms of the consent, especially, to be sure that that was ethical.

NIH was charged with putting together guidelines about how to do that review of stem cell lines, and those went into effect in July, and we have been receiving the information from many stem cell line developers since then and, as of today, there are 64 lines that have been approved.

Today's news was about two particular lines that go by the names H7 and H9, which were derived a long time ago, more than 10 years ago, and were heavily utilized by researchers between 2001 and now, and for which there was a lot of data. Those lines had not been submitted to NIH for review until about two weeks ago; there were some complications in terms of finding all the documentation. The materials were submitted, we reviewed them rigorously, and yesterday I approved them as now being appropriate for support by Federal funding. Those two lines actually accounted for a substantial amount of the publications that have occurred in this field up until now.

So many people in the research community were hopeful for this outcome and I am glad to say we were able to get there with complete adherence to rigorous standards of consent, which were part of the Obama Executive Order.

DR. RUTH KIRSCHSTEIN TRAINING AWARDS

Mr. OBEY. Okay, one other long observation. As you know, Dr. Ruth Kirschstein visited this Subcommittee many, many times. She was a legendary scientist and administrator at the National Institutes of Health, and she died October 6th of 2009 after a public service career that spanned more than 50 years. Dr. Kirschstein worked on polio research, made history as the first woman to head an NIH institute, and later served as Deputy Director and Acting Director of NIH. She was a pioneer.

A significant part of her legacy is the way she served as a champion for the advancement of women and minorities in biomedical research. She was a strong advocate for research training, especially interdisciplinary pre-doctoral programs and programs to increase the number of minority biomedical scientists, physician scientists, and scientists trained in emerging or evolving areas.

In 2002, as a fitting tribute to her many years of exceptional service, particularly in the area of research training, Congress renamed the National Research Service Award Program in her honor. The Ruth Kirschstein National Research Service Award is an important tool to ensure we have a pipeline of future investigators

ready to take over as the current workforce continues to age and move toward retirement.

In 2001, NIH agreed to work towards increasing entry-level stipends under this program to $45,000 a year. Currently, NIH pays just under $38,000 a year despite their advanced degree in specialized technical skills that would allow them to earn considerably more in the open market.

I understand that the President's budget proposes an increase of 6 percent in stipends under that program. How does that fit into your efforts to ensure a robust pipeline of young investigators? What is the current NIH policy for cost of living support in this program? And, more generally, how are we doing in attracting and keeping the next generation of biomedical researchers?

Dr. COLLINS. Well, Mr. Chairman, I appreciate your citation of Dr. Kirschstein and her role at NIH. It is impossible to overstate the remarkable impact that she had on the institution and on many of us personally, and she is greatly missed. We are having a symposium on May 17th, inviting many of the Ruth Kirschstein awardees to come back and talk about the science they have done in order to recognize the way in which her contribution has had a very specific personal effect on each of them, and we are expecting that to be a day of great celebration of her legacy.

In terms of what we are doing about training grants, yes, the President's budget does propose a 6 percent increase, which I think is long overdue. If one looks at the stipends that have been proposed by NIH for such trainees, they have remained essentially flat for a long period of time, even as inflation has been eating away at the buying power. This has—I can tell you, because I recently met with the National Postdoctoral Association in Pennsylvania. This news of at least a proposed increase was a big morale booster for a group that has begun to worry about just how valued are they.

Being in that kind of training circumstance, you can imagine why that might feel a little uncertain. You are not yet independent. You have a Ph.D., so you know some stuff, but you are not making much money and you are not necessarily sure where you are going. And to get that kind of pat on the back, saying we value you and we think you are a bit underpaid—probably a lot underpaid, but we are going to try to do something about it—was well received.

How are we doing in terms of recruiting? I would say okay, but not great. And certainly when you look at the way other countries—for instance, China and India—are doing as far as bringing new talent into the scientific research community, they are surpassing us in terms of their reach and their ability to encourage people to find their careers in this path, and we are flagging a bit.

More particularly, I am concerned about the fact that our trainees do not represent the complexion or the diversity of our Country, and we need to work harder on the diversity issue and recruiting more disadvantaged individuals into this area, because we need the best and the brightest no matter what their background happened to be; and some of our programs have succeeded at that and some have not, and we are looking at a new set of ideas through a Pathfinder Award to try to improve that outreach to groups that are traditionally not represented in our workforce and should be.

So we have a lot of work to do here between the graduate students and the post-docs, the clinical investigators, the M.D. Ph.D.s who I met with this past Saturday, who are also concerned about their future but enormously energized about the scientific potential; and this is one of my personal priorities, to be sure that we are not passing up the chance to be filling our pipeline with this next generation.

And there are risks here, because they do hear their elders wringing their hands and complaining about the fact that it is hard to get a grant funded, and that one chance out of seven of having your grant actually receive funding may be a bit discouraging to some of the young people; and a few of them who met with me in Chicago talked about being on the brink of going off to do something else because of their uncertainty about whether there was a place for them. We have to work hard on that to be sure that they do see there is a place, even in difficult budget times, and hoping that, in the longer term, we might ultimately get to a point where we have stable, predictable kinds of trajectories for medical research instead of the feast and famine up and down experience, which has been pretty hard on everybody, but specifically on young trainees.

TEN MOST IMPORTANT ADVANCEMENTS

Mr. OBEY. One last question. There is a very sour mood in the Country about a lot of things these days, and when that occurs people tend to overlook some very important things that have occurred in society and in government through the years. I mentioned earlier that I have been on this Committee since, I do not remember, 1973 or 1974, one of those, and the way politics works, I guess, if you produce something that is physical and tangible, like a missile or a space vehicle, a shuttle, people can see visibly what they get for their tax dollars. But in a field like health care, there is not much that you can put your hands on to say, yes, this is what improvement in cancer research looks like. I mean, you cannot touch it. It is very different. And I think it is important that taxpayers understand that a lot of times, in lots of places, their tax dollars do some very good things.

The problem is also that you cannot see that in any one year. But if you step back and look at it over time, then you can see some major changes that have occurred.

What I would like you to do—and I do not expect you to do it now, but I would like you, at least for the record, to do this. If you take a look at what has happened because of NIH funding through the years, what are the ten biggest improvements, what are the ten most important steps forward? What are the ten ways in which the public's health has been advanced because of what NIH and the researchers that it funds all around the Country have produced? If you can prepare that for the record, that would be useful.

Dr. COLLINS. I would appreciate the chance to do that.

[The information follows:]

TEN BEST SCIENCE ADVANCES

NIH Research and the Health of the Nation

In the first decade of the 21st century, life expectancy in the U.S. has continued to rise, standing now at an unprecedented 78 years for the total U.S. population. From 1986 to 2006 alone, life expectancy increased by 3 years.

Americans are not only living longer, they are healthier. Data from the National Long-term Care Survey shows that from 1982 to 2004, the age-standardized prevalence of reported chronic disability among American seniors (age 65 and older) dropped nearly 30 percent (28.3 percent) [1].There are many factors that contribute to this decline in disability, but NIH research has played a key role. A major contribution comes from improvements in prevention and treatment of heart attacks and strokes, including control of cholesterol levels and hypertension with pharmaceuticals as well as improvements in materials and devices such as drug-eluting stents. Other specific advances include treatment of arthritis with pharmaceuticals and joint replacements, and improvements in technologies such as safe and effective outpatient cataract surgery.

Below are ten specific examples of health improvements over the last several decades that originate from the nation's investments in NIH-funded research. Together with additional federal agencies and programs that ensure access to the best information and delivery of health care, these discoveries have transformed medical practice.

Heart Disease

The over 1,000,000 annual deaths from coronary heart disease seen 30-40 years ago have now been cut by more than half due to new drugs, procedures, and prevention programs developed through NIH research.

Thirty to forty years ago, there were approximately 1,000,000 deaths annually due to coronary heart disease. In 2006, that fell to 425,425 deaths. In the early nineties cardiac care was still relatively primitive. Bed rest was standard care for a heart attack. Bypass surgery was conservatively performed on only the youngest and healthiest. Heart failure was treated with 50 year old medications. Over the past several decades, there have been extraordinary advances in heart care, arising from NIH-funded research. In 2010, we have an array of new and more effective treatments such as use of clot-buster drug therapy during a heart attack to open up a blocked artery and use of angioplasty to open up blocked heart arteries that cause heart attacks. Bypass surgery and valve replacement surgery are now standard in 80 and 90 year olds, and "catheter ablation" treatment of a trial fibrillation and other heart rhythm problems is now standard and curative. In just 20

[1] The information on reported disability rates is gathered in successive waves of the National Long Term Care Survey (NLTCS) conducted during 1982, 1984, 1989, 1994, 199 and 2004/2005. The results are reported most recently in Kenneth G. Manton, XiLiang Gu, and Vicki L. Lamb, "Change in chronic disability from 1982 to 2004/2005 as measured by long-term changes in function and health in the U.S. elderly population." PNAS Nov. 28, 2006, vol. 103, no. 48, 18374-18379.

years time, thanks to investments in research, we have implantable defibrillators to keep the heart beat regular after a heart attack or in heart failure, new medications to prevent and treat heart failure, improved surgical treatments of congenital heart disease that result in survival well into adulthood, and safe and effective heart transplantation.

HIV/AIDS

In 1989 the diagnosis of HIV infection was a virtual death sentence; due to antiviral drugs developed by NIH, today an HIV positive 20 year old can be expected to reach the age of 70.

In 1989, HIV/AIDS was spreading rapidly throughout the world with no effective therapy available to treat the several hundred thousand infected people in the United States and the millions of infected people worldwide. By discovering how the human immunodeficiency virus destroys the body's immune system, NIH-funded researchers could identify vulnerable targets for drug intervention in the virus replication cycle. This led to the rapid development of an increasing number of antiretroviral drugs that have transformed the lives of HIV-infected individuals. In 1989, if an HIV-infected individual was seen for the first time at any hospital in the USA or internationally, the therapeutic options were few and the diagnosis of HIV/AIDS was a virtual death sentence. If a person presented to his/her physician with advanced HIV disease, the survival was measured in months. Just one drug (AZT) was available, and this only modestly increased survival.

If a child was born of an HIV-infected mother in 1989, there was a 25 to 30% chance that the child would contract HIV from the mother at or around the time of birth. In the years from 1989 to 1996, NIH-funded investigators developed and proved the efficacy of a large number of antiretroviral drugs that began the era of highly effective therapy for HIV/AIDS, referred to as HAART (highly active antiretroviral therapy). Thanks to the Ryan White CARE Act, drugs have been available for low-income, uninsured and under-insured HIV-infected patients since 1991. Now in 2010, if a 20-year-old patient newly infected with HIV comes into a clinic and is treated with these drugs, it is projected that his/her average life span would be greater than 69 years. And if a child is born of an infected mother here in the USA in 2010, there is less than a 1% chance that this child will contract HIV from the mother. These advances were accomplished in large part by NIH-funded research, representing some of the most striking successes of domestic and global public health. In sum, in 1989 more than 28,000 people in the U.S. died of AIDS. That number continued to grow to its peak in 1995, when more than 50,000 people died. By 2007, the number had been dramatically reduced to 14,500 deaths.

Age-Related Macular Degeneration (AMD)

40 years ago there was little or nothing one could do to prevent or treat advanced AMD and blindness; because of new treatments and procedures based on NIH research, 750,000 Americans who would have gone blind over the next 5 years will instead continue to have useful vision.

AMD is the most common cause of blindness in the elderly. For decades there was little or nothing one could do to prevent or treat advanced AMD. Now, NIH has developed new nutritional supplements that are able to slow the development of advanced AMD by 25%. Despite this advance, over 750,000 Americans are destined to develop the abnormal blood vessels associated with advanced AMD in the next 5 years. Because of a series of remarkable discoveries, which led to new laser-based treatments, and most importantly to agents that, when injected into the eye, will reduce abnormal blood vessel growth and fluid leakage, today most of these 750,000 Americans will continue to have some useful vision, allowing them to better enjoy their later years. In addition, researchers recently identified important new genetic risk factor associated with the development of AMD, which give scientists a totally new approach to the treatment or prevention of advanced AMD and will likely to lead to new and even more effective ways to prevent and treat AMD in the coming years.

Cochlear Implants

Because of NIH supported research, profoundly deaf children that receive a cochlear implant within the first two years of life now have the same skills, opportunities, and potential as their normal-hearing classmates.

One or two of every 1000 children in the U.S. are born profoundly deaf, and those numbers have not changed for decades. What is changing – at an unprecedented pace – is the number of those children under 3 who receive cochlear implants, electronic devices that mimic the function of delicate cells of the inner ear. About 40% of such children now receive a cochlear implant, up about 25% from five years ago. In the past, most deaf children were not diagnosed until they were 2-3 years old. These children fell behind their peers in language, cognitive and social skills and, ultimately, in their ability to get and hold a job. Because of NIH supported research, deaf children who receive a cochlear implant at a young age develop language skills at a rate comparable to children with normal hearing. Improvements in speech processors and other related technologies now allow children with cochlear implants to succeed in mainstream classrooms. Today, profoundly deaf children now have the same skills, opportunities, and potential as their normal-hearing classmates after receiving a cochlear implant within the first two years of life.

Breast Cancer

Thirty five years ago, the five-year survival rate for women diagnosed with breast cancer was 75 percent; because of NIH-supported research, the five year survival rate has risen to over 90 percent.

Thirty five years ago, the annual mortality rate for women diagnosed with breast cancer was 33.2 per 100,000. Because of NIH-supported research, the five year survival rate has risen to over 90 percent. Breast-conserving surgery followed by local radiation therapy has replaced mastectomy as the preferred surgical treatment. New non-surgical therapies include combination chemotherapies, hormonal treatments, and new monoclonal antibody approaches.

A treatment option, matched to patients whose tumors express the receptor HER2, includes a monoclonal antibody, trastuzumab (Herceptin) that blocks growth signals to breast cancer cells. NIH-sponsored clinical trials demonstrated in 2005 that the addition of Herceptin to standard adjuvant chemotherapy for the 20-25 percent of women whose tumors express this receptor decreased the risk of breast cancer recurrence by 40 percent, the most dramatic improvement in the post-surgical adjuvant treatment of breast cancer ever described. Many of the genes that contribute to breast cancer risk, including *BRCA1* and *BRCA2*, have now been identified and the results of such research are allowing life-saving screening for high risk individuals and early or preemptive treatments. And gene-based tests on the breast tumors of women with negative nodes now allow a large fraction of such women to forego chemotherapy, avoiding the toxicity of the treatment and saving the health care system approximately $100 million in 2009.

Colon Cancer

From 1974-1976, the five year survival for patients with colon cancer was 50 percent; in 2009, based on NIH-supported clinical trials, this same patient group has a five year survival rate of over 70 percent.

Mortality rates for colorectal cancer have declined in both men and women over the past 30-40 years, with a steeper decline since 2001. Twenty years ago, the five year survival for patients with colon cancer who had involved lymph nodes at the time of surgery was 40 percent. In 2009, based on NIH-supported clinical trials of surgery, chemotherapy combined with drugs, and targeted therapies such as Avastin , this same patient group has a five year survival rate of >70 percent. Twenty years ago, the median survival for patients with recurrent or metastatic colorectal cancer was <12 months. Based on a series of clinical trials conducted by the NIH, the median survival for these patients in 2009 was approximately 2 years. Progress in prevention is also encouraging -- two randomized controlled trials showed that taking aspirin daily for as little as three years reduces the development of colorectal polyps by 19 percent to 35 percent in individuals at high risk for cancer.

Cervical Cancer

Cervical cancer is the fifth most deadly cancer in women; due to groundbreaking NIH research, an FDA approved vaccine is now available which can prevent the development of cervical cancer.

Worldwide, cervical cancer is the fifth most deadly cancer in women. It affects about 16 per 100,000 women per year and kills about 9 per 100,000 per year. A few decades ago, NIH scientists established the link between human papillomavirus (HPV) and cervical cancer. This recognition set off a new quest: to develop a vaccine against a form of cancer that, at the time, claimed the lives of more than 5,000 American women each year. The researchers developed VLP (virus-like particle) technology that replicates the virus surface, boosting an immune response to the virus without accompanying viral genetic material being passed to the patient. FDA has now approved the first HPV-blocking vaccine to protect against cervical cancer. Approvals in Canada and Europe soon followed. Today, young women can be vaccinated to protect against the virus causing cervical cancer.

Type 1 Diabetes

Thirty to forty years ago, 30 percent of patients died within 25 years of a diagnosis of type 1 diabetes. Today, due to tight blood glucose control, heart disease and stroke in type 1 diabetics have been reduced by over 50 percent.

Thirty to forty years ago, 30 percent of patients died within 25 years of a diagnosis of type 1 diabetes One in four diabetics developed kidney failure, and diabetic retinopathy was responsible for 20 percent of new cases of adult blindness. The concept of controlling blood glucose tightly to prevent diabetes-related eye disease, nerve damage, and kidney failure was untested. In 1989, enrollment of 1,441 subjects was completed in the landmark Diabetes Control and Complications Trial (DCCT). Four years later, the trial was stopped early because intensive control of blood glucose was shown to reduce eye, kidney, and nerve complications by 50 percent to 75 percent. Remarkably, 92 percent of the participants continue to be followed in an ongoing successor study. We see not only continued dramatic reductions in eye, kidney, and nerve complications, but also that heart disease and stroke are cut by over 50 percent. After 30 years of diabetes, less than 1 percent of the intensively-controlled participants have become blind, required kidney replacement, or had an amputation. Upon completion of the DCCT, intensive therapy rapidly became the standard of care nationwide. The DCCT also established a measure of glucose control as the basis for FDA approval of new diabetes therapies. As a result, the treatment options and opportunities to individualize therapy have grown and the number of drug classes for diabetes therapy has increased from two in 1998 to ten in 2009.

Hepatitis B

In the mid 1980s, hepatitis B infection caused untreatable and fatal illness; Because of intensive vaccination programs based on NIH research, the rate of acute hepatitis B has fallen by more than 80 percent-a feat considered to be one of the great achievements of 20th century medicine.

In the 1970s, the country was in the midst of an epidemic of hepatitis B that lasted well into the 1980s, with more than 280,000 new infections per year from 1984 through 1987. Twenty years ago, hepatitis B was still the leading cause of acute liver disease in the U.S., including cirrhosis and liver cancer. End-stage liver disease from hepatitis B was an untreatable and fatal illness. Because of research, we can now prevent, diagnose, and treat chronic hepatitis B infection. Safe and effective vaccines were developed and are now given to all newborns and children in the U.S. and many other countries. Because of intensive vaccination programs, the rate of acute hepatitis B has fallen by more than 80 percent. This dramatic reduction in hepatitis B infection--and in the resulting liver cirrhosis and cancer--is considered to be one of the great achievements of 20th century medicine.

Infant Health

In 1976, the infant mortality rate was 15.2 infant deaths per 1,000 live births. By 2006, that rate had fallen to 6.7 deaths per 1,000 live births with much of this progress due to NIH research in the areas of new neonatal care unit procedures and new drugs administered to women at risk for premature birth.

Forty years ago, the infant mortality rate was 15.2 infant deaths per 1,000 live births. By 2006, that rate had fallen to 6.7 deaths per 1,000 live births. Much of this progress is due to NIH research. Early studies informed the development of neonatal intensive care units, which enabled many premature infants to be kept alive, and NIH research showed how use of antenatal steroids could prevent respiratory distress syndrome and related conditions that would often lead to death within the first days of life for very frail infants. More recent NIH research continues to make inroads in preventing preterm birth and its complications. For example, in 2003, NIH supported scientists discovered that the drug 17-alpha hydroxyprogesterone caproate reduced the chances of giving birth prematurely by 34 percent in a large category of at-risk women—those pregnant with a single child who had previously given birth prematurely. More recently, physician-scientists funded by the NIH demonstrated that preterm infants born to women who received intravenous magnesium sulfate to delay labor were less likely to develop cerebral palsy. NIH research also helped infants who fail to receive enough oxygen at birth and are, thus, at greatly increased risk of death and disability: scientists found that lowering the infants' body temperatures to about 92 degrees Fahrenheit within the first 6 hours of life greatly reduced the chances of disability and death. Because preventing preterm birth remains a national health priority, NIH research will continue to develop interventions that not only ensure that a greater number of babies born too soon or too small survive, but that they will also be able to lead healthy and productive lives.

Dr. COLLINS. Just very quickly, but not the full response that I know you expect, if one looks at what has happened to death rates, and the fact that we have seen longevity improve by one year about every six years, and that can be tracked to NIH research in a very large extent. That is a pretty good general indicator. Disability is dropping off.

In this document (NIH: Turning Discoveries Into Health) that we left for you, we tried to capture some of these others, such things as, for instance, what has happened with HIV/AIDS, which used to be a death sentence and which now the average person diagnosed at age 21 can expect to live to age 70. When you look at something like deafness, where children born with congenital deafness would have cost the Country, in the past, $1 million of extra educational efforts and would therefore have had many limitations on them, now, with the ability to treat that, you can in fact expect, and we have seen for 50,000 kids, that they can be mainstreamed because of the ability to repair the problem.

Heart disease dropping by 60 percent in the course of the last 30 years in terms of the deaths is another very good one to cite.

There is a lot there. But, you know, you are right, Mr. Chairman. I do not think that that is a story that is often told. It does not happen overnight; it happens over years. And when it does happen, people may not realize why it happened, and much of it is resting upon this foundation of medical research that this Subcommittee has supported down through the years.

Mr. TIAHRT. Can you put that all in 28 seconds, please?

RECOVERY ACT FUNDS

Mr. OBEY. What it really amounts to is—I mean, it is 35 years. It is a generation. And I think it is important people understand what has happened from one generation to another, what the taxpayer expenditures finally produce.

The other question I would have is you mentioned feast and famine. Some people might take that remark to suggest that that demonstrates that we made a mistake when we put the funding in that we did for the recovery package. So, again, I would like to know would it have been better had the Committee not provided that money over the last two years? Is it worth the discombobulation that you have because it is a two-year temporary shot in the arm? And you know what I am getting at.

Dr. COLLINS. I do.

Mr. OBEY. Is it worth it? Was it worth it? Was it a mistake? And is it worth the complication, I guess I would put it that way?

Dr. COLLINS. Well, Mr. Chairman, thank you for the opportunity to correct any misapprehension that might have arisen from my use of that particular phrase. It has been a wonderful investment in medical research. This $10 billion came at a time where there was a great pent-up demand and need, and a whole series of innovative ideas that were not possible to support; and they came forth in great numbers, and scientists supported by the Recovery Act are doing remarkable things right now, and we will see the consequence of those; not overnight, because science does not operate overnight, but in the long-run, as having been a very wise investment in advancing research.

It does create some stresses for the system when this comes forth in a two-year period and we cannot see sort of a more stable trajectory, and we are going to be experiencing those stresses, I fear, in fiscal year 2011, but it was worth every bit of it to get the research done that has been possible to support through the Recovery Act.

Mr. OBEY. Any other last questions?

ALZHEIMER'S FUNDING CARE VERSUS CURE

Mr. KENNEDY. On those questions that you would have Dr. Collins come back with, if there could be—we are spending a lot of money on the care of people with certain illnesses. I am thinking Alzheimer's is one. Lots and lots of money is going to continue to go and it is going to go up.

However, if we put a fraction of the money that we are going to be putting into long-term care into researching the cure, or even researching delaying the onset of Alzheimer's, how does that budgetarily pay for itself by averting costs averted from the actual dollars that we would otherwise be spending in the costly care of folks with these illnesses? If you could try to figure out a way how we put some metrics to that.

[The information follows:]

COST DIFFERENCE BETWEEN CARE VERSUS CURE FOR ALZHEIMER'S DISEASE

Alzheimer's disease (AD) imposes enormous economic costs on the health care system. The Alzheimer's Association estimates that in 2010, health care spending on persons over age 65 with AD or dementia totaled $172 billion plus $144 billion imputed to informal care provided mainly by families. Using data from the Health and Retirement Study, NIA-supported researchers are developing more sophisticated and reliable estimates of the costs imposed by AD, including the cost impact of AD on Medicare and Medicaid as well as the impact on private health insurance and out-of-pocket expenses.

In addition to vastly improving quality of life, curing, delaying, or preventing AD could potentially bring enormous economic benefits. The Lewin Group estimates that a major scientific breakthrough that substantially delayed onset of AD and slowed its progression could lead to annual Medicare savings of up to $51 billion in five years and up to $126 billion in fifteen years; corresponding annual Medicaid savings on nursing home care would be $10 billion and $23 billion, respectively. We would make two important points about these figures:

- The savings estimates cited above in the Lewin study are based on very optimistic assumptions about the new therapies. For many types of preventive medical services, expanded utilization leads to higher, not lower, medical spending overall – i.e., in order to avert one case of costly illness, it is usually necessary to provide preventive services to many patients. Accordingly, prospects for savings depend critically on the cost of the intervention and the successful targeting of the highest-risk groups.

- In addition, the Lewin study assumed that all Medicare spending for those with AD/dementia is due to AD/dementia without adjusting for age and other expensive chronic comorbidities including cardiovascular disease, cancer, renal disease, diabetes, etc.

In considering the net impact of an intervention on costs of illness, multiple factors must be considered. It is important to estimate whether or not a preventive service increases longevity, thus increasing federal spending because total Social Security outlays rise when people live longer; Medicare outlays could also rise because even if a preventive service lowers a beneficiary's risk of one illness, a longer lifespan allows for more time to incur health care expenses. Also, if an intervention delays the onset of AD symptoms without increasing longevity, it might prolong the working lives of individuals or raise productivity.

Mr. KENNEDY. And on Dr. Kirschstein, I too, David, want to just say what a pleasure it was working with her, and the fact that we were able to, with her help, put the network of basic behavioral research together, and encourage you to try to get med schools to incorporate behavioral education into their medical school curricula. I know that is a priority of yours. If you could keep the pressure going on our State boards to include that in their medical school curriculum.

Dr. COLLINS. Point well taken.

Mr. OBEY. Thank you gentlemen. Thank you all.

ACCOMODATING THE FIVE THEMES IN THE FY 2011 BUDGET

Mr. Obey: The NIH budget overview and your testimony both describe five major themes or areas of scientific opportunity considered ripe for advances that could yield substantial benefits: genomics and other high-throughput technologies, translational science, activities that help enable health reforms, global health, and reinvigoration of the biomedical research community.

Please provide specifics as to how each of these themes is reflected in the fiscal year 2011 budget request, including any proposed redirection of resources and changes in policy.

Dr. Collins: The FY 2011 budget request includes resources to pursue aggressively the scientific opportunities articulated in the Director's Five Themes. Specifically, NIH will dedicate approximately$70 million to support innovative high throughput technologies associated with the *Genomics / High-Throughput Technologies* theme, including DNA sequencing, imaging, and computational biology; we will dedicate slightly under $90 million to expand activities in the *Translating Basic Research* theme. NIH will dedicate slightly under $90 million to research to improve the efficacy of health care and potentially lessen the cost associated with expanded access to health services within the context of the *Healthcare Reform* theme. Another $90 million is directed to ensuring the robustness of NIH training programs for the next generation of scientists as part of the *Reinvigorating the Biomedical Research Community* theme, as highlighted by a 6 percent increase for training stipends. Approximately $20 million will be directed to the *Focusing on Global Health* theme in order to support research to address the often-neglected diseases of low-income countries that contribute to staggering levels of morbidity and mortality.

INTRAMURAL RE-ALIGNMENT

Mr. Obey: Has NIH taken steps to re-align its intramural research program based on these themes, or are there plans to do so?

Dr. Collins: The NIH intramural research program (IRP) has been and will continue to be deeply involved in all 5 of Dr. Collins major themes. NIH hopes that the IRP will lead the way in developing new technology and programs that facilitate these goals. Some examples are given below:

1. High throughput approaches: The NIH IRP houses the NIH Chemical Genomics Center (NCGC) that has pioneered high throughput approaches to the discovery of new small molecules and small interfering RNAs to interrogate potential new therapeutic targets for a variety of diseases. This facility serves both the IRP and the whole community of non-NIH investigators.

2. Translational research: The NIH Clinical Center (CC) is the Nation's foremost clinical and translational research facility. It enables rapid transfer of laboratory discoveries on the NIH campus and elsewhere into early phase clinical trials. To facilitate this role for the CC, the NIH is undertaking the following: (1) The Scientific Management Review Board, at the request of the NIH Director, is in the process of recommending changes in the way the CC is funded to enhance its ability to support both extramural and intramural clinical research; (2) The Therapeutics for Rare and Neglected Diseases (TRND) program is utilizing the IRP and the CC to pilot new approaches to the diagnosis and treatment of these diseases; (3) The Undiagnosed Diseases Program at NIH is drawing patients from around the country who have complex disorders in need of diagnosis and new treatments; (4) The processes for scientific review and regulatory oversight of clinical research in the IRP are being re-engineered.

3. Health reforms: The IRP is pioneering new approaches to the harvesting of medical information for research purposes from electronic medical records. This program, called the Biomedical and Translational Information System (BTRIS) will accelerate the ability of physician-scientists to detect adverse reactions to therapies, to compare existing therapies, and to gain new insights into causes and treatments of disease, including the possibility of repurposing existing drugs. This information will reduce both research and patient care costs.

4. Global health: The IRP has traditionally been a major participant in Global Health efforts. A recipient inventory of the dozens of projects in the IRP related to Global Health can be found at (insert website). IRP contributions to global health include vaccine development such as recent Ebola and HPV vaccines, epidemiologic studies of cancer and infectious diseases, and the establishment of laboratories throughout the world to enable local research activities in areas endemic for specific diseases.

5. Re-invigoration of the research enterprise: The IRP is at the forefront of efforts to diversify and accelerate the training of the next generation of laboratory and clinical researchers. For example, the IRP is exploring the development of new programs to promote early career independent and strengthen interactions between the intramural and extramural programs.

FIVE THEMES

Mr. Obey: The NIH budget overview and your testimony both describe five major themes or areas of scientific opportunity considered ripe for advances that could yield substantial benefits: genomics and other high-throughput technologies, translational science, activities that help enable health reforms, global health, and reinvigoration of the biomedical research community.

Please describe plans for further development in each of these themes or areas in years after fiscal year 2011; and d) For each theme or area, please discuss anticipated results and impacts, and what milestones and benchmarks might be appropriate for measuring progress.

Dr. Collins: The five themes were chosen because each presents unprecedented opportunity and is a critical component for the development of a robust biomedical research enterprise. These will continue to be NIH's major areas of focus well past FY 2011. The NIH ICs as well as the OD program offices and the Common Fund have all increased their investments in these five areas and will continue to invest in these areas as well as reap the benefits of this investment for a number of years.

Several specific examples of such ongoing investments in these areas and anticipated results, impacts, and benchmarks for measuring progress include the following.

High-throughput technologies: Cancer is a prime example of how high-throughput technologies promise new and improved treatments. Additional high-throughput technologies will enable assessment of gene expression and epigenomic regulatory alterations of gene transcription and translation within a given cancer. This will allow cancer diagnostics to evolve into a new paradigm, where classification is based on what molecular pathways are abnormal in the tumor. That classification will improve the ability to predict potential response to therapy, and there will be a substantial increase in new cancer drug targets. Based on these new targets, new promising compounds will be developed, often through partnerships, in both the public and private sectors. The majority of NCI-sponsored clinical trials will include complete genomic analysis of every tumor in order to match genomic findings with the appropriate drug combination. A key benchmark will be a significant increase in the number of novel compounds in Phase 1-3 clinical trials for cancer.

Translational Science: The National Heart Lung and Blood Institute provides informative examples of how NIH translates basic research findings into new and better treatments. The Bench to Bassinet (B2B) program is just getting underway, and in the future will create a critical mass of collaborative research across three interacting consortia. The Cardiovascular Development Consortium will probe the details of the transcriptional regulatory networks that govern cardiac development, using complementary animal models. The Pediatric Cardiac Genomics Consortium will recruit children into a common protocol to speed discovery of causative genes and evaluate the effects of genetic variation on short and long term outcomes in patients with congential heart disease. These two Consortia will align with the third component of B2B, the Pediatric Heart Network, a multi-center clinical research enterprise. Ultimately, the results of B2B will be seen in the acceleration of the pace of fundamental discovery while simultaneously establishing a new paradigm for conducting translational research. One important benchmark for the success of these

Consortia will be the identification of new minimally invasive treatments for patients using image-guided interventions.

An important new effort in the area of translation science is the NIH Therapeutics for Rare and Neglected Diseases Program (TRND). TRND will build upon the successes of the NIH Chemical Genomics Center (NCGC). NCGC facilitates drug development from the basic research lab to the pre-clinical stage, which is when researchers begin to lay the groundwork for possible human testing of candidate drugs. Picking up where NCGC's work leaves off, TRND will concentrate on the pre-clinical stage of drug development. TRND's aim will be to move candidate drugs forward in the drug development pipeline until they meet Food and Drug Administration (FDA) requirements for an Investigational New Drug (IND) application. Once TRND generates enough data to support an IND application for a candidate drug, the drug would then be handed off to an experienced organization outside of NIH, such as a pharmaceutical company, for human testing and other aspects of clinical development. There may be situations in which TRND starts or remains involved in clinical studies. Like NCGC, TRND will pull together researchers with expertise in a broad and diverse range of scientific disciplines and disease areas.

Enabling Health Care Reform: Reinventing health care is thus an urgent national priority. NIH can make substantial contributions to this effort. Among projects that will be pursued are:

-- *Comparative effectiveness research (CER).* NIH continues to evaluate the outcomes of different medical treatment options. Examples include the Diabetes Prevention Program that demonstrated substantially better benefits of exercise and lifestyle changes over medication in preventing the onset of diabetes, and the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study that compared older, cheaper antipsychotic drugs with newer ones, demonstrating that the older drugs worked just as well and had a better side-effect profile. With support from the American Reinvestment and Recovery Act (ARRA), NIH is investing $400M in such studies in FY09 - FY10, and expects to continue high levels of support in the future.

-- *Prevention and personalized medicine.* Advances in pinpointing individual genetic and environmental risk factors for disease now make it possible to focus prevention strategies more effectively on those who need them most. For example, research to establish the utility of newly derived information about individual genetic risks associated with breast cancer, colon cancer, or prostate cancer, will help inform the timing of mammography, colonoscopy, or PSA screening. Some of these answers can be derived from retrospective analysis of legacy studies, but others will require prospective designs – including the possibility of initiating large scale cohort studies. Behavioral research focusing on how individual information about disease risk actually alters health behaviors and clinical outcomes will be a critical component of this program. A new NIH Basic Behavioral and Social Science Research Opportunity

Network (OppNet) has just been convened to explore the most effective ways to support this research.

-- *Health disparities research.* The health of racial and ethnic minorities, people living in poverty, and other disadvantaged groups in the United States is substantially worse than the health of the overall population. Using new and powerful tools to disaggregate environmental and genetic contributions, NIH will seek to pinpoint the causes of health disparities and point the way towards solutions.

-- *Pharmacogenomics.* Already there is compelling evidence of a correlation between genotype and drug response for more than a dozen drugs and that number is growing. But prospective studies will be needed for many of these applications, if FDA is to be convinced to require genotyping on the label, and insurance companies are to be convinced to reimburse for the cost of genotyping.

-- *Health research economics.* While the major justification for biomedical research will always be the relief of human suffering and the prolongation of life, further precision is needed in assessing the economic value of research initiatives, especially those that are large and expensive. Models that attempt to capture this cost-benefit balance in DALYs, QALYs, Value of Investment approaches, or other metrics are only partially successful in providing the kind of information that policymakers need. NIH could contribute usefully to this situation by initiating a grants program to encourage development and application of more rigorous models.

Global Health: Much of recent global health research has justifiably been focused on AIDS, tuberculosis, and malaria, given the enormous human toll from these common and life-threatening disorders. But it is also critical to go beyond the focus on the "big three" diseases to apply some of these same strategies to neglected tropical diseases (NTDs) of low income countries that contribute to staggering levels of morbidity and mortality. In collaboration with other sources of support such as the Bill and Melinda Gates Foundation, NIH is well positioned to play a major role in ramping up the discovery of novel targets in both pathogen and host, to facilitate advances in prevention, diagnostics, and therapeutics. Additional resources will be committed to respond to the growing challenge of chronic non-communicable diseases and injuries, which are now responsible for more than half of deaths in the developing world.

Reinvigorating the Biomedical Research Community: NIH will continue to develop innovative approaches to maintain a vibrant biomedical research community that evolves with changing conditions and is poised to exploit critical opportunities for growth and innovation. The NIH Office of the Director will continue to identify important areas of emerging scientific opportunities, rising public health challenges, and knowledge gaps that deserve special attention. NIH will continue to coordinate and oversee the planning, implementation, and evaluation of a series of trans-NIH programs supported by the NIH Common Fund. The Common Fund supports a number of new grant award mechanisms such as the Pioneer awards and the Transformative Research

Projects Initiative that provide funding for innovative research approaches. In the future, the Common Fund will remain a nimble source of funds for the NIH Director to develop new programs that address emerging challenges and opportunities.

FY 2010 STIPEND UNDER RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARD

Mr. Obey: What is the current NIH budget policy regarding stipends under the Ruth L. Kirschstein National Research Service Awards program in future years?

Dr. Collins: Enhanced training stipends are currently a key element of one of the NIH Director's top five priorities, "Reinvigorating the Biomedical Research Community." NIH is committed to improving research training stipend levels so that they reflect the extensive education and specialized skills that graduate students and newly trained investigators in the biomedical sciences bring to their vocation. The FY 2011 President's Budget includes a 6% increase. . This phased multi-year approach will seek to attain the stipend levels identified in 2001 in response to a report from the National Academy of Sciences -- $25,000 for pre-doctoral trainees and $45,000 for entry-level post-doctorate recipients.

RECRUITING AND TRAINING

Mr. Obey: What is your judgment regarding future needs for biomedical researchers?

Dr. Collins: Talented and dedicated scientists are the lifeblood of biomedical research. Today approximately 300,000 scientists and research personnel perform medical science at more than 3,100 universities, medical schools, hospitals and other research facilities located in all 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad. The number of trainees supported by NIH formal research training programs is in fact only a fraction of the total number of individuals being trained for careers in biomedical research; a larger proportion are preparing for research careers by serving as research assistants on research projects supported by the NIH and other sources. The National Academies of Science has emphasized that the formal training program, although a small percentage of the overall training effort, sets the standard for quality and serve as an essential way to recruit talented individuals into the biomedical research careers. However, researcher training programs face many challenges. Stipends for graduate students have failed to keep up with inflation, a challenge recognized in the FY 2011 request with a 6% stipend increase versus FY 2010.

We also need to train and support a diverse biomedical research community of the best and brightest scientists, support and fund new investigators following their training, and attract and retain physician scientists, a need which will become more critical with increased emphasis on translational research to accelerate the translation of

basic science discoveries into new and improved diagnostic and treatment advances. Our success in increasing healthy life spans and preventing and treating disease -- especially given the demands of an aging population and health care reform -- depends upon a cadre of well-trained physician scientists.

Mr. Obey: Are we likely to be facing a shortage of well-trained and well-qualified principal investigators in future years, or should we be more concerned that there may be more researchers than can realistically be supported with likely public and private research funding?

Dr. Collins: Predicting the optimum size of the scientific workforce in the future is difficult and depends on many variables, including the overall research budgets of NIH, other Federal Agencies, and the for-profit and non-profit sectors. Estimates of future numbers have been derived by assessing the population of biomedical, behavioral, and clinical scientists currently employed at research universities and medical schools, biotechnology companies, the pharmaceutical industry, other large commercial biomedical research firms, small businesses engaged in biomedical research, and public and private research instituions; estimating the future growth of these enterprises, and the numbers of senior scientists leaving the workforce each year due to retirement. The studies conducted on a periodic basis by the National Academies of Science use these approaches and comprehensively consider the nation's needs for biomedical researchers when making recommendations about the size and nature of the NIH research training and career development programs. The most recent report issued in 2005 indicated that there was reasonable balance between the supply and estimates of future demand. However, NIH believes it is time to develop better models about the optimum size and nature of the U.S. workforce for biomedical research. Scientific opportunities abound for well-trained basic and clinical scientists.

Mr. Obey: Should NIH and government generally be trying to encourage more students and graduates to enter this field?

Dr. Collins: The biomedical research enterprise depends on students and postdoctorates to provide a continuing and renewable supply of new, independent investigators. These individuals are the drivers of innovation, staffing labs that create new knowledge to answer critical, health-related research questions. Today there are unprecedented opportunities in biomedical research, including genomics and other high-throughput technologies, translational research, personalized medicine, nanotechnology, and stem cell therapy—to name but a few. As a nation, we must encourage the best and the brightest young minds to exploit these extraordinary opportunities and address the health needs of our citizens.

ATTRACTION AND RETENTION OF NEXT GENERATION

Mr. Obey: In addition to the Kirschstein NRSA fellowships, what other measures is NIH undertaking or planning in order to attract and retain the next generation of biomedical researchers?

Dr. Collins: The Ruth L. Kirschstein National Research Service Awards (NRSA) program serves to replenish the Nation's corps of biomedical and behavioral research investigators. Through institutional awards and individual fellowships, NIH supports both basic and applied research training in biomedical and behavioral sciences, funding more than 17,000 Full-Time Training Positions (FTTPs) annually. The FY 2011 President's Budget provides stipend increases of 6% versus FY 2010.

Over the last five years, NIH has developed a number of new programs and policies designed to minimize the length of research training and retain newly trained investigators in research. These programs include the Pathway to Independence Awards, to help postdoctorates transition to research independence, and the NIH Director's New Innovator Awards, designed for creative new investigators.

NIH also has adopted policies to ensure a continuous flow of new, independent investigators by offering opportunities to previously unfunded applicants. Applications for traditional research grants (R01s) from new investigators are clustered at review to provide better comparisons across investigators at the same career stage. Institutes and centers also equilibrate the success rate for new investigators with the success rates for experienced investigators submitting applications for new projects (type 1). This ensures that approximately a quarter of all competing R01 awards involve new investigators. In addition, the NIH specifically identifies new investigators who are within 10 years of their terminal research degree or within 10 years of the completion of their medical residency. These individuals are called Early Stage Investigators (ESI) and current policy specifies that a majority of all new investigators will be ESIs. Recognizing that the path to independence can be interupted by life events, the ten year ESI period can be extended to accommodate a career delay associcated with illness, disability, family care responsibilities, military service and other factors. We believe these policies will help protect the supply of new investigators and will encourage universities to accelerate the advancement of biomedical scientists to independence.

DECREASE IN THE NUMBER OF COMPETING RPGs

Mr. Obey: Following are several questions about recent trends in Research Project Grants (RPGs), the basic mechanism NIH uses to support investigator-initiated research:

Under the budget request, the number of competing RPGs is estimated to decrease by 199 in fiscal year 2011, compared to the level expected to be supported with the FY

2010 regular appropriation (i.e., excluding Recovery Act funds) What is the reason for this decrease?

Dr. Collins: Support for RPGs remains a high priority in the FY 2011 Budget. The nominal 2 percent decrease in the estimated number of competing RPGs from FY 2010 is a result of several factors. A major one is the fact that there is a larger commitment base for prior multiyear grants in FY 2011 than in many past years, making fewer dollars available for new grants. In addition, NIH opted to provide an average cost increase of 2% for both competing and non-competing grants to help cover inflation, but which further reduced the pool of funds available for new grants. Furthermore the FY 2011 Budget request for Buildings and Facilities (B&F) included an increase of approximately $26 million over the FY 2010 enacted level of $100 million to provide funds for specific projects related to building safety and regulatory compliance, as well as to implement facility repairs to help the NIH fulfill its continuing commitment to sustain its extensive infrastructure measured by overall Condition Index (CI). Finally, NIH is requesting a 5 percent in the Research Management & Support (RMS) mechanism to support more high-level, hands-on, and state-of the-art skilled managers of scientific portfolios that mirror the growth in the complexity of science.

ESTIMATED COMPETING RPGS FOR FY 2010 AND FY 2011

Mr. Obey: The estimates provided with the fiscal year 2011 budget request indicate that the number of competing RPGs in fiscal year 2010 is now expected to be almost 600 fewer than the estimated last year when the fiscal year budget was submitted, even though Congress appropriated $250 million more than requested for NIH. Why has the estimated number of competing RPGs supported in fiscal year 2010 decreased so dramatically since last year?

Dr. Collins: The decrease in the number of projected competing RPGs between the FY 2010 column for the FY 2011 President's Budget and the FY 2010 conference estimate is related to adjustments for FY 2009 Actual results. It reflects the net impact that ARRA had on the FY2009 Actuals and the impact of recalculating for competing RPGs as NIH continued to apply an average cost policy of 2% in FY 2010.

FY 2009 COMPETING RPG AVERAGE COST INCREASE

Mr. Obey: In fiscal year 2009, the number of competing RPGs supported with regular (non-Recovery Act) appropriations decreased by 626 compared to FY 2008. This decrease seems to be associated with a 13.1% increase in the average cost of competing grants, given 2% average cost increase policy. Why was there such a large increase in the average cost? Were there also other reasons for the decrease in the number of competing grants?

Dr. Collins: In FY 2009, the American Recovery & Reinvestment Act (ARRA) resulted in the blending of economic stimulus and science advancement goals of critical interest to both Congress and the Administration. Average cost projections for RPGs were calculated prior to NIH receipt of $10.4 billion from ARRA where the funds needed to be obligated before Sept 30, 2010. In order to meet the goals of ARRA to accelerate high-quality science that could be accomplished within two years, NIH leveraged the one-time ARRA resources to pay for meritorious research that was smaller in scope (i.e., shorter duration awards of two-years or less). Larger projects, which often need more than two years of support, were then overrepresented in the pool of awards funded by regular annual appropriated funds, skewing the competing RPG average cost statistic.

RESEARCH PROJECT GRANTS

Mr. Obey: Following are several questions about recent trends in Research Project Grants (RPGs), the basic mechanism NIH uses to support investigator-initiated research:

What actions does NIH take to manage the number and average cost of RPGs based on the figures reflected in the budget request, to avoid unanticipated decreases in the number of grants supported?

Dr. Collins: NIH takes several actions to manage the number and average cost of RPGs. Each year, a budget policy is developed and circulated to the Institutes and Centers by the Office of the Director. In addition, NIH publishes a yearly fiscal policy for grant awards. This policy is specifically designed to help stabilize the yearly variation in number of awards made by carefully determining equitable inflationary adjustments for existing non-competing renewal awards. The annual average inflation increase has varied from zero in FY 2007 to 3 percent in FY 2009 and 2 percent in FY 2010. The FY 2010 policy can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-039.html

Mr. Obey: Please explain if this indicates a shift to lessened emphasis from investigator-initiated RPGs used to support basic biomedical research? Please explain what level of basic investigator-initiated RPGs does NIH feel is desirable, and why, to ensure a robust pipeline of future scientific discoveries are available to translate into improved health?

Dr. Collins: The one year estimated decrease in competing RPGs does not reflect a change in our commitment to investigator-initiated research or a lessened emphasis on the research project grant mechanism. The RPG mechanism is NIH's primary mechanism for funding investigator-initiated biomedical research. These grants support investigators in a wide array of research programs across the entire medical research continuum, from basic scientific research at the molecular and cellular levels to translational research to develop treatments that are then tested in clinical trials. Most

grant applications originate with individual investigators who develop proposals for research in their area of interest. NIH experience suggests that an RPG success rate ranging between 20 and 30 percent is optimal for capturing highly meritorious research that is of interest to the researchers and is of high priority to NIH.

Mr. Obey: For each NIH institute and center, please briefly summarize three significant advances in scientific understanding or development of new therapies that have occurred over the past several years or are expected shortly that will have a tangible impact on health and that involved funding or other support through that institute or center. *[Note: This request is in addition to the hearing for the record question for NIH to provide the top 10 biggest or most important advances that NIH funded in the past 30 years to advance public health.]*

COMMON FUND

Dr. Collins: The information follows:

Molecular Libraries and Imaging Program
The Molecular Libraries and Imaging Program is supported by the Common Fund to develop specific chemicals that can be used either as probes to study biological processes or as new lead compounds for therapeutic development. The program has collected over 350,000 diverse small molecule compounds with many of the properties of successful drug candidates. These compounds are distributed to seven screening centers that test their biological activities in assays designed by academic researchers. Compounds found active in these assays are optimized for maximum biological performance by developing chemical analogs. To date, the program has produced 164 probes, including several that are lead candidates for therapies against critical diseases including cancer, neurological and psychiatric disorders (cognitive impairment, schizophrenia, Parkinson's disease, multiple sclerosis, Alzheimer's disease), and infectious diseases. All the data from these screens is rapidly released to the public through the PubChem database, which contains structures of over 26 million compounds and has over 60,000 daily users.

Human Microbiome Project
In FY 2008, the Common Fund launched the Human Microbiome Project to characterize the multitude of bacteria and viruses that live on and in us, including the many microbes necessary to maintain healthy digestive and immune systems. The program is creating a catalog of microbial genome sequences to enable researchers to associate specific health conditions with changes in certain microbes. To date, it has sequenced the genomes of over half of the planned 900 bacteria and made these publically available. To link changes in the microbiome with health status, the program is characterizing bacteria in samples from the mouth, nose, gut and skin of 300 healthy human volunteers using advanced, high-throughput technologies. To date, 286 people have been sampled once, 174 people have been sampled twice and 28 people have been sampled three times, which will allow the program to identify changes in the healthy

microbiome over time. In addition, the Human Microbiome Project is supporting 15 projects focused on associating changes in the microbiome with conditions that include obesity, cancer, acne, infant mortality, and Crohn's disease. The results of the Human Microbiome Project will increase opportunities to improve human health through monitoring or manipulation of the human microbiome.

Epigenomics Program

The Epigenomics Program is intended to provide genome-wide maps of several epigenetic marks in a variety of cell types so that epigenomic changes may be correlated with diseases, conditions, and aging. The Epigenomics Program also provides support for discovery and technology development to advance the field of epigenomic analysis. Researchers funded through an initiative to generate human reference epigenome maps have completed almost 360 experiments. As of April 1, 2010 the Epigenomics Mapping Centers have mapped at least one epigenomic mark (DNA methylation or histone modification) for 28 distinct human cell/tissue types. These cell/tissue types include human embryonic stem cell types, induced pluripotent stem cell types, hematopoetic cell types, breast cell types, kidney, brain, lung, heart, and pancreatic islet cells. Using the Mapping Center definition of epigenome (global mapping of DNA methylation analysis and six histone marks) a total of six epigenomes have been mapped to date. Analysis of the data sets is well underway. These data sets deposited at the National Center for Biotechnology Information are being utilized by the scientific community. Over the past two weeks more than two thousand people have viewed Roadmap Epigenomics Program records and more than two hundred data downloads occurred. Investigators funded through this program have also successfully developed new technologies for epigenomic analysis that are being adopted throughout the research community.

FOGARTY INTERNATIONAL CENTER

Circumcision in HIV-Infected Men Does not Reduce Risk of HIV Infection in Female Partners

Recent clinical studies conducted in sub-Saharan Africa demonstrated that circumcision reduced risk of HIV infection in men by 50-60%. A study in Rakai, Uganda was the first randomized controlled trial to assess whether circumcision in HIV-infected men would reduce transmission of the virus to uninfected female sexual partners. Researchers found that circumcision of HIV-infected men did not reduce transmission of HIV to uninfected female partners over a 24 month study period. The results also suggested a higher risk of HIV transmission in couples who resumed intercourse before complete surgical healing from circumcision. As HIV prevention programs promoting male circumcision are scaled up in high disease burden areas, it is likely that HIV-infected men would also seek circumcision, in part, to mask HIV status and avoid HIV-related societal stigma. Given the findings of this study, the authors recommended that male circumcision should be offered in conjunction with HIV counseling services, condoms, and HIV prevention education for HIV-infected circumcised men and their

partners. Moreover, sexual intercourse should be resumed only after full healing of the wound after surgery.

Genomic Traits Predict Transmission of Viruses between Humans and Livestock
Many emerging infectious diseases that pose a threat to humans, such as SARS and West Nile Virus, are transmitted from animals. Researchers constructed and analyzed a database of genetic factors likely to affect the ability of a virus to infect another species. Surprisingly, researchers found that livestock viruses that replicated in the cytoplasm rather than the nucleus of the cell were more likely to infect humans. As evidenced by the rapid spread of infectious diseases in an increasingly globalized world, it is important to identify viruses that have the potential to cause pandemics. The finding that viral replication in the cytoplasm is the best predictor of animal to human transmission will assist scientists in future identification of viruses that have the potential to cause infectious disease epidemics or pandemics.

Fears of HIV/AIDS Stigma and Discrimination Discourage Women from Receiving Maternal Services in Kenya
In Sub-Saharan Africa, the intersecting epidemics of HIV/AIDS and maternal mortality have taken a terrible toll on young African women. Women comprise approximately 60% of adults living with HIV/AIDS in the region. Prior studies suggested that HIV/AIDS-related fears may adversely affect both use of facility-based delivery services and the quality of care provided on maternity units, but few have examined that link directly. In interviews by researchers, study participants reported that HIV-related fears, including HIV testing without consent, involuntary disclosure of HIV status, and HIV/AIDS stigma, are among the reasons that women avoid giving birth in health facilities. Importantly, women of unknown HIV status seemed to cause health workers considerable anxiety and were more likely to be targets of discrimination by healthcare workers than women who were HIV-positive. This study suggests that measures to counter stigma are important not only for HIV/AIDS diagnosis and treatment, but also for the improvement of maternal health and that greater outreach is needed to sensitize healthcare workers on issues related to patient consent and confidentiality.

NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE

Ginkgo biloba Does Not Slow Cognitive Decline in Large Study of Older Adults
Although the herb *Ginkgo biloba* is widely marketed and used to improve cognitive health in aging adults, rigorous scientific evidence of its effect on long-term cognitive functioning has been lacking.

NIH-supported researchers rigorously analyzed *Ginkgo biloba's* effects on memory. Results showed that ginkgo did not reduce dementia in Alzheimer's patients or slow cognitive decline. The 2007 National Health Interview Survey found that over 11 percent of American adults who reported using natural products reported using ginkgo,

making it the seventh most used natural product among adults. Such results, which demonstrate no effect from ginkgo in reducing overall incidence of dementia or slowing cognitive decline, are important to share with the American public so they can make informed health care decisions.

Physicians Use of Placebo Treatments for Patients
Treating patients with placebos has a long, complicated, and often controversial history. Nonetheless, little is actually known about U.S. physicians' current attitudes toward and use of placebo treatments. A recent survey found that about half of the physician respondents prescribed placebo treatments on a regular basis. Most (62%) said they think the practice is ethical. Among physicians who prescribed placebos, few said they used inert treatments such as saline injections or sugar pills; they were more likely to recommend over-the-counter analgesics (41%) or vitamins (38%). The survey provides insights into the complex relationship between placebo use and physicians' traditional role in promoting positive expectations in their patients. Understanding the many dimensions of the placebo effect remains an extremely important topic for biomedical and behavioral research, and prescribing placebo treatments remains an appropriate topic for ethical and policy debates.

Grape Seed Extract May Help Neurodegenerative Diseases
A group of neurodegenerative conditions such as Alzheimer's disease have been linked to the build-up of "misfolded" tau proteins in the brain. In an *in vitro* study investigators showed that grape seed polyphenol extract (GSPE) is capable of interfering with the generation of tau protein aggregates and of disassociating preformed aggregates, suggesting that GSPE may affect processes critical to the onset and progression of tau-associated neurodegeneration and cognitive dysfunction. This work followed an earlier study in which GSPE reduced Alzheimer's-type neuropathology and cognitive decline in a mouse model of Alzheimer's disease, and inhibited an Alzheimer's-linked process called cerebral amyloid deposition. The study's findings, together with indications that this GSPE is likely to be safe and well-tolerated in people, support further research and development of GSPE for the treatment or prevention of tau-associated neurodegenerative disorders such as Alzheimer's disease.

NATIONAL CANCER INSTITUTE

New Target Found for Common Childhood Cancer
Rhabdomyosarcoma (RMS) is the most common type of sarcoma found in children. This aggressive cancer arises from skeletal muscle cells and can occur in many places in the body. Less than 30 percent of children with metastatic RMS survive more than five years. New evidence suggests that increased activity of FGFR4—a protein expressed during muscle development and highly expressed in RMS—may play a role in the growth and spread of RMS. Analysis of tissue from patients showed that high expression of the *FGFR4* gene is associated with advanced-stage disease and poor patient survival. Depletion of wild-type *FGFR4* in human RMS cells transplanted into

mice resulted in reduced tumor growth and fewer lung metastases. Experiments in mouse RMS cell lines showed that expression of these mutant genes resulted in activation of FGFR4 and downstream signaling pathways as well as increased tumor proliferation and metastatic potential. These results indicate that *FGFR4* acts as an oncogene in RMS and provide a rational basis for targeting the FGFR4 pathway in patients with advanced-stage RMS, who currently have very poor long-term prognoses.

Elucidating the Role of Antisense RNA Regulation in Cancer

Antisense RNA, which is complementary to protein-encoding RNA, can play a role in regulating cellular processes. When expressed correctly, antisense RNA molecules can manage organization of the chromosomes and regulate gene expression; however, improper accumulation of antisense RNA can have harmful effects on the cell, such as the loss of growth control and tumor development. Recent studies indicate that a protein called H2A.Z and the RNA interference (RNAi) machinery (that degrades RNAs) have important roles in preventing the accumulation of antisense RNA. Cells that were genetically altered to remove H2A.Z exhibited a large increase in antisense RNA production. These experiments suggest that H2A.Z, together with the RNAi machinery, recognizes improper antisense RNA and facilitates its degradation before it can alter cellular processes. It is likely that aberrations in antisense RNA regulation contribute to cancer and other diseases. This knowledge expands our understanding of the cellular events that contribute to cancer initiation and progression and may help identify new therapeutic targets.

The Cancer Genome Atlas Reports First Results of Comprehensive Study of Brain Tumors

The Cancer Genome Atlas (TCGA) Research Network aims to catalogue and discover important cancer-causing genome changes through large-scale analyses and provide the data rapidly to the research community. Initial results of the comprehensive study of the most common and deadly brain tumor in adults, known as glioblastoma (GBM) provided new insights into the roles of three cancer-related genes—ERBB2, NF1, and TP53. The results also uncovered some of the focal points disrupted in three major cellular pathways and implicated them in the development of GBM. Determination of the patterns of deregulation of different major pathways in glioblastomas may be informative in guiding future therapeutic decisions. Together, these findings demonstrate the usefulness of the type of large-scale analysis carried out by TCGA for rapidly expanding our knowledge of the molecular basis of cancer.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

Effectively Recruiting Minorities into Clinical Research

Although minority populations disproportionately bear the burden of many chronic illnesses and diseases, they are often under-represented in clinical research and traditional methods of engaging minority populations in clinical research have often proven ineffective. Using a Community Based Participatory Research (CBPR)

approach, academic researchers and community members collaborated to test the effectiveness of a range of strategies intended to recruit low-income minority persons in a diabetes prevention intervention. Results of this research suggested that recruitment approaches in which researchers partner with members of the targeted community are the most effective at recruiting and enrolling minority populations in clinical research (68% of enrollees). Identifying effective recruitment strategies is a huge initial step towards enrolling and retaining minorities in clinical research trials; determining whether the health practices or interventions under study are effective for members of minority groups; and reducing or eliminating health disparities.

The Role of Community Nutrition Programs in Reducing Obesity in Children from Medically Underserved Communities

The prevalence of overweight in children is high in the United States. Current estimates indicate that 17% of children and adolescents are obese, representing a threefold increase compared with two decades ago. This cross-sectional study of 2- to 12-year-olds living in medically underserved areas examined the proportion of children meeting the food group intake recommendations for fruits, vegetables, total grains, dairy, and meat/meat alternatives by age group and body weight status. Overall, the proportion of children meeting the food group intake recommendations was low with the exception of the meat group, which was met by 52% and 93% of the 2- to 5- and 6- to 12-year-old children, respectively. The data support the importance of community-level nutrition intervention programs to improve children's diet quality in low-income, medically underserved areas and suggest that such interventions may help reduce the risk of obesity. The Community Health Center setting may be an appropriate venue for community-level intervention studies aimed at improving the dietary intake habits of children at high risk for childhood obesity.

Increasing the Capacity of Health Sciences to Address Health Disparities

In order to create a cohort of investigators who are engaged in health disparities research, scholarship, and practice, and to increase the amount of funding in the university that is invested in research focused on reducing health disparities, the San Diego EXPORT Center implemented 2 major initiatives: (1) the support of development of diverse junior faculty who are interested in health disparities research and (2) the funding of pilot research grants in health disparities. Ninety-five percent (18 of 19) URM junior faculty completed the faculty development program, and 83.3% (15 of 18) of the completers are advancing in their academic careers at the University of California San Diego (UCSD) and are teaching, working with populations at risk and/or conducting research in health disparities. EXPORT awarded 7 investigators a total of $429,186 to conduct pilot research, and 71.4% (5/7) have now obtained $4.7 million in independent extramural funding. The UC San Diego EXPORT Center has shown that both junior faculty development programs and pilot grant funding are ways in which universities may increase research capacity, strengthen infrastructure for health disparities research, and create a cohort of successful URM junior faculty who advance in their academic careers.

Novel Therapy for Hepatitis C
Chronic Hepatitis C virus (HCV) infection affects more than 170 million people worldwide who may subsequently develop liver cirrhosis or liver cancer. Chimpanzees are the only animals other than humans in which HCV meaningfully replicates, although HCV does not typically cause disease in chimpanzees. A novel treatment strategy relies on a drug directed against a host cell RNA, microRNA 122, which is needed for HCV to replicate. An oligonucleotide that interferes with microRNA 122 successfully blocked virus production in animals. This new class of drug that targets a cellular product needed for HCV replication (therefore, removing the potential for the development of drug resistance by the virus) showed excellent efficacy in chimpanzees. Further testing will be needed to assess safety in infected populations, and to potentially develop additional agonists with an acceptable efficacy/safety profile in humans.

Method to Judge Effectiveness of HIV Vaccine Candidates Identified Through Use of a Monkey Model of AIDS
The multi-decade effort to develop an HIV/AIDS vaccine has been hampered by the lack of a valid surrogate marker for effectiveness, which would help select hopeful vaccine candidates for testing in human clinical trials. Such markers would reduce costs and save time expended on human clinical trials. Scientists developed a mechanism-based method to predict vaccine effectiveness in a monkey AIDS model. The methods are based on counting "targets" (i.e., retrovirally infected cells that need to be killed by the host), and "effector cells" (i.e., relevant host immune cells that are available at the right time and the right place to kill the infected cells). Using this method, the location, timing, and magnitude of the immune responses from vaccination will enable pre-evaluations of HIV/AIDS vaccines tested in monkey models to predict whether an analogous approach is likely to be effective in humans.

Molecular markers enhance the diagnosis and treatment of Non-Hodgkin's Lymphoma
There are many different forms of non-Hodgkin's lymphoma, which is among the most common and deadly malignancies in adults. The many forms of lymphoma are very hard to distinguish using current clinical tests because the cancerous cells are virtually indistinguishable. This has a significant impact on diagnosis and treatment. The NCRR-supported Mass Spectrometry Resource for Biology and Medicine at Boston University has played a key role in developing a new approach to diagnosis and characterization of non-Hodgkin's lymphoma using the molecular signatures of proteins that are produced by these cancerous cells. There are two important novel aspect of this strategy. First, information on protein markers is combined with gene expression data. This combination makes each approach significantly more powerful. Second, the protein signature of cancerous cells is compared not just with normal cells, but also normal cells that are rapidly growing and multiplying. This allows the researchers to distinguish the unique cancer signature from changes that occur when cells grow normally. Effective, reliable molecular "markers" of disease, particularly cancers, is an important goal of biomedical research. This study demonstrates the significantly

increased analytical power and molecular specificity of molecular markers that is possible through modern mass spectrometry and related techniques.

NATIONAL EYE INSTITUTE

Clinical trial network demonstrates comparative effectiveness of Lucentis for reversing some vision loss caused by diabetes

Diabetic retinopathy is a leading cause of blindness in the US. Fluid leaking from newly formed, but abnormal, blood vessels in the eye leads to retinal swelling and vision loss. For the past 25 years, diabetic retinopathy has been treated by using a laser to destroy abnormal blood vessels. Laser therapy slows progression of the disease, but new therapies are required to improve care and prevent further vision loss.

Evidence has accumulated that abnormal blood vessel growth in diabetic retinopathy is caused by a protein, vascular endothelial growth factor (VEGF). This trial compared the effectiveness of laser therapy alone to laser therapy combined with Lucentis, a drug that prevents VEGF from stimulating abnormal blood vessel growth. Nearly 50 percent of patients who received the combination of Lucentis and laser treatment experienced substantial visual improvement after one year, compared with only 28 percent who received laser treatment alone. Lucentis is currently FDA-approved for treating age-related macular edema, which is also caused by leaky abnormal blood vessels. Although the use of Lucentis for diabetic retinopathy is currently off-label, the results of this trial are already changing clinical practice.

Clinical Trial of Gene Transfer Therapy for Congenital Eye Disease Finds Lasting Visual Improvement

In 2007, the National Eye Institute launched a phase I clinical trial to assess the safety of gene transfer in humans with a form of Leber congenital amaurosis (LCA). This is the first clinical trial to assess gene therapy in humans with eye disease. People with LCA are born with severe visual impairment or lose their vision in early childhood. The form of LCA being evaluated in this study results from mutations in the RPE65 gene which plays a critical role in the visual cycle, the set of biochemical reactions that convert light into an electrical signal to initiate vision. Mutations in the RPE65 gene disrupt the visual cycle resulting in LCA. Fortunately, the structure of the retina remains relatively intact into early adulthood, providing an opportunity to intervene therapeutically. In 2009 investigators published one year follow-up results of the three patients who received this investigational therapy. The patients, ranging in ages from 22-25, remained healthy and experienced no adverse events. Statistically significant increases in light sensitivity were found in the first three months of the trial in all patients and remained unchanged at one year. Gene transfer is particularly well-suited to the treatment of retinal degenerative diseases. Nearly 200 single gene defects have been implicated in these diseases. This clinical trial is an important step in treating LCA and in establishing proof-of-concept for gene transfer as a viable therapy for an entire family of eye diseases.

Elimination of Blinding Trachoma Unexpectedly Reduces Childhood Mortality
Trachoma is a leading cause of blindness in the developing world and affects an estimated 8 million people. Children are most susceptible to this infectious disease that is caused by exposure to *Chlamydia trachomatis*, a microorganism which spreads through contact with other infected people and through transmission by flies. An NIH-supported clinical trial demonstrated that six treatments of azithromycin for more than 90 percent of the population in two severely affected Ethiopian communities over a three year period eliminated trachoma. Additional analysis by these investigators showed that treating these villages with azithromycin also sharply reduced childhood mortality. This unexpected effect most likely occurred because the antibiotic was also active against undiagnosed respiratory infections, gastrointestinal diseases, malaria and other endemic diseases. The strategy of local elimination of trachoma in severely affected villages provides evidence that it is possible to eradicate the disease worldwide and significantly improve child health.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Large-Scale Genetic Study on Lung Cancer Opens Door to Individualized Treatments
More than 150,000 people die of lung cancer each year in the United States. Lung adenocarcinoma, the most frequently diagnosed form of lung cancer, arises over the course of years from cumulative DNA changes, which are poorly understood. The Tumor Sequencing Project (TSP) consortium identified 26 genes that are frequently mutated in lung adenocarcinoma. In particular, over two-thirds of the tumors studied had at least one mutation affecting the mitogen-activated protein kinase (MAPK) pathway. This pathway likely has a crucial role in lung cancer, and now serves as an area of future study and development of therapeutics. Also, researchers found that tumors from smokers had a threefold increased mutation rate compared to tumors from patients who had never smoked. The discovery of additional genes and pathways involved in lung cancer will inevitably help pave the way for more individualized approaches for detecting and treating the nation's leading cause of cancer deaths. By utilizing the important subgroups identified by the study, doctors will be able to better characterize individual tumor types and suggest more effective, personalized therapies.

High throughput screening and medicinal chemistry used to identify lead compounds to treat trypanosomiasis Trypanosoma is a group of parasites that infect and replicate inside a host. Spread by blood-sucking bugs, *T. cruzi* causes American trypanosomiasis, commonly called Chagas disease. About 16 million people are infected with the parasite, primarily in Latin America. The chronic form of Chagas disease can damage the heart, esophagus and peripheral nervous system. A related species, *T. brucei*, which is transmitted by tsetse flies, causes African trypanosomiasis, or African sleeping sickness. If untreated, the parasite migrates to the central nervous system, causing seizures, mental disorders and, ultimately, death. NIH researchers designed an automated, high-throughput screen to search for and identify chemical compound that block a key group of enzymes that are essential to *Trypanosoma* survival and reproduction. Medicinal chemists further modified the structure of the chemical

compounds, resulting in 350 times more power to inhibit key *Trypanosoma* enzymes than the original compounds. In addition, the modified compounds demonstrated greater activity against live *T. brucei* parasites grown in the laboratory. This discovery provides an exciting starting point in the effort to create effective drugs for the devastating *Trypanosoma* infections and demonstrates how high throughput facilities can quickly translate scientific discoveries into potential therapies.

Researchers Discover New Genetic Variants Associated with Increased Risk of Stroke
Stroke is the third leading cause of death in the United States and causes serious long-term disabilities for many Americans. There are two major types of stroke. The most common kind, ischemic stroke, is caused by a blood clot that blocks a blood vessel in the brain. The second type, hemorrhagic stroke, is caused by a blood vessel that breaks and bleeds into or around the brain. Scientists identified a previously unknown connection between two genetic variants and an increased risk of stroke, providing strong evidence for the existence of specific genes that help explain the genetic component of stroke. The researchers discovered that two previously unsuspected common genetic variants or single-nucleotide polymorphisms (SNPs) were consistently associated with total stroke (all types) and ischemic stroke in white persons. The genetic variants were discovered by analyzing the genomes of individuals from the CHARGE (Cohorts for Heart and Aging Research in Genomic Epidemiology) consortium. This extensive resource includes participants from the Framingham Heart Study, Atherosclerosis Risk in Communities study, Cardiovascular Health Study and Rotterdam Study. As we learn more about the role that an individual's unique genetic makeup plays in their overall health, we will ultimately be able to tailor care to better diagnose, prevent, and treat conditions such as stroke.

NATIONAL HEART LUNG AND BLOOD INSTITUTE

Researchers Identify New Treatment for Sickle Cell Disease (SCD)
Individuals with SCD produce an abnormal form of hemoglobin that causes red blood cells to sickle, blocking circulation. Patients with milder cases of the diseases often have elevated levels of fetal hemoglobin (HbF). Therefore, a major goal of SCD research is to develop therapies that raise HbF levels. Researchers recently demonstrated that a small genetic change known to correlate with HbF levels affects the function of the gene BCL11A, and that lower levels of BCL11A activity are associated with higher levels of HbF. The investigators showed that artificially reducing levels of BCL11A activity in human red blood cells dramatically increased HbF production, suggesting that blocking BCL11A in patients with SCD also might elevate HbF and ameliorate symptoms. These findings advance the prospects for developing highly effective treatments for SCD via inhibition of BCL11A. SCD is responsible for substantial mortality and significant use of health care resources. The ability to eliminate symptoms and prevent complications would substantially improve the health of millions of people worldwide.

Comparative Effectiveness Study: New Surgery for Heart Failure Patients May Be Unnecessary

Heart failure is the inability of the heart to pump sufficient blood to provide proper nourishment to the body. It can develop when arteries feeding the heart tissue become blocked, as happens with a heart attack. In such cases, a healthy artery or vein from another part of the body can be used to route oxygen-rich blood around the blockage to the heart muscle, a procedure known as coronary artery bypass grafting (CABG). In many patients with heart failure, however, the heart expands like a balloon, further weakening it. Surgical ventricular reconstruction (SVR), a newer surgery that can be performed at the same time as CABG, was designed to eliminate the ballooned, scarred, and thinned area of heart. However, the health benefit of performing this additional surgical procedure during a CABG operation is not known. A comparative effectiveness trial was designed to determine whether CABG alone or CABG plus SVR is the better strategy for management of heart failure caused by obstructed coronary arteries. 1,000 heart failure patients from 96 medical centers in 23 countries were randomly assigned to undergo CABG alone (499 patients), or CABG plus SVR (501 patients). After 4 years of follow-up, researchers found no difference between the two groups in combined rates of death and heart-related hospitalizations. Moreover, no differences were observed in the ability to exercise or in symptoms such as chest pain. The study concluded that SVR offered no benefit over CABG alone in this population. Five million people suffer from heart failure in the United States. The finding that performing SVR in addition to CABG does not improve survival or reduce hospitalizations will help physicians decide how to treat heart failure patients.

New Research Holds Promise for Preventing High Blood Pressure

For years, scientists commonly thought that high uric acid levels (often associated with hypertension) were a result of hypertension rather than a cause. New research demonstrated that lowering blood uric acid levels with drug treatment can reduce blood pressure. In 30 adolescents with hypertension and high levels of blood uric acid, treatment with allopurinol, which lowers uric acid levels, was associated with decreased blood pressure. The results were dramatic—20 of the 30 adolescents attained normal blood pressure while taking allopurinol. Although the findings await confirmation in larger clinical trials, if high uric acid levels are determined to play a role in the etiology of hypertension, treatment with allopurinol may one day be used to delay, or even prevent, the development of hypertension.

NATIONAL INSTITUTE ON AGING

Extending Lifespan

Calorie restriction has been tested in laboratory animals and on a limited basis in humans and found to have a variety of positive effects on health and longevity. Despite these findings, calorie restriction may not be practical or safe for most people. Rapamycin, an inhibitor of the mTOR (mammalian target of rapamycin) pathway that helps to regulate cell growth and proliferation, is one of several compounds being studied for effects that might be similar to those of calorie restriction. Investigators

demonstrated lifespan extension when mice began receiving rapamycin in their chow at 270 or 600 days of age, when some age-associated changes have already begun. Although lifespan extension had been achieved in fly and worm models using pharmacological interventions, this is the first time a drug has been shown to extend lifespan in a mammal. Unfortunately, rapamycin has caused serious side effects in humans. Because of adverse side effects, rapamycin is not the ideal drug for extending the lifespan of humans. However, this research has more clearly identified the mTOR pathway as important across species for extending lifespan and may guide researchers to target different proteins in the same pathway in ways that do not cause harmful side effects.

Brain Amyloid Deposits in Cognitively Normal People May Predict Alzheimer's disease (AD) Risk

The progressive accumulation of beta-amyloid plaques is a hallmark of AD and is considered to be part of the degenerative process of the brain in this disorder. Although the amount of beta-amyloid in the brain is usually associated with the severity of the disease, researchers have long known that some individuals may have a considerable amount of beta-amyloid in their brains but remain cognitively unimpaired. Imaging techniques such as positron emission tomography (PET) used in conjunction with a new tracer compound called Pittsburgh compound B (PiB), which was developed by NIH investigators, allows scientists for the first time to visualize beta-amyloid in the brains of living individuals. Investigators used PiB PET imaging, magnetic resonance imaging, and standardized cognitive tests to explore the relationship between brain beta-amyloid and dementia risk in cognitively normal people. They found that higher amounts of the protein deposits in dementia-free people were associated with an increased risk of developing dementia over time and with loss of brain volume and subtle declines in cognitive abilities. These findings suggest that brain beta-amyloid may in fact be a preclinical sign of disease even among individuals who appear cognitively normal and represents an important step toward development of a comprehensive profile of AD in its earliest stages, before symptoms appear.

Measurement of Biomarkers Shows Promise in Diagnosing Alzheimer's Disease

Alzheimer's disease (AD) is an irreversible, progressive brain disease that slowly destroys memory and thinking skills, and eventually even the ability to carry out the simplest tasks. Research suggests that the earliest AD pathology begins to develop in the brain long before clinical symptoms yield a diagnosis. Therefore, it is critical to detect signs of the disease at the earliest point possible in order to test interventions and, ultimately, treat the disease as early as possible. One of the most comprehensive efforts to date is the Alzheimer's disease Neuroimaging Initiative (ADNI). In the first ADNI cerebrospinal fluid (CSF) biomarker study, NIH-supported researchers established a method and standard of testing levels of both tau and beta-amyloid proteins, known biomarkers for AD, in the CSF. Researchers correlated levels of these proteins in the CSF with changes in cognition over time and determined that changes in these two protein levels in the CSF may signal the onset of mild AD. This is a significant step forward in developing a test to help diagnose the initial stages of

Alzheimer's disease earlier and more accurately so that treatment efforts may begin and potentially delay the development of more severe AD symptoms. This effort may open the door to the discovery of an entire panel of CSF biomarkers that will not only predict people at risk of developing AD, but also assess how the patient responds to therapies.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

Activation of Aldehyde Dehydrogenase-2 Reduces Damage from Heart Attack
Oxygen starvation to working heart muscle due to reduced or blocked blood flow (ischemia) causes a heart attack, which affects nearly one million people in the US every year and is the leading cause of death in developed countries. Prior exposure to certain chemicals such as ethanol and adenosine, and selective activation of protein kinase Cε (PKCε) has a protective effect and reduces the amount of damage during a heart attack. Previous studies demonstrated that exposure to alcohol activates PKCε. However, it was not known whether activation of PKCε □or activation of other proteins was critical for the cardiac protection. Investgators found that a change in the enzyme aldehyde dehydrogenase 2 (ALDH2) caused cardiac protection and that PKCε activation increased ALDH2. The investigators demonstrated that protection by alcohol against heart damage during a heart attack is due to the activation of mitochondrial ALDH2 in response to PKCε activation. Therefore, agents that activate PKCε □and/or ALDH2 might be beneficial in treating patients with heart attacks as well as patients that experience cardiac ischemia for other reasons, such as bypass surgery.

Prevention of Risky Youth Behavior Associated With a Gene Polymorphism - A Test of the Interaction of Genes and Environment
It is thought that both genes and environment influence the behavior of youth, including risky behaviors such as alcohol consumption, illicit drug use, and unprotected sexual intercourse. One genetic factor that affects the likelihood of initiation of risky behavior is a polymorphism in the gene that encodes the serotonin transporter (5HTT), which is known as the "short" variant. Individuals that have the "short" variant display more risky behaviors than individuals with the "long" variant of 5HTT. _Investigators used a randomized prevention trial to test whether rural African American youth, possessing the short 5HTT, were less likely to engage in risky behaviors if they participated in a family-centered prevention program, SAAF (Strong African American Families Program). The researchers found that adolescents with the short variant of 5HTT who participated in the SAAF program were no more likely than control participants who possessed the long 5HTT, to engage in drinking, marijuana use, and sexual activity; and were half as likely to have engaged in these risky behaviors as their counterparts with the short 5HTT who did not participate in the family prevention program. This is the first study to test the interaction between genes and environment in a randomized prevention trial. It demonstrates that African American youth with a particular high-risk genotype benefited more from positive factors in their environments, such as enhanced parenting practices, than did youth with the low-risk, genotype. Parenting that includes high levels of control, vigilance, emotional support and racial socialization

helped young African Americans with the short 5HTT avoid situations that promote risky behavior including affiliation with peers who are likely to engage in these behaviors, and to internalize parental norms for alcohol and drug use.

Fetal Exposure to Ethanol Has Long-Term Effects on the Severity of Influenza Virus Infections

Prenatal alcohol exposure is known to cause numerous birth defects including growth retardation, muscular and skeletal abnormalities, and intellectual and behavioral impairments. Fetal alcohol exposure also causes a variety of immune deficits both in human and animal models. To determine the long-term effects of fetal alcohol exposure on disease susceptibility and on the adult immune system, researchers exposed mice in utero and while nursing to ethanol, and then tested their response as adults to direct viral infection of the lungs. Fetal alcohol exposure resulted in serious long-term impairment of the adaptive immune response and these immune changes were associated with reduced body weight and decreased survival times after influenza viral infection when compared to mice that were infected with virus but were not exposed to alcohol. Whether adult humans exposed to alcohol in utero have the same increased susceptibility to viral infections as observed in these mouse studies is not known; however, these results highlight the need for longitudinal clinical studies to assess the effects of in utero alcohol exposure on long-term immunity.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Vaccine Regimen Shows Modest Reduction in Risk of HIV Transmission in Thailand

The development of a safe and effective vaccine against the human immunodeficiency virus (HIV) is critical to controlling the pandemic worldwide. Traditionally, HIV vaccine studies have focused on a strategy that "primes" or initiates the immune system to respond to the virus followed by a "boost" at a later time period to strengthen the original response. This trial evaluated the administration of four priming injections with a recombinant whole virus vaccine, called ALVAC-HIV, followed by two booster injections of a separate recombinant vaccine that encodes the HIV surface protein gp120, called AIDSVAX B/E. The prime-boost vaccine regimen was found to be safe and 31 percent effective in preventing HIV infection. Patients were monitored for signs of HIV infection in the blood after a 6 month vaccination series and, subsequently, every 6 months thereafter for 3 years. Overall, 74 of 8,198 placebo recipients became infected with HIV compared with 51 of 8,197 participants who received the vaccine regimen. The well tolerated ALVAC-HIV prime and AIDSVAX B/E boost vaccine regimen may reduce the risk of HIV infection in a community-based population. Although the results show only a modest benefit, this finding represents a major step forward for HIV vaccine research, providing the first evidence that development of a safe and effective preventive HIV vaccine is possible.

Rapid Characterization of the 2009 H1N1 Influenza Virus

In April 2009, a new H1N1 influenza virus emerged in Mexico and the U.S. and quickly spread worldwide - the first influenza pandemic of the twenty-first century, as

declared by the World Health Organization. The NIAID Centers of Excellence for Influenza Research and Surveillance (CEIRS), established in 2007 to support the HHS Pandemic Influenza Plan, rapidly redirected funds and other resources to complement public health efforts in response to the emergence of the virus. Within two months investigators decoded the virus genome and found that it had genomic pieces from avian, human and swine flu viruses. Using a ferret model, investigators determined the new virus was more pathogenic than seasonal flu viruses, infecting cells deeper in the lungs than did seasonal viruses that typically stay in the nasal cavity. These researchers also analyzed human sera from different age groups to determine if pre-existing antibodies react to the new pandemic virus. Interestingly, they demonstrated that sera from older patients had the ability to bind and neutralize human H1N1 and 1918 viruses—suggesting that older people may have residual immunity to the new virus. This basic research supported by the NIAID CEIRS helped to rapidly analyze the genetics, pathogenicity, transmissibility, and antiviral susceptibility of a new emergent influenza virus. The CEIRS studies provided the Government the necessary information to begin implementing tools and strategies to control and lessen the impact of the pandemic.

New Biomarkers of Kidney Transplantation Status Identified

Immune-mediated graft rejection is one of the major barriers to the long-term success of organ transplantation. Currently, there is no way for doctors to detect very early stages of transplant rejection and tailor medications accordingly. Prevention and reversal of graft rejection requires potent immunosuppressive medications that are associated with a wide range of adverse effects and can increase susceptibility to serious infections and cancer. NIH-supported researchers found that biomarkers in the transplanted kidney or blood of kidney recipient patients may indicate whether the kidney is functioning well or if it will be rejected by the host. The researchers measured levels of microRNAs, small pieces of nucleic acids that regulate gene expression, in biopsies from healthy transplanted kidneys and in transplanted kidneys undergoing acute rejection. Patterns of microRNA expression were identified that distinguished healthy kidneys from those undergoing rejection or that were functioning poorly. MicroRNA patterns were similar between kidney biopsies and white blood cells from the same patient. Elevated levels of three specific microRNAs indicate that infiltrating immune cells are damaging the kidney by setting off inflammation. These results suggest that microRNA levels in a transplanted kidney or in the kidney recipient's blood may be useful for diagnosing rejection and for predicting how well a transplanted kidney will function. These measurements might one day enable doctors to diagnose rejection and tailor immunosuppressive medications to the needs of individual patients without a kidney biopsy. In addition, this approach may prove applicable to other transplanted organs.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Identification and Treatment of Rare Pediatric Inflammatory Diseases
Neonatal-onset multisystem inflammatory disease (NOMID) is a rare, debilitating autoinflammatory disease. The first sign of the disease is a rash that develops within the first six weeks of life. However, the disease can also affect numerous other body systems, including the joints, eyes, and central nervous system. Other problems, including fever, meningitis, hearing loss, and mental retardation, can often follow and as many as 20 percent of children with NOMID do not survive to adulthood. While the mechanism of NOMID is not completely understood, research in recent years has revealed a particular genetic mutation in 60 percent of patients with the disease. The mutations lead to an imbalance of a chemical messenger, called interleukin-1 (IL-1), which is believed to drive the inflammation that causes the disease. This fact has suggested that anakinra, a drug best known for treating rheumatoid arthritis, might be effective in treating NOMID. Anakinra blocks the effects of IL-1beta (IL-1ß), and is used to stimulate or restore the ability of the immune system to fight disease and infection. Research published in 2006, found that anakinra treatment led to the disappearance of some NOMID symptoms within 3 days, and over the course of a few months, major organ functions were improved. In 2009, these results helped lead to the discovery of a new genetic autoinflammatory syndrome in children called DIRA (deficiency of the interleukin-1 receptor antagonist), as well as demonstrations of effective therapy for DIRA with anakinra. This new therapy will improve the lives of those young people suffering from these, and potentially many other, autoinflammatory diseases.

Surgical versus Nonsurgical Treatments for Three Common Causes of Low Back Pain
Low back disorders are common, costly, and often disabling. Back surgeries in Americans are one of the fastest growing areas of medical care, with hospital costs exceeding $21 billion per year. Before the 13-center Spine Patient Outcomes Research Trial (also known as "SPORT"), many people who had chronic low back pain were conflicted about whether to undergo surgery; some were not sure surgery was worth the risk, while others feared that delaying surgery might cause even more damage. In the past 4 years, SPORT demonstrated that, indeed, surgery is superior to nonoperative treatments for the 3 most common causes of severe low back pain: intervertebral disk herniation and lumbar spinal stenosis with or without degenerative spondylolisthesis (the slipping of vertebrae). However, people who have one of these conditions—and whose conditions are not worsening—are not subjecting themselves to further harm if they adopt a "wait-and-see" approach before committing to surgery. The benefits were particularly noteworthy for those patients with more severe disease and major neurologic deficit, whereas patients with minor complaints and without major neurologic deficit appeared to do comparably well with non-operative treatments. Likewise, SPORT findings are providing additional insight into which patients with herniated disks are likely to benefit most. Patients with a herniated upper lumbar disk

benefited significantly more than those who had lower lumbar herniations, while patients treated for middle lumbar herniations had intermediate benefits.

An X-Chromosome Gene, IRAK 1, Involved in Risk and Pathogenesis of Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE), or lupus, is a devastating, multi-system autoimmune disease, characterized by autoantibody production and tissue damage. Although the cause of SLE is unknown, several lines of evidence support a complex interaction of multiple genes and environmental factors. The disease affects females more frequently than males, at a rate of almost nine to one. Despite the strong sex bias, little is known about whether genes on the X chromosome directly influence disease susceptibility. Interleukin-1 receptor associated kinase 1 (IRAK1), which is encoded by a gene on the human X chromosome, is a critical mediator in the immune system's ability to recognize and respond to pathogens in a non-specific manner. However, little was known about potential IRAK 1 involvement in lupus. In a study involving over 10,000 individuals who had contracted SLE either as children or adults, investigators found five *IRAK1* gene variants, which were more common in patients of multiple ethnic backgrounds, and three of the five overlapped in both childhood- and adult-onset lupus. To examine the biological relevance of *IRAK1* in SLE, the investigators generated *IRAK1*-deficient mice by engineering a strain that is prone to developing the disease. In the absence of *IRAK1*, the animals lacked symptoms associated with lupus, including kidney abnormalities, autoantibody production, and activation of various types of immune cells. Collectively, these results provide compelling evidence that support *IRAK1* as a disease gene in lupus, and its location on the human X chromosome as a possible explanation for female predominance of the disease. Identification and characterization of lupus-associated genetic markers should aid in the diagnosis of patients at risk, provide important insights into pathogenic mechanisms and contribute to the development of novel therapeutic interventions.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Detecting Tumor Cells in Blood at Concentrations as Low as One Part per Billion

Cells that spread, or metastasize, from a primary malignant tumor to distant organs are responsible for 90% of cancer-related deaths, a number that exceeds 500,000 every year in the U.S. alone. Circulating tumor cells (CTCs), which detach from the original tumor and enter the bloodstream, represent a direct link between the primary malignant tumor and its metastases. Although CTCs are present in low concentrations (parts per billion) in the blood, CTC analysis is being developed as an alternative to invasive biopsies as a source of tumor tissue for the detection, characterization and monitoring of many types of cancer. A team of scientists, engineers and clinicians has developed a microfluidic lab-on-chip device that can efficiently and reproducibly isolate CTCs at concentrations as low as one cell per billion from the blood of patients with metastatic cancers. The device consists of microfluidic channels and posts that have been coated with molecules that bind only to the CTCs. When a whole blood sample is run through the device, the CTCs are captured by the posts, while the background cells are carried

through the device by fluid flow. By coating the posts with molecules that have an affinity for different types of cells, the device can be adapted for use in a broad range of clinical settings. An attractive practical feature is that the chip has a simple design and sorts cells directly from whole blood in a single step without any need for sample pre-processing. These features make it conducive to point-of-care use and rapid integration into clinical practice. This new technology provides an early and preemptive diagnosis of disease, as well as the identification of new biomarkers to predict clinical outcomes using a simple blood-based test. In addition, the ability to capture and analyze CTCs in peripheral blood may be used in the development of therapeutic strategies that can be tailored to the individual patient and monitor an individual's responses to cancer therapies.

Intelligent Prosthetic Leg Improves Locomotion for Individuals With Above-the-Knee Amputations

There are more than 300,000 above-the-knee amputees in the United States and 30,000 new amputations are conducted each year. One significant limitation of current lower-limb prosthetic technology is the inability to provide adequate power generation at the knee and ankle joints, which impairs the ability of the prosthesis to restore normal locomotive function during many activities. NIH-supported researchers developed a powered knee and ankle that is self-contained and can be used for both single and double amputees. Parameters such as friction, the type of activity (e.g. walking, standing, sitting and stair climbing), estimators of user intent, movement speed and type of terrain are all accounted for in a real-time control system that provides safe, natural, reliable, and effective control of the powered prosthesis this system. This allows for full user control in which the user implicitly communicates with the powered lower limb prosthesis. This represents the next generation of powered lower limb prostheses capable of implementing user intent in real-time. Vanderbilt University has been approached by three prosthetics companies interested in bringing this technology to market. This would immediately improve the quality of life for the thousands of wounded soldiers, as well as other individuals with leg amputations.

Hi-Tech Drug Delivery for Treating Myocardial Infarction and Other Inflammatory Diseases

Excessive inflammation, with chronic elevation of inflammatory cytokines and reactive oxygen species, is elicited following a myocardial infarction (MI), resulting in cardiac dysfunction. Many clinically approved small molecule inhibitors of inflammation have been identified, however, a safe vehicle to deliver these drugs, that have great potential for improving cardiac dysfunction following an MI, has been lacking. The development of a vehicle to deliver small molecule drugs within the myocardium with controlled and sustained release to slow or halt the progression of cardiac dysfunction following an MI is an area of great need and opportunity. Researchers have formulated polymer microspheres loaded with the inhibitor SB239063 which acts on p38, a mitogen-activated protein kinase that regulates the production of key inflammatory mediators. Studies in rats indicate that the microparticles: 1) were retained in the myocardium and reduced inflammatory signaling; 2) reduced fibrosis within the left ventricular wall; and

3) significantly improved cardiac function over time. All of these results were observed with just a single injection into the infarct zone of the rat left ventricle. This new microparticle holds great promise for controlling inflammation and reducing cardiac dysfunction following an MI, and could potentially be used to similarly treat many other inflammatory diseases.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Genetic Risks of Autism Spectrum Disorders and Brain Cell Connections

Autism spectrum disorders (ASDs) are a complex range of neurodevelopmental disorders that last throughout a person's life time. Even though ASDs appear genetically heritable, little progress has been made in identifying the genetic risk factors linked to ASDs. Part of the challenge is that there are many genes that seem to contribute to ASDs. In two separate studies, NIH-funded researchers identified common and rare genetic factors that affect the risk of ASDs. The results point to genes that are involved in forming and maintaining the connections between brain cells. These results support previous findings on the genetic contributions to ASDs and abnormal cortical connectivity in people with ASDs. These research results support earlier research that examined genetic contributions and abnormal brain connectivity in people with ASDs. In addition, these studies represent a successful application of the genome-wide association study (GWAS) approach to identify common genetic susceptibility alleles and are a significant step forward in a larger effort to understand the complex genetic architecture of ASDs.

Treating Even Mild Gestational Diabetes Reduces Birth Complications for Infants and Mother

Severe gestational diabetes (GDM) occurs when pregnant women develop diabetes during pregnancy, and affects up to 14 percent of pregnancies in the United States. Treating severe GDM is known to benefit mothers and infants. Although treatment is routinely prescribed for all women with gestational diabetes, there was no evidence that treating mild GDM benefited, or posed risks for, mothers and/or their infants.

In clinical studies, researchers found that compared to their untreated counterparts, women treated for mild GDM had smaller, leaner babies less likely to be overweight or abnormally large, and less likely to experience shoulder dystocia, an emergency condition in which the baby's shoulder becomes lodged inside the mother's body during delivery. Treated mothers were also less likely to undergo cesarean delivery, to develop high blood pressure during pregnancy, or to develop preeclampsia, a life-threatening complication of pregnancy that can lead to maternal seizures and death. This study provides the first conclusive evidence that treating pregnant women who have even the mildest form of gestational diabetes can reduce the risk of common birth complications among infants, as well as certain health complications among mothers.

Researchers Develop DNA "Patch" for Canine Form of Muscular Dystrophy
Muscular dystrophies are a group of disorders causing muscle deterioration and weakness. Duchenne muscular dystrophy occurs almost exclusively in males, affecting 1 in every 3,500. Most boys with the condition lose the ability to walk by age 12, and death usually occurs by the early 20s, from heart and respiratory failure. Duchenne muscular dystrophy results from errors in the gene for dystrophin, a key component of muscles. The locations and kinds of the mutations occurring in the gene can vary. To study the disease, scientists use a dog model. The canine version of Duchenne muscular dystrophy occurs naturally in dogs, and affects the same gene that is affected in the human form of the disease. Using a novel genetic technology that covers up genetic errors, researchers funded in part by the NIH developed a successful treatment for dogs with the canine version of Duchenne muscular dystrophy. The technology, known as "exon skipping," uses tailor-made snippets of DNA-like molecules as molecular "patches." The patches, DNA-like molecules called morpholinos, are manufactured in a laboratory. Injections of the morpholino cocktail directly into the dogs' bloodstream curbed deterioration of the animals' skeletal muscles and improved muscle functioning. However, the treatment was unable to prevent deterioration of the animals' hearts. The researchers theorized that the muscles of the heart are less porous than the skeletal muscles, and did not absorb sufficient quantities of the morpholinos to curb the deterioration. These findings lay the foundation for developing therapies in humans by using a cocktail of morpholinos to patch most mutations that occur in the human form of the disorder. Additional research is needed to develop other means of delivering the morpholinos to the heart.

NATIONAL INSTITUTE ON DRUG ABUSE

Anti-Drug Vaccines—A Medication Innovation for Treating Drug Abuse and Addiction
Vaccination, which harnesses the body's own immune system to counter a broad range of disease agents, is being explored as an addiction treatment. Immunotherapy causes the body to generate antibodies that bind to specific drugs while they are still in the bloodstream, preventing their entry into the brain, thus blocking their pharmacological and behavioral effects. In FY09, NIDA awarded a $10 million grant to Nabi Biopharmaceuticals (Nabi) to conduct the first Phase 3 trial testing the efficacy of a nicotine vaccine (NicVax) against tobacco addiction, moving it closer to final FDA approval. Nabi entered an agreement with GlaxoSmithKline to receive an additional $40 million to exclusively in-license NicVAX on a worldwide basis and develop follow-on, next-generation nicotine vaccines, with the possibility of an additional $500 million depending on the outcome of the trial. Preliminary results of a cocaine vaccine are also promising. A proof of concept clinical trial has already occurred, this being the first immunotherapy tested against an *illicit* drug. Findings showed it to be effective in participants who achieved significant antibody levels in their blood, decreasing their cocaine use significantly during the period when their titers were up. Successful vaccines would represent a stunning breakthrough that could enhance the impact of existing therapies, particularly in the case of cocaine addiction, for which no

medications are currently available. Cessation programs for nicotine addiction would also benefit, since vaccines could assist in curbing the exceedingly high relapse rates among quit attempters.

Studies Link Gene Cluster to Nicotine Addiction: Potential for New Therapeutic Development

In the past few years NIDA-supported research has collected multiple and convergent evidence that polymorphisms in the nicotinic acetylcholine receptor subunits α5, α3, and β4 gene cluster are implicated in early initiation of smoking, the transition to nicotine dependence (ND), and two smoking related diseases: lung cancer (LC) and peripheral arterial disease (PAD). Previous research had focused on the α4 and β2 subunits, which were known to play a role in nicotine's rewarding properties. A better understanding of how these genetic variants affect nicotinic receptor function and behavioral responses to nicotine will accelerate the development of new pharmacotherapies. Notably, the α5 is a particularly promising target because its relative low abundance in the brain may lead to medications with fewer side effects.

The Impact of Chronic Cocaine on Epigenetic Factors

Chronic use of an addictive drug, like cocaine, can cause long-lasting changes in the patterns of gene expression in selected brain areas, which may underlie or contribute to addiction. These changes are called "epigenetic" because they influence genetic traits without changing a gene's DNA sequence.

A new study has identified an important mediator of cocaine's epigenetic effects in the nucleus accumbens (a key area of the brain's reward center). The finding sheds light on the long-term functional changes in the brain, brought about by chronic cocaine exposure. Researchers gave several doses of cocaine to young mice. Only animals exposed to chronic cocaine developed a strong preference for cocaine as adults. In addition, these animals showed a significant reduction in the expression of G9a, an enzyme that demethylates histones, effectively loosening up the packaging of genes along the DNA molecule, thus increasing the likelihood that particular genes will be expressed. Importantly, the authors were able to show that by artificially producing large amounts of G9a in the nucleus accumbens, they were able to compensate for cocaine's effects and prevent the establishment of cocaine preference, effectively inhibiting the animal's "craving" for cocaine. These results provide a more complete picture of the epigenetic processes affected by chronic cocaine and will not only help us identify additional pathways and mechanisms involved in the development of cocaine addiction, but potentially aid in the development of new therapeutic approaches.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

Autistic Children Hear Speech Differently

One of the primary distinguishing features of autism spectrum disorder (ASD) is language impairment, particularly in the social and communicative use of language.

Several deficits in the higher processing of language have been identified previously; however, little is known about how the brain of autistic children translates sounds into meaningful information. Researchers presented non-speech (click) sounds and basic speech sounds (in this case a single syllable, /da/) to both children with normal development and children with ASD and then recorded the responses at the most basic level of the brain, called the brainstem. The researchers determined that both groups processed non-speech sounds the same; however, speech sounds were processed differently at the brainstem. Children with ASD did not show the same synchronization of brain activity as normal children, and they also were less able to translate speech signals when combined with background noise. This study is the first to identify deficits in the most basic levels of speech processing in children with ASD. The processing of speech information at the brainstem is easily recorded in a passive and non-invasive manner. These brainstem responses may eventually be used to identify specific deficits in speech processing to aid diagnosis of children with ASD and may also be used to measure the effectiveness of auditory training programs to assist children with ASD.

Restoration of Hearing by Generating Auditory Hair Cells in the Cochlea
Sensorineural hearing loss is a common form of hearing impairment which occurs when either sensory hair cells of the inner ear or auditory nerve cells are destroyed. Until recently, scientists believed that auditory hair cells in mammals could never be replaced if they were injured or destroyed. In a 2005 landmark study, NIDCD-supported scientists treated deafened guinea pig ears with a viral vector carrying the gene *Atoh1*. Eight weeks after treatment the researchers found new hair cells in the ears treated with the *Atoh1* gene, and auditory testing confirmed that the generation of hair cells coincided with partial restoration of hearing. This is the first demonstration of the use of gene therapy to improve hearing in deafened animals. Following this discovery, another group of scientists successfully produced functional auditory hair cells in the cochlea of the newborn mouse inner ear using gene therapy with *Atoh1*. The gene was inserted along with green florescent protein (GFP) which is the molecule that makes a species of jellyfish glow. GFP is often used in research as a "marker" that a scientist can use to determine, in this case, the cells expressing the *Atoh1* gene. Using this method, the researchers were able to trace how the inserted genetic material successfully led to hair cell production resulting in the appearance of more hair cells than are typically observed in the ears of early postnatal mice. Successful production of functional sensory hair cells in the inner ears of mice suggests that a new therapy to regain hearing may be possible for humans in the future.

Viewing Tinnitus in Action
Tinnitus is the perception of sound in the absence of sound (i.e. ringing, roaring, hissing, or clicking sounds in the ears). It is generally associated with hearing loss as a result of aging or noise exposure. Among individuals ages 65 and older in the United States, 12.3 percent of men and nearly 14 percent of women are affected by tinnitus. In addition, tinnitus is the number one cause of service-connected disability for American veterans returning from the wars in Iraq and Afghanistan. NIDCD-supported scientists

utilized a rat model of pharmacologically-induced tinnitus combined with brain imaging (microPET and MRI) techniques to identify brain regions in the rat that are affected during tinnitus.

Following experimental induction of tinnitus, the animals were then injected with a tracer chemical (fluorine-18 fluorodeoxyglucose, FDG) and their brains imaged using microPET and MRI both during tinnitus and under normal conditions. Two regions of the brain (inferior colliculus, IC, and temporal cortices, TCx) were identified to have increased activity during high dose, aspirin-induced tinnitus. These regions are consistent with those identified in humans experiencing either noise- or age-induced tinnitus.

This study is the first to demonstrate microPET and MRI techniques can identify brain regions involved in tinnitus. This technique may now be used to study other causes of tinnitus (such as noise) as well as to evaluate the efficacy of potential therapeutic treatments for tinnitus.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

Pediatric Clinicians Can Help Reduce Rates of Early Childhood Caries: Effects of a Practice Based Intervention

Early Childhood Caries (ECC) is a serious and preventable condition characterized by severe decay in the teeth of infants or young children. ECC disproportionately affects low income and minority populations.

Not only can ECC be an expensive disease to treat properly, but manifestations of ECC may go beyond pain and infection. ECC has the potential to affect speech and communication, nutrition, productivity, and quality of life, even into adulthood. A multifaceted practice-based intervention was implemented treating 635 children vulnerable to ECC, comparing results with those from a similar nearby clinic providing usual care to 454 children. The intervention component provided communication skills training for pediatricians and pediatric nurses using patient-centered counseling, edited the electronic medical record to prompt counseling, and provided parents/caregivers with an educational brochure. Provider knowledge about ECC increased after the intervention training from 66% to 79% in terms of accurate knowledge about ECC and children at the intervention site had a 77% reduction in risk for developing ECC at follow up. The practice-based intervention increased provider knowledge and counseling, and significantly attenuated incidence of ECC. If validated by additional studies, similar interventions could have the potential to make a significant public health impact on reducing ECC among young children.

New Model Reveals Novel Molecular-Targeted Strategies for Oral Cancer Prevention and Treatment

Head and neck squamous cell carcinoma (HNSCC) is the 6th most common cancer in the developed world, affecting nearly 45,000 patients each year in the US, and resulting

in around 11,000 deaths annually. There is an urgent need for new chemopreventive strategies and treatment options for HNSCC patients and emerging information on the deregulation of normal molecular mechanisms that results in the cancer's progression provides the possibility of mechanisms-based therapeutic approaches for these aggressive oral malignancies. Scientists recently found that the drug rapamycin exerted a remarkable anticancer activity. It decreased the tumor burden of mice having early and advanced tumors, and even brought about the regression of recurrent squamous cell skin cancers. The scientists reported that the persistent activation of mTOR, the mammalian Target of Rapamycin, occurs frequently in HNSCC patients and that its inhibition by rapamycin causes cell death and regression of human oral cancer tumors implanted in mice. To test the involvement of mTOR in tumorigenesis, scientists developed a chemically induced mouse model of HNSCC and found that m TOR activation was an early event in tumorigenesis.

This carcinogenesis model demonstrates that the use of mTOR inhibitors may provide a novel molecular-targeted strategy for chemoprevention and treatment of not only head and neck but other oral squamous cell cancers.

Bone Marrow Stromal Cells Help Fight Sepsis

Sepsis is a serious medical condition that affects 18 million people per year worldwide, and is characterized by a generalized inflammatory state caused by bacterial infection. Widespread activation of inflammation and blood clotting pathways leads to multiple organ failure, collapse of the circulatory system (septic shock) and death. Bone marrow stromal cells (BMSCs, also known as mesenchymal stem cells) are potent modulators of immune responses. In this study in an animal model, BMSCs were administered before or shortly after inducing sepsis by puncturing the intestine in order to determine whether BMSCs injected into the circulation would have a beneficial effect in preventing or attenuating septic shock. Infusion of BMSCs significantly decreased sepsis-induced mortality and increased organ function. The effects appear to be mediated by the production of Prostaglandin E2 when BMSCs are activated during the early stages of sepsis. Prostaglandin E2 subsequently induces the recipient's macrophages to produce substantially more IL-10, a factor that dampens the inflammatory response, which if left unabated, leads to death. This is the first determination of a mechanism by which BMSCs modulate the immune response in an animal model of sepsis. As many people die of sepsis annually as from heart attacks. A new treatment or preventative regimen is desperately needed. Since the animal model suggests that the BMSCs need not be isolated from the same individual as will receive them, it is possible that cells isolated from non-related donors could be prepared and stored for use in patients with high risk for sepsis.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Gut Microbes Protect Against Type 1 Diabetes in Mice

Type 1 diabetes is an autoimmune disease in which the body's own immune system attacks and destroys insulin-producing beta cells in the pancreas. Scientists do not know exactly what triggers the body's immune attack on beta cells in type 1 diabetes. During past decades, researchers saw clues in the observed increased incidence of type 1 diabetes in developed countries. The scientists suspected that changes in the environment, including the microbes that live in our bodies, may be influencing the disease. Research in mice has found that the trillions of bacteria and other microbes that live in the gut can blunt the immune system attack that causes type 1 diabetes. Receptors on certain immune cells recognize molecular patterns that mark the surface of microbes. These immune cells signal through a protein called MyD88 to launch an immune system response. When researchers disrupted the gene for MyD88 in a mouse model susceptible to type 1 diabetes, the mice no longer developed the disease.

The researchers then raised the mice in a germ-free environment. These same mice developed type 1 diabetes when raised in this type of environment, showing that the disease is not dependent solely on the MyD88 pathway. These experiments show that a complex interaction between the immune system and bacteria in the gut may help to lower the risk of developing type 1 diabetes. The widespread use of antibiotics and more aggressive cleanliness of modern society can alter the mix of microbes living in our body and an unintended consequence of this environmental change is an increased risk of autoimmune diseases like type 1 diabetes. The idea opens avenues for further exploration and hints at the possibility of developing bacteria-based interventions to preempt or treat autoimmune diseases.

Newly Identified Genetic Variations Account for Much of the Increased Burden of Kidney Disease among African Americans

As many as 26 million U.S. adults over the age of 20 are estimated to have some degree of impaired kidney function, and over a half million Americans were receiving life-sustaining kidney dialysis or were living with a kidney transplant at the end of 2006. The leading causes of kidney disease are diabetes and high blood pressure. African Americans bear an especially heavy burden of kidney disease, however, from any cause. In one form of kidney disease called focal segmental glomerulosclerosis (FSGS), the tiny filtering units of the kidneys—the glomeruli—are damaged and scarred. Most FSGS arises from unknown causes and is termed "idiopathic" FSGS. African Americans are approximately 5 times more likely to develop idiopathic FSGS compared to individuals of other racial backgrounds, and are 18 to 50 times more likely than whites to develop FSGS related to infection with HIV, the virus that causes AIDS.

In the fall of 2008, researchers announced that variations near a single genetic locus were strongly associated with some forms of kidney diseases that disproportionately affect African Americans. Researchers identified several variations in the region of the

MYH9 gene on chromosome 22 as major contributors to excess risk of non-diabetic kidney disease among African Americans. *MYH9* risk variants account for nearly all of the increased risk for idiopathic FSGS and HIV-associated FSGS among African Americans compared to European Americans and a portion of the increased risk for kidney disease associated with high blood pressure. Future studies will focus on the pattern of *MYH9* expression across tissues, investigation into the role played by *MYH9* in kidney function, and how its functions might be disrupted in individuals carrying the risk variant.

Obesity Associated with Unique Mix of Intestinal Bacteria
Although microbes in the human body are estimated to outnumber human cells by ten to one, little is known about these bacteria because of the difficulty in isolating and culturing them in the laboratory.

Scientists are now gaining insight into these bacteria by studying the collective genomes of microbial communities, such as the "gut microbiota," using new DNA sequencing technologies. A recent study compared the human gut microbiota of obese and lean adult twins and their mothers by analyzing fecal samples to determine whether host obesity, genetics, or environment is associated with the bacterial composition of the microbiota. Obesity was associated with significantly less bacterial diversity than leanness. Additional analysis revealed that family members have more similar microbiota than unrelated individuals. Surprisingly, the identical twins were not more similar in their gut microbes than fraternal twins, suggesting that composition of the gut microbiota is influenced more strongly by environmental factors than by an individual's genes. This study does not demonstrate cause and effect—whether differences in human microbiota help cause obesity or leanness, or whether obesity or leanness leads to changes in gut microbes. However, earlier research showed that the composition of gut microbiota can influence weight gain in mice. This advance provides evidence of a link between obesity and the gut microbiome, including the identification of several hundred genes that represent biomarkers of unique gut bacterial activity in obese individuals. These biomarkers may lead to more personalized healthcare and potential probiotic interventions to prevent or treat obesity.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Transplacental Exposure to Airborne Polycyclic Aromatic Hydrocarbons and Childhood Asthma
Asthma is the most common chronic childhood disease and its risk may be strongly influenced by prenatal events. Low income communities experience some of the highest childhood asthma rates in the US and new preventive strategies are lacking due in part to the absence of predictive biomarkers.

Preliminary evidence suggests that transplacental exposure to polycyclic aromatic hydrocarbons (PAHs) derived largely from traffic-related air pollutants may be a risk factor for the early development of asthma-related symptoms in this cohort. This study

explored whether transplacental exposure to PAHs in humans induces epigenetic reprogramming involving aberrant DNA methylation of specific genes that might be mechanistically related to childhood asthma or airway inflammation. Methylation of a 5'-CpG island (CGI) in *acyl-CoA synthetase long-chain family member 3* (*ACSL3*) was found to be positively and significantly associated with the level of maternal PAH exposure and with a parental report of asthma symptoms prior to age five. Researchers identified *ACSL3* as a candidate biomarker/gene whose 5'-CGI methylation status appears to be related to transplacental PAH exposure and further associated with PAH-associated asthma. Thus, *ACSL3* may be the first potential surrogate endpoint for environmentally related childhood asthma. A biomarker like *ACSL3* would be very useful in assessing PAH exposure and as a clinically relevant predictor for asthma risk in children born to mothers exposed to air pollutants such as traffic-related combustion emissions.

Researchers Map the First Human Epigenome

Researchers developed a high-throughput method to determine the methylation status of every cytosine molecule in the genome and to layer the resulting epigenomic map onto the genome it regulates. The technique was then applied to human fibroblasts and human embryonic stem cells to determine if the epigenomes differed between differentiated cells that perform a specific job and cells that have the potential to become any cell type. The results showed that the fibroblasts had a high degree of expected CG-methylation, but the stem cells showed a surprising result. Their methylation pattern exhibited non-CG methylation, which previously had been considered a laboratory artifact. A comparison of the epigenomes of embryonic stem cells and fibroblasts shows a pattern of methylation unique to stem cells. The novel methylation pattern may help to explain how stem cells maintain their pluripotent state. These reference epigenomes provide a foundation for future studies exploring this key epigenetic modification in human disease and development.

Heterocyclic Aromatic Amine Pesticide Use and Human Cancer Risk

Imazethapyr, a heterocyclic aromatic amine, is an agricultural herbicide used to control weeds in corn, soybean, dry bean, alfalfa and other crops. Occupational aromatic amine exposure has long been recognized as a causative factor for bladder cancer, and several specific aromatic amine compounds have been implicated as human bladder carcinogens. Since information about the health effects resulting from exposure to imazethapyr is limited, cancer risks associated with exposure to this aromatic amine pesticide, particularly for bladder cancer, were investigated in the Agricultural Health Study. Significant excess risks of bladder and colon cancers were observed in the AHS among applicators exposed to imazethapyr. For bladder cancer, participants in the highest exposure category of imazethapyr had a 137% higher risk than nonexposed pesticide applicators. For colon cancer, detailed analysis by subsite revealed that imazethapyr use was significantly associated with a 173% increased risk of proximal cancers, but not with distal or rectal cancers. Interestingly, there is no evidence of mutagenicity or genotoxicity with exposure to imazethapyr in animal models. The

findings of this study provide new evidence for the possible role of imazethapyr and other heterocyclic aromatic amine compounds in the etiology of these cancers.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Scientists Create iPS Cells Without Using Viruses
First identified in 2007, induced pluripotent stem cells, or iPS, have stimulated intense interest in the research and medical worlds. Created by re-programming ordinary skin cells, iPS cells appear to look and act like human embryonic stem cells, which can change into any of the body's more than 200 cell types.

Now, the same researchers who created iPS cells have gone a step further by reprogramming skin cells to an embryonic-like state with a technique that avoids introducing potentially harmful genes. Instead of using a virus to deliver reprogramming genes into adult cells, James Thomson of the University of Wisconsin-Madison used a plasmid, a small ring of self-copying DNA that remains separate from the chromosomes in the cell's control center, the nucleus. The new method removes a key safety concern from the use of iPS cells in research and potential treatments. As iPS cells become easier to make and safe to use, they could be an important technology on the road to personalized therapies. Patient-specific, customized cells made using the new iPS method could generate replacements for injured or diseased tissues and serve as powerful tools to study diseases and drugs in the laboratory.

"Super Antibody" Attacks Wide Range of Flu Viruses
Over the past century, three human influenza A pandemics have killed millions of people worldwide. The 2009 H1N1 influenza outbreak is a reminder that constantly changing viruses pose a serious and ongoing health threat. Previous pandemic viruses emerged, in part, when bird and human viruses mixed genes and gained new and deadly properties that allowed them to evade the human immune system. Researchers have made an important advance on this front by developing a research version of a "super antibody" that recognizes both seasonal and pandemic influenza viruses. Working with a European pharmaceutical company, Ian Wilson of the Scripps Research Institute in La Jolla, California, solved the structure of an antibody that attaches to several types of flu from both birds and humans. The researchers screened millions of antibodies to find one that has unique cross-flu properties and also used resources produced by the NIGMS-led Protein Structure Initiative (PSI) to prepare and analyze high-quality protein samples. The work is an important step toward the development of a durable and cross-protective universal influenza virus vaccine. Ultimately, such a flu vaccine could be given to a person just once to protect against most subtypes of influenza, including pandemic viruses.

Researchers Develop Novel, Resistance-Free Antibiotic Molecules
Bacterial resistance to antibiotics is one of medicine's most urgent problems. An antibiotic drug treats infection by knocking out hundreds of strains of "sensitive" bacteria in the body. But left behind are many non-sensitive or resistant strains. With no

stops in place, the resistant microbes repopulate themselves and spread rapidly. To combat this problem, chemists made a molecule that locks onto a microbial enzyme, blocking the bacterium's ability to "talk" to its neighbors. In lab tests, the molecule completely prevented the development of resistance even after many generations of growth. The antibiotic molecules proved effective in lab tests against *Escherichia coli* O157:H7, which causes lethal food poisoning, and *Vibrio cholerae*, which causes cholera. Since other dangerous microbes use the same communication strategy, the approach may have broad applications against various infectious diseases.

NATIONAL INSTITUTE OF MENTAL HEALTH

Clinical Trials Assessing the Efficacy of Antipsychotic Interventions

Schizophrenia, which affects approximately 2.4 million Americans, is a chronic, severe, and disabling brain disorder characterized by hallucinations, delusions, and disordered thinking. Antipsychotic medications are effective in treating the symptoms of the disorder, but can be associated with serious side effects such as weight gain, muscle spasms, rigidity, and tremors. To provide much-needed information to guide the everyday treatment of people with schizophrenia, NIMH supported the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Study, which compared the effectiveness and side effects of five medications — both new ("atypical) and older ("typical") antipsychotics. Overall, the study found that the medications were comparably effective but were associated with high rates of discontinuation due to intolerable side effects or failure to adequately control symptoms. One new medication, olanzapine, was slightly better than the other drugs but also was associated with significant weight-gain and metabolic changes. Surprisingly, the older, less expensive medication used in the study, perphenazine, generally performed as well as the newer medications. CATIE also provided information that will help doctors and individuals choose subsequent treatments if the first treatment option is discontinued. During the course of the CATIE study, almost three quarters of the patients switched from their first medication to a different medication. People who switched to clozapine from their first medication because it failed to manage symptoms adequately were twice as likely to continue treatment as patients who switched to other antipsychotic medications. The CATIE study has vital public health implications because it provides doctors and patients with information that will help them choose the most appropriate medication according to the patients' individual needs.

The Complex Genetic Underpinnings of Mental Disorders

Based on twin and family studies, we have long known that some mental disorders have a high degree of heritability, as great, as or greater than most other common medical disorders. In recent years, NIMH-supported researchers have discovered several genes that are associated with autism spectrum disorder (ASD), schizophrenia, and bipolar disorder. However, the genomic variants discovered to date can explain only a small fraction of the genetic risk. It is becoming clear that people with serious mental disorders are more likely to have *rare* variations, known as copy number variations (CNVs), than to share common variations, as is the case for diseases such as diabetes.

CNVs are variations within the genome that results from deletions or duplications of genomic segments, sometimes involving millions of bases of DNA. Although these large CNVs are 10 times more common in people with schizophrenia or autism, most of the known CNVs do not seem to be associated with any single neurodevelopmental disorder. Even within a single family, the same genetic lesion appears to be associated with different mental or developmental disorders. And even though these may be huge mutations, some CNVs by themselves have subtle effects unless there is a second insult such as a second mutation or an environmental influence. Another important area of focus is epigenomics--the mechanisms through which environmental and experiential influences interact with genes to control their function. For example, a rare CNV associated with ASD deletes the gene that codes for the oxytocin receptor. In many individuals with ASD who do not have this deletion, the gene is silenced by epigenomic modifications, essentially producing the same outcome as a gene deletion. Investigating rare genetic variation may hold promise for improved diagnosis, as well as more personalized prevention and treatment strategies for schizophrenia, ASD, and similar neurodevelopmental disorders.

Flow of Potassium into Cells May Play a Role in Schizophrenia
Evidence suggests that schizophrenia stems from complex interactions between multiple genes and environmental factors. Researchers have worked to uncover what precise cellular functions are affected by candidate genes in order to determine effective treatment approaches with fewer adverse side effects. A study on schizophrenia has implicated cellular machinery that maintains the flow of potassium in cells as having a significant role in the development of schizophrenia. Expression of a previously unknown form of a key potassium channel was found to be 2.5 fold higher than normal in the hippocampus and prefrontal cortex—brain regions essential to memory formation—of people with schizophrenia. Experiments suggest that selectively inhibiting the gene variant that encodes production of this particular form of potassium channel (known as KCNH2) could help correct disorganized brain activity in schizophrenia—without risk of cardiac side effects associated with some existing antipsychotic medications.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Gene silencing prevents neurodegenerative diseases in mice and promises new strategy for treating people
In dominantly inherited disorders, a single defective gene from either parent produces a harmful protein that causes disease. Huntington's disease, spinocerebellar ataxias, and an inherited type of amyotrophic lateral sclerosis (ALS) are among the dominantly inherited neurological disorders. All of these diseases are progressive and currently untreatable. RNAi is a widespread, but previously unrecognized, regulator of gene activity in plants, invertebrates, and mammals. The mechanism is based on the classic DNA matching code—a short RNA molecule matches up with a particular segment of DNA and silences activity of the specific gene. Scientists are unraveling how RNAi influences diverse processes from normal development to protection from viruses and

harnessing the phenomenon as a general tool for studying gene functions. RNAi also presents an appealing strategy for specifically silencing harmful genes in dominantly inherited disorders. Researchers have now shown that RNAi can slow neurodegeneration and improve performance on behavioral tests of movement ability in strains of mice that mimic dominantly inherited ALS, Huntington's disease, and spinocerebellar ataxia. In each case, scientists designed a specific RNAi probe to silence the gene responsible for disease and delivered the agent by using a modified (and harmless) virus.

RNAi may be applicable to many dominantly inherited diseases, as well as non-inherited problems, such as brain tumors, that arise from improper activation of genes. NINDS is supporting continued basic and translational research to develop RNAi to the point where it is sufficiently safe and effective to warrant clinical trials in people.

Comparative effectiveness research provides evidence-based approach for treating childhood absence epilepsy

Childhood absence epilepsy is the most common form of epilepsy in kids, affecting an estimated 10 to17 percent of new epilepsy cases among children each year. Absence seizures, resulting in a sudden loss of awareness for 10-30 seconds, can occur dozens to hundreds of times per day, and many affected children have cognitive deficits and long-term psychosocial difficulties. The three medications most commonly used as initial therapy for childhood absence epilepsy are ethosuximide, valproic acid, or lamotrigine, but a comprehensive comparison of their relative efficacy and profile of side effects has been lacking. Researchers have now compared the effectiveness of ethosuximide, valproic acid, and lamotrigine for the initial treatment of childhood absence epilepsy. Overall, they found that ethosuximide, one of the oldest available anti-seizure medications in the U.S., provided the best combination of seizure control and least adverse effects on children's attentional abilities over a 16- to 20-week period of initial treatment. Decisions among available treatment options must take into account both comparative efficacy in reducing disease symptoms as well as relative tolerability in terms of adverse side effects. By establishing clinically important differences between the three most commonly used medications for the initial treatment of childhood absence epilepsy, this landmark study supports evidence-based recommendations to inform treatment decisions for this common childhood seizure disorder.

Scientists Restore Movement to Paralyzed Limbs through Artificial Brain-Muscle Connections

Previous efforts to compensate for paralysis after spinal cord injury (SCI) have used brain activity to control the movement of prosthetic limbs or other devices. An exciting alternative approach would enable patients to move their *own* limbs by using brain activity to drive functional electrical stimulation of paralyzed muscles. Investigators successfully used signals from individual neurons in the motor cortex of monkeys to drive voluntary movement of paralyzed muscles. As the monkeys modulated their neurons' activity, electrical stimulation drove wrist movements that were used to direct the position of a cursor on a screen--as if the monkeys were being stimulated to control

a computer mouse. This research demonstrates, for the first time, that artificial connections between the brain and specific muscles can restore voluntary movement in paralyzed limbs and suggest a promising approach to developing assistive technology for SCI that would allow patients to move their own muscles.

NATIONAL INSTITUTE OF NURSING RESEARCH

Women's Cytokine Levels Remain Higher Post Stress Event

Stress is both a pervasive and necessary component of life. There is well documented evidence of differences in the cardiovascular responses to acute psychological stress by gender; less is known regarding whether these differences extend to inflammatory processes and immune function. Researchers looked at biological indicators of immune and inflammatory responses, known as cytokines. Some of these markers included: interleukin-1beta (IL-1β), interleukin-6 (IL-6), and tumor necrosis factor-alpha (TNF-α). Blood samples from midlife men and women were repeatedly tested, including after the performance of a public speech task. Following the end of the stressor, all measured pro-inflammatory cytokines were elevated in men and women. However, immediately post-stress, men demonstrated a drop in cytokine production that was significantly lower than the stable levels measured in women. Further, post-menopausal women demonstrated greater subsequent increases in IL-6 and TNF-α production from baseline-to-post-task when compared to men. These data bolster existing evidence that stress causes the immune system to produce larger inflammatory responses. The results also demonstrate possible gender differences in stress-related cytokine activity, and suggest that post-menopausal women may be more susceptible to stress-related inflammatory responses. While stressors and the human response to stress are normal aspects of life, understanding the internal chemicals that moderate the immune and inflammatory effects of excess short term or continued stress can help prevent negative health consequences. Given the increased risk among women, especially after menopause, for development of inflammatory illnesses and conditions, further study of gender differences in stress-related production of pro-inflammatory cytokines could help illuminate pathways for therapeutic intervention and prevention.

Speed-of-Processing Cognitive Intervention Reduces Risk of Depressive Symptoms in Community-dwelling Elderly

Depressive symptoms in elderly persons have been consistently linked to increased risk for disease development and exacerbation of existing comorbidities. While pharmacological interventions have been demonstrated to be safe and effective in the treatment of depression, they come with an increased risk of medication interactions among populations, such as the elderly, who often take multiple medications for chronic health conditions. A group of researchers evaluated the effects of three cognitive training interventions for active, community-dwelling elderly persons on depressive symptoms. The training provided in the three treatment groups involved: 1) memory training focused on verbal strategies for remembering; 2) reasoning training focused on problem solving and executive function, and, 3) speed-of-processing training focused on visual search in a divided-attention format, respectively.

Participants in the speed-of-processing group were significantly less likely to experience clinically important increases in depressive symptoms at 1-year and 5-year post baseline. No differences were observed among the control, memory, or reasoning groups at either time period. While many studies of cognitive and behavioral interventions for depression have been undertaken in recent years, this is the first study to include the speed-of-processing intervention. These results indicate that the speed-of-processing intervention provides a plausible, readily available and non-pharmacological intervention to reduce the risk of depressive symptoms in community-dwelling elderly.

Serotonin Transporter Gene Polymorphisms are Associated with Increased Risk for Post-stroke Depression

Post-stroke depression (PSD) is thought to affect approximately 33% of stroke survivors. While the precise etiology of PSD is unknown, it is likely multifactorial, and may be linked, like other mental illnesses, to polymorphisms of the serotonin transporter gene (or, 'SERT'). Variations in the SERT gene have been widely used as possible risk factors for psychiatric illness. A team of researchers sought to determine whether variations of the serotonin transporter gene (specifically, the 5-HTTLPR, STin2 VNTR, and rs25531 polymorphisms) are associated with post-stroke depression (PSD) in stroke survivors. Stroke survivors with a specific 5-HTTLPR variation had 3-fold higher odds of having post-stroke depression. Participants with variations in ST*in*2 had 4-fold higher odds of PSD. These results indicate that the 5-HTTLPR and the ST*in*2 VNTR polymorphisms of the serotonin transporter gene are significantly associated with PSD in stroke survivors. These findings provide further evidence of a role of SERT polymorphisms in mediating resilience to biopsychosocial stress and represent the first study to characterize an association of SERT polymorphisms with increased risk for PSD. These findings are a critical first step toward identifying those at risk for developing PSD and the development of possible preventive therapeutics.

NATIONAL LIBRARY OF MEDICINE

Newborn Screening Coding and Terminology Guide

Newborn screening is an important part of public health because it can detect rare disorders in babies who may look healthy at birth. When certain disorders are detected right away, serious health problems can be prevented with rapid intervention. Because the disorders are so rare, wide variations among states in the ways tests are conducted and results recorded make it difficult to aggregate data and conduct quality assurance needed to improve testing and treatment methods. NLM worked with many other agencies to organize standard definitions and codes for more than 100 newborn screening conditions and the tests used to detect them. The NLM Newborn Screening Coding and Terminology Guide is a new Web site that indicates the preferred standard terminologies and codes for all the conditions and tests. The new Web site is a translator, to help deal with current complexity and help states move toward the use of common terminology and coding standards. The NLM Newborn Screening Coding and Terminology Guide will support quality health care for children by harmonizing standard coding, terminology and electronic messaging methods in newborn screening.

Interoperable electronic messaging can help ensure that pediatricians get the information they need to interpret newborn screening results and act quickly to save lives.

Implementation of the ClinicalTrials.gov Results Database
The ClinicalTrials.gov registry and results database provides the public with summary information about interventional and observational clinical research studies and, since September 2008, summary results data. The site provides descriptions of over 84,000 recruiting and completed studies, of which 1,200 studies have results information posted. In September 2008, NLM launched the ClinicalTrials.gov results database to provide researchers, health care professionals, and members of the public, with access to basic data resulting from completed clinical studies. In September 2009, NLM implemented the requirements for sponsors to report adverse event information as specified by FDAAA 801. The results database is seamlessly integrated into the ClinicalTrials.gov site, allowing users to search for information about clinical research studies and their results, if available, with a single set of search and navigation tools. The ClinicalTrials.gov results database represents a first-of-its-kind, publicly accessible source of summary clinical study results, whether published or not. Systematic posting of basic results data for certain publicly and privately funded clinical research studies will not only help mitigate the problem of selective reporting of "positive" study results, but will also contribute toward fulfilling the ethical responsibility to those who volunteered to participate in research.

Health Information Exchange, Biosurveillance Efforts, and Emergency Room Crowding During the Spring 2009 H1N1 Outbreak in New York City
Novel H1N1 influenza spread rapidly around the world in spring 2009, widely-affecting the New York region, and resulting in a crowding crisis due to record numbers of emergency room visits. Biosurveillance efforts by public health agencies can lead to earlier detection, potentially forestalling spread of outbreaks and leading to better situational awareness by frontline medical staff and public health workers as they respond to a crisis. This research explored the use of health information exchange networks, which enable secure flow of clinical data among unaffiliated providers across regions, as a tool for automated biosurveillance reporting in real-life emergency. This study in preparedness tested whether health information exchanges can reliably replace inefficient manual biosurveillance reporting, with the potential to be implemented nationally. Because reporting was automated and imposed no additional burden on hospitals during the crisis, the daily response rate was 100%. Based on retrospective analysis of a single measure, emergency department visit rates, this preliminary study suggests the potential is great for more robust data across multiple health information exchanges to be leveraged in the future and for new biosurveillance information to be provided in real time. Health information exchanges have great potential for providing real-time biosurveillance information to public health agencies and healthcare organizations, to support their situational awareness and ability to react to crises more swiftly. Coordination with existing health information exchanges may assist public health officials and hospitals with data monitoring during future outbreaks.

AMERICAN RECOVERY AND REINVESTMENT ACT

Mr. Obey: Please describe how NIH planned to make use of each major category of funding provided in the American Recovery and Reinvestment Act, and the progress to date in implementing those plans.

Dr. Collins:
1. NIH's plans for the ARRA funding included:

- Scientific Research. The NIH Recovery Act Implementation provided $8.2 billion for scientific research. A plan for these funds was developed to benefit three main activities:
  a. Specific areas of health research that will exploit new technologies or are likely to yield significant outcomes, as well as will cultivate a stronger biomedical research infrastructure;
  b. Meritorious research programs that previously could not be supported by NIH's base appropriation, to accelerate the pace of ongoing research; and
  c. New investments in programs that offer potentially transformative approaches to address major challenges in biomedical research.

- Shared Instrumentation. The NIH Recovery Act Implementation provided $300 million to facilitate "state-of-the-art" research using advanced technologies to enable better images, diagnostics, data analysis, and new discovery tools, as follows:

  a. Shared Instrumentation Grants (approximately $140 million) support groups of three or more NIH-supported investigators at public and non-profit domestic institutions for the purchase of commercially available instruments costing from $100,000 to $500,000, including confocal and electron microscopes, biomedical imagers, mass spectrometers, DNA sequencers, biosensors, cell sorters, X-ray diffraction systems, and NMR spectrometers, among others.
  b. High-End Instrumentation Grants (approximately $160 million) support groups of three or more NIH-supported investigators at public and non-profit domestic institutions for the purchase of a single major item of biomedical research equipment costing from $600,000 to $8,000,000, such as structural and functional imaging systems, macromolecular NMR spectrometers, high-resolution mass spectrometers, cryoelectron microscopes, and supercomputers.

- Extramural Construction. The NIH Recovery Act Implementation provided $1 billion to facilitate and enhance biomedical and behavioral research by supporting the design and construction of non-Federal basic and clinical research facilities, as follows:

a. Extramural Research Facilities Improvement Program (approximately $800 million) provides grants to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for biomedical and behavioral research.
b. Core Facility Renovation, Repair, and Improvement Program (approximately $200 million) provides grants to public and nonprofit private entities to renovate, repair, or improve core facilities (i.e. a centralized shared resource that provides access to instruments or technologies or services, as well as expert consultation to investigators).

- Comparative Effectiveness Research (CER). The NIH Recovery Act Implementation provided $400 million to compare different interventions and strategies to prevent, diagnose, treat, and monitor health conditions. The ARRA funds allowed NIH to expand its portfolio of landmark CER to fund additional comparisons within ongoing clinical trials, support new CER projects, and bolster CER infrastructure and training.

- Building and Facilities. The NIH Recovery Act Implementation provided $500 million to make contract awards on projects that will enhance NIH's ability to conduct biomedical research, to include the following specific projects:

a. The John Edward Porter Neuroscience Research Center Phase II Project ($175.7 million) will complete the consolidation of most of the NIH neuroscience research community into one facility. The Center will support bench-to-bedside research by basic and clinical neuroscientists, engineers, mathematicians, and computer scientists under one roof.
b. The Building 10 F Wing funding ($160.3 million) will renovate one of the NIH's Clinical Research hospital's oldest wings dating back to 1955 which is no longer able to support biomedical research and training. The conversion of the F Wing (Phases A for Anatomical Pathology and B1-B2, Floors 6-13) from hospital to laboratory space will support translational research for nine of the twelve Institutes and Centers.
c. The Build-Out of Building 3 ($21 million) will transform an unused, vacant building into useable space to provide offices for Scientific Directors and their administrative staff.
d. Conversion of Building 7 ($6.2 million) at the Rocky Mountain Laboratories in Hamilton, Montana will convert unused, former mechanical space to laboratories providing critical additional space for National Institute of Allergy and Infection Diseases (NIAID) research program.
e. The West Utility Tunnel ($22.3 million) increases the size and capacity of chilled water and steam distribution systems available to support future renovations in the F and Distal-Wings of building 10. This

project is very close award. It will be awarded as a task on a competitively awarded IDIQ contract.

f. Renovation of Building 4 ($11.3 million) replaces obsolete laboratories and improves aging building systems on the first and second floor to ensure compliance with current codes and accreditation requirements. This project is very close to award. It will be a competitively awarded contract.
g. Building 12 Continuous Power and Upgrade to NIH Data Center ($8 million) Phase 3 completes the project to ensure liability of the NIH Data Center supporting critical, enterprise-wide applications. This project is very close to award. It will be a competitively awarded contract.
h. Other R&I Projects ($95.2 million) are focused to improve the reliability and condition of several other NIH facilities.

2. What is the progress, to date, in implementing the ARRA categories:

- Scientific Research. NIH is making excellent progress and is on target in meeting the goals of this plan. NIH has awarded over 12,000 grants to research institutions in all 50 States, supporting innovative projects to address major challenges in biomedical research, accelerate critical breakthroughs and support applied research on cutting-edge technologies. The funds, for example, are allowing NIH to expand the Cancer Genome Atlas, collecting more than 20,000 tissue samples to sequence the DNA of more than 20 types of cancer and provide the potential to better treat this destructive disease. NIH also awarded more than 50 autism research grants, the result of the largest funding opportunity for research on autism spectrum disorders to date. The remaining funds will be obligated by September 30, 2010 as described in the implementation plan.
- Shared Instrumentation (SI). NIH is making excellent progress and is on target in meeting the goals of this plan. NIH has awarded several grants. To include 29 cell sorters; 17 computers, 8 crystallography units; 40 DNA and protein sequencers; and 17 electron microscopes. The remaining funds will be obligated by September 30, 2010 as described in the implementation plan.
- Extramural Construction (EC). NIH is making outstanding progress and is on target in meeting the goals of this plan. NIH has awarded over 142 extramural construction grants to various non-Federal institutes improving basic and clinical research facilities as well asanimal facilities to meet the needs of biomedical and/or behavioral research The remaining funds will be obligated by September 30, 2010 as described in the implementation plan.
- Comparative Effectiveness Research (CER). NIH is making progress and is on target in meeting the goals of this plan. NIH has awarded 166 projects totaling $342 million. The balance of funding will target methodology development, training, and three research gap areas: Upper Endoscopy in

Gastro-Esophageal Reflux Disease (GERD); Eradication Methods for Methicillin Resistant Staphylococcus Aureus (Staph); Dementia Detection and Management Strategies. The remaining funds will be obligated by September 30, 2010 as described in the implementation plan.

- Building and Facilities (B&F). NIH is making progress and is on target in meeting revised goals. B&F will obligate a total of $500 million for these awards; $49.7 million of which was obligated in FY 2009 and the remaining $450.3 million is being obligated in FY 2010. Of the 15 original Building and Facilities ARRA projects , five projects – PNRCII, Building 10 F Wing, Building 3, RML Building 7, and the Electrical Vaults (under Other R&I), require awarding via newly competitive contracts. One project – the RML Installation of a Dedicated Electrical Feeder – was executed through collaboration with the local utility. Three projects in Building 10- The Tube Nest Condensate Line Repair, The Cell Processing Deficiency Corrections, and The Anatomical Pathology HVAC Repair- were awarded as task orders to existing contracts that had previously been awarded to participants in the 8(a) small disadvantaged business program (FAR 19). Existing competitive contracts can be used to implement the remaining projects.

ARRA AND ITS SIGNIFICANT IMPACTS

Mr. Obey: What would you consider among the most significant investments made with the Recovery Act funds, and what impact on health can be expected from each?

Dr. Collins: With the generous $10.4 billion in ARRA funds, NIH has made over 12,000 awards for exciting projects that will address virtually every disease, medical condition and critical challenge in biomedical research. These are all significant investments. Specific projects that are worth highlighting are several of the ARRA signature projects. Signature projects are major initatives, developed by the Institutes and Centers, in areas of research where there are unprecedented opportunities to make significant biomedical progress. In addition, the following signature projects were so compelling, they were selected by the Office of the Director for co-funding to ensure that these important opportunities were met with the most vigorous and comprehensive response possible.

Acceleration of The Cancer Genome Atlas Project: This joint NCI/NHGRI signature project will accelerate The Cancer Genome Atlas Project (TCGA) to enable full examination of tumor genomes to discover new causative mutations in cancers. The pilot project has already demonstrated that knowledge of these mutations can be exploited for rapid translation in the clinic. ARRA funds will be used to rapidly move from the pilot phase of TCGA to identify all of the relevant genomic alterations in 20-25 tumor types by the end of FY 2014.

Evaluating the Safety of Engineered Nanomaterials: Engineered nanomaterials represent a significant breakthrough in material design and development for medicine, industry, and consumer products. This signature project will provide much needed data in the areas of toxicity profiles for nanomaterials, biochemical/molecular characterization of toxic effects in model systems, biomarkers for nanomaterials exposure, identification of susceptibility issues for nanomaterials health effects, and intervention strategies for prevention of public health episodes due to environmental nanomaterial exposures. The result will be the accelerated development of safe nanomaterial-based medical interventions.

DNA Sequencing of Well-Phenotyped Population Cohorts for the Identification of Disease-causing Genetic Variants and Understanding of Biological Pathways: Although genome-wide association studies (GWAS) have been successful in identifying high frequency genetic variants that are associated with numerous common complex traits and diseases, they are incapable of identifying specific disease-causing genetic variants, especially those of lower frequency and potentially larger effects. Finding those variants will require large-scale DNA sequencing of thousands of individuals from well-phenotyped populations. With recent technological advances, the feasibility of such a project is now within reach. Through this signature project the well-phenotyped NHLBI cohorts will be sequenced in order to identify actual disease-causing genetic variants of low frequency that may have large effects on the development of important common diseases including myocardial infarction, stroke, diabetes, obesity, hypertension, chronic pulmonary disease, and anemia.

Enhancing Electronic Health Records: This initiative will support basic and applied research in biomedical informatics to develop real-time decision aids and data visualization capabilities within electronic health records to help physicians, public health officers and researchers make complex diagnostic and treatment decisions. The goals of the project are to develop tools to allow physicians to see a high-level portrait of a patient's total condition; to draw in appropriate data from a variety of sources to aid in a clinical decision; to visualize the effects of interventions on the patient; and to perform real-time health research by mining data in large repositories housed at multiple sites.

Genome-wide Association Studies and Replication of Studies in Minority Populations: The purpose of this signature project is to expand the use of genome-wide association to understudied diseases and phenotypes within the NIDDK mission to identify associated loci and genes. Genome-wide association studies (GWAS) have been undertaken in type 1 diabetes, type 2 diabetes, inflammatory bowel disease, obesity, and kidney disease but, in general, these studies have concentrated on available European populations. Studies to replicate key GWAS findings are necessary, as is extending these findings to other ethnic groups that comprise the U.S. population. Highest priority will be given to studies in minority populations or studies that are addressing diseases or phenotypes that have not been the subject of previous GWAS.

Integration of Pharmacogenomics with Electronic Health Records (EHR): This signature project focuses on the critical relationship between genotype and the response of individuals to a particular drug in a real-world setting, with the goals of improved patient care, reduced errors and safe and effective use of medications. Recent progress in several areas sets the stage for the realistic implementation of personalized medicine: 1) the discovery and validation of many significant genetic predictors of drug responses; 2) the widespread implementation of electronic health records; and 3) advances in bioinformatics and clinical decision-making algorithms. As a result, there are unprecedented opportunities to invest in system-wide demonstration projects for applying genomic information to personalized health care.

Framework Programs for Global Health: This signature project responds to the huge and growing demand on U.S. college campuses (including in the IDeA states) to prepare students to address global health issues. This program will be funded through administrative supplements to approximately 26 U.S. awardees. The goal is to significantly increase the process of building the multidisciplinary teams, curriculum and infrastructure needed to address global health research at U.S. universities.

TRANSLATIONAL RESEARCH

Mr. Obey: One of the themes emphasized in your testimony and the budget request is translating research results into new therapies available to treat patients. Please provide an inventory of the principal efforts already underway at NIH and proposed for fiscal year 2011 to advance this objective, including estimated funding levels for fiscal years 2009, 2010 and 2011?

Dr. Collins: In the broadest sense, translational research advances scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to improve healthcare and public health. The translational continuum spans basic science discovery; preclinical testing; all phases of clinical investigation; dissemination of new technologies, therapeutics and information; and finally adoption as standards of care. "Translating Basic Science into New and Better Treatments" represents one of the Five Themes I have developed as NIH Director which I emphasized in the NIH FY 2011 President's Budget request. A number of major initiatives underway at NIH are directly associated with this Theme and are summarized below.

- A national consortium of medical research institutions, funded through the Clinical and Translational Science Awards (CTSAs), is transforming clinical and translational research across the nation. This unique network of organizations is working together to accelerate laboratory discoveries into treatments for patients, to engage communities in clinical research and to train clinical and translational researchers. Currently, the consortium comprises 46 medical research institutions in 23 states. When fully implemented by 2012, 60

institutions will be linked together to advance the discipline of clinical and translational science.

- An important new effort in the area of translation science is the NIH Therapeutics for Rare and Neglected Diseases Program (TRND). TRND will build upon the successes of the similarly structured NIH Chemical Genomics Center (NCGC). NCGC facilitates drug development from the basic research lab to the pre-clinical stage, which is when researchers begin to lay the groundwork for possible human testing of candidate drugs. Picking up where NCGC's work leaves off, TRND will concentrate its efforts on the pre-clinical stage of drug development. TRND's aim will be to move candidate drugs forward in the drug development pipeline until they meet Food and Drug Administration (FDA) requirements for an Investigational New Drug (IND) application. Once TRND generates enough data to support an IND application for a candidate drug, the drug would then be handed off to an experienced organization outside of NIH, such as a pharmaceutical company, for human testing and other aspects of clinical development.

- Cancer Therapy Evaluation Program (CTEP) is responsible for coordinating the largest, publicly funded oncology clinical trials organization in the world, with over 900 active trials enrolling annually 30,000 study participants, nearly 400 grants and cooperative agreements, and about 100 investigational new drugs (INDs). CTEP has been able to effectively team with different companies to develop multiple targeted therapies in phase 1-2 trials. These combinations hold the promise for both more effective and less toxic treatments for many cancers. Thanks to CTEP's Cooperative Group program, active treatments found in phase 2 studies can be moved rapidly into definitive phase 3 trials.

- Basic and applied research programs sponsored by the National Institute of General Medical Sciences (NIGMS) and others are working toward a better understanding of how compounds bind and cause effects, thereby providing tools that will increase the efficiency of drug design. Research in pharmacogenomics and the NIGMS Pharmacogenomics Research Network (PGRN) sheds light on who will benefit from and who will experience adverse events as a result of treatment, improving the ability to design trials showing safety and efficacy of medications and allowing more personalized treatments to be made available.

- Enabled by high-throughput screening tools, combined with a growing assortment of *in vitro* assays and computational methods, the Tox21 partnership -- comprising the National Toxicology Program, the NIH Chemical Genomics Center, and the U.S. Environmental Protection Agency -- seeks to identify new mechanisms of chemical activity in cells, to prioritize the backlog of untested chemicals for more extensive evaluations, and to develop better predictive models of human response to toxicants. Tox21 scientists are now working to

identify and map toxicity pathways and the ways chemicals interact with the biochemical processes involved in cell function, communication, and the ability to adapt to environmental changes.

- The Molecular Libraries Roadmap offers public sector biomedical researchers access to the large-scale screening capacity necessary to identify small molecules that can be optimized as chemical probes to study the functions of genes, cells, and biochemical pathways. These projects facilitate the development of new drugs, by providing early stage chemical compounds that enable researchers in the public and private sectors to validate new drug targets, which could then move into the drug-development pipeline. This is particularly true for rare diseases, which may not be attractive for development by the private sector.

- The NIH Rapid Access to Interventional Development (RAID) program makes available, on a competitive basis, certain critical resources needed for the development of new therapeutic agents. This program uses resources of NCI's Developmental Therapeutics Program and the National Heart Lung and Blood Institute's (NHLBI) Gene Therapy Resource Program. Services available include: production, bulk supply, GMP manufacturing, formulation, development of an assay suitable for pharmacokinetic testing, and animal toxicology. Assistance is also provided in the regulatory process, through access to independent product development planning expertise.

- Research Centers in Minority Institutions (RCMI) Translational Research Network provides opportunities for multi-site clinical and translational research among minority and other collaborating institutions throughout the nation. Investigators at these institutions are focused on cancer, diabetes, renal disease, infant mortality, HIV/AIDS, and cardiovascular diseases—diseases that disproportionately affect minority populations.

- With regard to the commercialization of NIH technologies, the Office of Technology Transfer is highly efficient and effective at identifying and disseminating access to NIH inventions. Their facilitation of roughly 400 new inventions reports per year, 300-400 new patent applications per year, about 250 new licenses of NIH technologies per year, and receipt of royalties of about $90M per year demonstrates the effectiveness of an approach which seeks to emphasize non-exclusive licensing to entities capable of making NIH inventions viable to improve the public health.

There are also a number of programs underway at individual Institutes and Centers. Representative examples are described below.

- The Office of Translational Research of the National Institute of Environmental Health Sciences (NIEHS) strives to convert environmental health research into

information, resources, or tools that can be used by public health and medical professionals and by the public to improve overall health and well-being, especially in vulnerable populations.

- The National Institute of Neurological Disorders and Stroke (NINDS) Office of Translational Research aims to facilitate the preclinical discovery and development of new therapeutic interventions for neurological disorders by: 1) supporting preclinical development from discovery candidate therapeutics through Investigational New Drug (IND) and Investigational Device Exemption (IDE) applications to the FDA; 2) supporting the design, implementation, and management of research infrastructure activities that apply advanced research technologies to problems in neuroscience and neurology; and 3) supporting translational research projects and networks.

- The National Institute of Mental Health (NIMH) Division of Developmental Translational Research supports integrative, multi-disciplinary research on: 1) neurobehavioral mechanisms responsible for the development of psychopathology; 2) trajectories of risk/illness based on the combined and interactive influences of genetics, brain development, environment, and experience; and 3) design and testing of innovative and personalized preventive and treatment interventions.

- The National Institute of Allergy and Infectious Diseases (NIAID) Respiratory Pathogens Translational Research Services Program comprises three components: the Bacterial Respiratory Pathogens Research Unit, the Viral Respiratory Pathogens Research Unit, and the Bacterial Respiratory Pathogens Reference Laboratory. These components provide four types of services to facilitate the development of treatments targeting specific pathogens: a biological research repository, *in vitro* testing, *in vivo* testing, and clinical trial units.

- The National Institute on Aging (NIA) Translational Initiative is a multi-component translational initiative to facilitate early drug discovery and drug development research by academic scientists and small biotechnology companies for treating and preventing Alzheimer's disease, mild cognitive impairment, and age-related cognitive decline. This initiative provides small grants for early, exploratory drug discovery efforts and larger cooperative grants for various stages of preclinical drug development, in which new compounds are tested for safety and efficacy in test tube and animal studies before being tested in humans. The grants are awarded to investigators who have identified new compounds that need to be refined and characterized in relevant animal models in order to receive FDA's Investigational New Drug (IND) approval.

Estimated funding levels for NIH Translational Research are:

FY 2009	$6.229 billion
FY 2010	$6.357 billion
FY 2011	$6.517 billion

CURES ACCELERATION NETWORK

Mr. Obey: The recently enacted health reform legislation authorizes a new program to advance the objective of translating research into treatments called the "Cures Acceleration Network." In your professional judgment, what are the advantages and disadvantages of this newly authorized program compared to other programs and mechanisms currently in use at NIH for translational research?

Dr. Collins: The "Cures Acceleration Network" (CAN) is intended to advance the development of "high need cures" by reducing and overcoming the barriers between research discoveries and new treatments in areas that the private sector is unlikely to pursue. The program will smooth the pathway for developing new drugs, biologics, and devices and focus on addressing problems in the so-called "valley of death" phase of the therapeutic pipeline, which is a period between basic and clinical research where potentially promising candidates are identified and tested for potential first-in-man clinical trials. The valley of death represents a particularly challenging research development phase in which companies are becoming increasingly reluctant to invest. CAN will help minimize some the financial risks to others associated with this phase of development and provide a pathway for private sector investment in the later stage development of promising compounds.

The legislation establishing CAN provides NIH with a number of new authorities and flexible funding mechanisms. For example, NIH is now authorized to use up to 20% of the funds using the Flexible Research Authorities mechanism, as is currently utilized by DARPA. These authorities also enable the program to move quickly to integrate, direct and make course corrections to projects as needed. For the first time, NIH grantees will be able to use funds for technical assistance to meet FDA regulatory requirements, and NIH will ensure that funded activities are coordinated with FDA approval requirements. The Flexible Research Authorities mechanism, as is currently utilized by DARPA, and in a manner not currently permissible under traditional grant and contract mechanisms, enable the program to move quickly and make course corrections to projects as needed.

If Congress appropriates new funds for the program, individual awards of up to $15 million can be made to support the development of novel compounds as well as abandoned products that might be revised or repurposed. CAN will allow NIH to pay for so-called "failed compounds" and explore, using high-throughput and other technologies, whether they can be repurposed for other preventative, diagnostic, and therapeutic applications. CAN will partner with FDA, industry, patient advocacy, and

other non-profit entities in the coordinated and accelerated pursuit of new diagnostics, therapies, and cures. The program will identify, fund, and work collaboratively with individual subject matter experts, creating teams as necessary on a project-by-project basis. In this way, NIH will be able to direct the project, set and monitor specific milestones, and stay substantially involved both scientifically and administratively. NIH will be able to fund exactly what is needed to clear the precise scientific and developmental hurdles presented by each case.

The CAN program also offers the opportunity to carry out systematic process engineering on the drug development pipeline. Unlike private sector companies, which generally conduct development programs in isolation and treat process improvements as proprietary information, CAN will publish both positive and negative results to demonstrate what can be done and to remove technical hurdles for all parties in the field.

CAN will build on other programs and mechanisms currently in use at the NIH for translational research, leverage existing NIH resources and programs, and incentivize collaborations between sectors, including intramural and extramural programs. The current NIH infrastructure and resources provides efficiencies of scale. For instance, access to state-of-the-art technologies and resources will facilitate the conduct of the studies necessary to identify a target, find a lead compound and optimize it, and meet regulatory requirements for taking the compound into clinical trials. These programs include the NIH Molecular Libraries Screening Center Network and Probe Production Center which aim to enhance chemical biology efforts through high throughput screening to obtain small molecule probes effective at modulating a given biological process or disease state; NIH Chemical Genomics Center, which consists of a robotic, high-throughput screening system and a library of more than 350,000 compounds for use in basic discoveries and as probes of cellular pathways. Certain molecules with potential therapeutic properties that emerge from NCGC screening process can be fed into the Therapeutics for Rare and Neglected Diseases (TRND) drug development pipeline; the TRND program is a drug development pipeline for producing new treatments for rare and neglected diseases; and the Clinical and Translational Science Award (CTSA) Institutions which have established infrastructure and trained personnel for performing clinical investigations.

NIH recognizes that along with the many opportunities provided by CAN, there are challenges. CAN may have successes but also failures if the safety and efficacy data generated by CAN projects still do not meet the standards or regulatory criteria necessary for marketing approval. It will be important for NIH to assess and manage the risks of the program.

HEALTH REFORM LEGISLATION AND NIH

Mr. Obey: What are the major provisions of the recently enacted health reform legislation that affect the activities of NIH? What changes in NIH operations and activities do you anticipate as a result?

Dr. Collins: Section 10409 of the Patient Protection and Affordability Act (PPACA) establishes the Cures Acceleration Network (CAN) within the NIH Office of the Director to bridge the "valley of death" in medical product development. See Mr. Obey Question above "CURES ACCELERATION NETWORK" above.

NATIONAL CHILDREN'S STUDY

Mr. Obey: Please provide an update on the National Children's Study, including the status of the comprehensive review now underway, major schedule milestones, and cost estimates for fiscal years 2010 and 2011.

Dr. Collins: The National Children's Study (NCS) is a large multi-year research study with the goal to examine the relationships among the environment (as broadly defined), genetics, growth, development, and health of 100,000 children from before birth through age 21 years. Several components collectively constitute the NCS. The current pilot phase is the Vanguard Study, to be followed by a larger Main Study. The NCS is actively implementing the Vanguard phase to determine the feasibility, acceptability, and cost of such aspects as recruitment, sample and information collection and storage, and visit assessments.

Although the unique nature of the NCS is what makes it so valuable, it also means that prior studies may not be useful organizational models. Thus, we have adopted an empirical approach to the further development of the study; we will design the Main Study based on information collected and analyzed during the Vanguard phase and minimize reliance on other sources. For instance, the pilot recruitment in the Vanguard locations made it clear that the initial assumptions regarding recruitment strategy and efficiency were overly optimistic. Thus, the Vanguard Study is currently implementing three additional recruitment strategies to determine the feasibility, acceptability, and cost of each. We expect to develop sufficient empirical data to develop a comprehensive recruitment strategy that allows customized recruitment for specific areas and populations and an efficient and cost-effective, field-tested strategy for the Main Study.

In addition to these new recruitment strategies, formative research sub-studies are occuring in parallel to develop feasibility, resource, and cost estimates for the Main Study with as much precision as possible. All aspects of study operations including logistics, supplies, communications, data transfer, and sample storage are being analyzed and evaluated. We are in contact with, and regularly track, the efforts of other

large ongoing longitudinal studies, which though they differ from the NCS in many ways, might provide lessons and practices that could be applicable to the NCS.

The NCS planning process assumes essentially flat budgeting for FY 2010 and FY 2011. The FY 2010 NCS appropriation is $193,880,000. The FY 2011 planned budget is $194,400,000.

Major Schedule Milestones:

November/December 2009 - The NCS developed three alternate recruitment strategies in addition to the household based strategy used in the original study design. Requests for Letters of Interest (LOI) to implement the new strategies were sent to the 36 Study Centers currently under contract.

January 2010 – The NCS convened a review panel to evaluate the LOI responses on feasibility, scientific rigor, and feasibility. An additional 30 study centers were selected, and the centers were notified of the selection.

July/August 2010 - The new recruitment strategies will begin in the expanded Vanguard Study Centers and continue for one year.

July/August 2011 – The NCS will commence analysis of expanded Vanguard Study results and develop the Main Study Protocol.

September/November 2011 – A scientific panel review will review the expanded Vanguard Study results and the Main Study Protocol.

January 2012 – The NCS plans to commence the Main Study after final decisions are reached on issues of feasibility, acceptability, and cost.

H1N1

Mr. Obey: Please describe the role that NIH played in preparing for a possible H1N1 influenza pandemic.

Dr. Collins: Pandemic preparedness has been and continues to be an important component of the National Institutes of Health (NIH) influenza research program. Led by the National Institute of Allergy and Infectious Diseases (NIAID), NIH-supported influenza research includes basic research as well as applied and clinical research focused on the development of vaccines, diagnostics, and therapeutics against influenza. Research activities on seasonal and pandemic influenza are integrated; increased understanding and preparedness for one inherently furthers understanding and preparedness for the other.

A comprehensive research infrastructure and ongoing preparedness efforts enabled the Institute to respond both rapidly and effectively to the 2009 H1N1 pandemic. NIAID rapidly initiated and continues to conduct a series of clinical trials across the United States to test the safety and immunogenicity of the 2009 H1N1 influenza vaccine. These trials have generated critical information for the nationwide and worldwide immunization campaigns against 2009 H1N1 influenza. For example, the studies have shown that a single standard 15 μg-dose of the vaccine is safe and effective in inducing an immune response that would be predictive of protection in adults, the elderly, pregnant women, and older children. As with the seasonal influenza vaccine, two doses of the vaccine were necessary to induce a robust immune response in children aged six months to nine years. The vaccine also is being tested in HIV-positive individuals and people with asthma. NIAID also is supporting research to develop new and improved influenza vaccines. These efforts include optimizing delivery methods, improving manufacturing procedures and expression systems, and identifying new antigenic combinations. Efforts also include research toward the ultimate goal of developing a "universal" influenza vaccine that would protect against all influenza subtypes, obviating the need for annual updating.

NIAID also conducted and supported basic research on the newly emerged 2009 H1N1 influenza. For example, investigators at the NIAID Centers of Excellence in Influenza Research and Surveillance (CEIRS) helped to rapidly analyze the genetics, pathogenicity, transmissibility, and antiviral susceptibility of 2009 H1N1 influenza viruses. In addition, NIAID-supported investigators studied the ability of existing antiviral drugs to combat several pandemic H1N1 influenza virus strains, including in children. NIAID also supported research on rapid diagnostics for H1N1 influenza.

AUTISM STRATEGIC PLANNING

Mr. Obey: The Combating Autism Act of 2006 requires the Interagency Autism Coordinating Committee (IACC) to develop a strategic plan for autism research and to update it each year. Has that been done? What progress has been made in implementing the plan?

Dr. Collins: The IACC released its first strategic plan, the *2009 IACC Strategic Plan for Autism Spectrum Disorder (ASD) Research*, in January 2009, and an update in January 2010. The Plan advises the Secretary of Health and Human Services on needs and priorities for ASD biomedical and services research. It is organized around seven critically important questions for people with ASD and their families regarding diagnosis; the biology of autism; risk factors; treatments and interventions; services and supports; issues faced by adolescents, adults, and older adults with ASD; infrastructure; and surveillance. Each chapter in the Plan includes a brief discussion of what is currently known and what is needed prior to listing research objectives that address biomedical aspects of ASD as well as services research. The 2009 Plan incorporated extensive input from the public and the scientific community to identify over 30 objectives for research. With additional public and scientific input, the revised Plan

adds 32 new research objectives and contains an entirely new chapter on infrastructure needed to support ASD research.

The new objectives cover topics such as health disparities in early diagnosis; characterization of children with reported regression; and the biology and treatment of co-occurring conditions, such as epilepsy and gastrointestinal disorders. The additional chapter on infrastructure development includes objectives aimed at enhancing the ASD research workforce; data sharing; surveillance programs; biological specimen repositories; and communication and implementation of research findings. In addition, the updated Plan more fully addresses the needs of the people with ASD across the spectrum, from young children to adults, and places new emphasis on both non-verbal and cognitively-impaired people with ASD.

The release of the 2009 Plan coincided with the passage of the American Recovery and Reinvestment Act of 2009 (Recovery Act or ARRA). In 2009, NIH was able to use the IACC Strategic Plan to guide investment of approximately $64 million of Recovery Act funds in new research on ASD. With this addition, NIH funding for ASD research reached its highest level yet in 2009 at a total of $196 million. (For a full listing of funded projects, please refer to the NIH RePORT website.) NIH projects funded under the Recovery Act in 2009 addressed each major objective of the Plan, including research on rapid screening tools; risk factors for ASD; biomarkers for early diagnosis; genetics and environmental epigenomics of ASD; potential behavioral and drug interventions; adult services; telehealth; and how autism manifests in the second half of life. In 2010, NIH will continue to address priorities identified in the IACC Strategic Plan to advance treatments and research to benefit people with ASD and their families. For more information about the IACC and its Strategic Plan please see: www.iacc.hhs.gov.

OFFICE OF SCIENCE EDUCATION

Mr. Obey: With respect to the NIH Office of Science Education----Please describe the types and levels of outreach and support that the Office of Science Education provides to schools and educators across the country.

Dr. Collins: The NIH Office of Science Education directs a number of programs for K-12 teachers and students nationwide. The OSE website, http://science.education.nih.gov, is the main access point for these resources. Specific programs are:

NIH Curriculum Supplements

Since 1997, OSE has partnered with NIH Institutes and Centers to develop, distribute, and support 17 NIH Curriculum Supplements (seven for high school, nine for middle school, and one for grades 1 and 2) that bring cutting edge biomedical research into the classroom: http://science.education.nih.gov/supplements. Topics covered include cancer, scientific inquiry, sleep, metabolism, oral health, and bioethics.

To date they have been distributed to over 92,000 educators nationwide upon their request, http://science.education.nih.gov/map. While the vast majority of these 380,000 total supplements have gone directly to classroom teachers, the materials are also being utilized in home schools, colleges, universities, afterschool programs, law enforcement activities, and health-care facilities. OSE partners with dozens of educators, school districts, universities, and education- and health-related organizations to promote the lessons and support the teachers who use them. To better facilitate their use under *No Child Left Behind*, each set of lessons is aligned to individual state education standards for English, science, mathematics, and health.

LifeWorks

OSE maintains an interactive database of 150 (and growing) careers in the health and medical science: http://science.education.nih.gov/LifeWorks. These web pages were visited more than 220,000 times in the last month, April 2010. Students can explore the breadth and diversity of occupations and use a career finder to identify specific jobs related to their unique interests. Lifework also contains information on college and career planning for grades 8 through 12. Many of the careers descriptions include written interviews with individuals working in the profession. A recent addition to the website is 3-minute video interviews of unique careers such as biochemist, forensic science technician, and recreational therapist. The videos are also posted on NIH's YouTube channel.

NIH Educational Resources Database

The OSE homepage features a database of 1,500+ NIH educational resources for K-12 teachers and students: http://science.education.nih.gov. Examples include pamphlets on cancer, PowerPoint presentations on the mechanisms of drugs in the brain, and web-based games on sleep. To meet the needs of teachers, these resources are organized by topic, grade level, and format. The resources come from across NIH and are carefully selected for their relevance to elementary and secondary education. In the last month, April 2010, these resources were visited 80,500 times.

Women Are Scientists Career Videos

In partnership with the NIH Office of Research on Women's Health, OSE produced a series of five 30-minute videos (DVDs) that feature women in specific fields of medical research: http://science.education.nih.gov/womenare. The videos show women as pathologists, surgeons, researchers, and dental researchers. A fifth video highlights women scientists with disabilities. Over 21,000 videos have been sent to teachers nationwide upon their request. The videos are posted on the OSE and NIH YouTube websites.

Scientists in Science Education – the NIH Science Education Nation

Recently, OSE developed a web-based resource for scientists across the countries who are interested in improving K-12 science education: http://science.education.nih.gov/NIHSciEdNation. The site includes an overview of today's K-12 education system and how it could benefit from scientist input. Details on

how to develop meaningful scientist-educator partnerships and specific examples of ways to help are provided. This site is being received enthusiastically by professional science societies as an important outreach guide for their members. OSE is continuing to promote the new site and has been asked to present it at the annual meeting of the Council of Engineering and Scientific Society Executives this July in Pittsburgh. A key goal of the NIH Science Education Nation website is to promote and support participation in National Lab Day effort promoted by President Obama.

Mr. Obey: Please indicate the budget and staffing level (in FTEs) for the Office in each of fiscal years 2007 through 2009 and the estimates for fiscal years 2010 and 2011.

Dr. Collins:

Year	Budget	FTEs
FY2007	3,852,000	9
FY2008	3,942,000	9
FY2009	3,981,000	9
FY2010	4,039,000	9
FY2011	4,169,000	9

RESEARCH MANAGEMENT AND SUPPORT INCREASE

Mr. Obey: One of the largest percentage increases in the NIH fiscal year 2011 request is for the Research Management and Support mechanism. Why the relatively large proposed increase for this area? How would the increased funds be used and what results can be expected?

Dr. Collins: We have requested $1.525 billion for the Research Management and Support (RMS) budget, an increase of $72.6 million or five percent over the FY 2010 RMS budget. This increase will support many functions, including scientific oversight and management by NIH staff in the review, award, and performance monitoring of extramural awards (research grants, training awards, and research and development contracts), administrative and technical support for Congressionally mandated review groups and advisory councils and bodies; and special interest organizations; monitoring of advances emerging from basic science laboratories to determine possible clinical applications for treatment and prevention.

The increasing complexity of contemporary scientific research involves highly sophisticated and newly emerging technologies that integrate genetic and other information (medical chemistry, toxicology, clinical and behavioral study data, medical histories, and population based studies) from a variety of sources. State-of-the-art skilled managers of scientific portfolios are essential to manage these resources and to ensure that the maximal scientific value of the investment is realized. In addition, translational research and the advancing of these scientific discoveries arising from the

laboratory into clinical applications will require managers with expertise in every phase of the translational continuum. The need for this level of expertise contributes to larger payroll expenditure. Additional staff will provide NIH with sufficient capacity to manage its research portfolios, and to improve stewardship of all funds. In addition, the increase will enable NIH to expand information technology infrastructure in support of scientific staff, support services for our prevention programs, and education initiatives.

OPPORTUNITIES TO ACHIEVE EFFICIENCIES

Mr. Obey: Please describe opportunities and plans to achieve better economy and efficiency by consolidating procurement and management activities across multiple institutes and centers. In particular: To what extent does NIH currently consolidate purchasing and/or management in areas such as equipment purchases, development and management of IT, and contracts for other services?

Dr. Collins: It is NIH's practice to consolidate purchasing and use all contract capabilities available to us to achieve both cost and time savings wherever possible. This is demonstrated by the following:

- In FY 2009, the NIH Office of Acquisition Logistics and Management (OALM), in partnership with the NIH Office of Intramural Research, implemented a Consolidated Scientific Equipment pilot program to consolidate our purchases of various types of scientific equipment using American Reinvestment and Recovery Act (ARRA) funding. As a result, in FY 2009 the NIH achieved a cost savings of $3.6M or 16% of our total FY09 ARRA Scientific Equipment Acquisitions.
- The consolidation of commodities through the use of strategic sourcing contract vehicles. These vehicles are established to leverage the Federal Government's buying power with industry.
- The NIH Supply Center is aggressively initiating contracts for strategic sourcing of NIH supply products, by leveraging Departmental capabilities, GSA commodities contracts, the Defense Logistics Agency (DLA), as well as trans-NIH contracts. Recently, contracts have been negotiated for Office Supplies, Paper products, Gas Cylinders and Medical Surgical supplies. Personnel at the center are now initiating a contract for Laboratory supplies, and over 250 products are now sourced through DLA using its vast economies of scale for buying commodities.
- The NIH also consolidates the acquisition of administrative services. We have awarded a long-term administrative services contract which provides a range of administrative capabilities to all of NIH through multiple contract awardees. NIH recently awarded a technical services contract, whereby the NIH community can obtain technical services at very competitive prices.
- The NIH Information Technology Acquisition and Assessment Center (NITAAC) manages three Government-Wide Acquisition Contracts (GWACs). These contracts are used by many Federal agencies, in addition

to the NIH research institutes and centers. We are currently utilizing reverse auctioning procedures to obtain maximum cost savings and efficiencies.

- In 2005, NIH consolidated Offices of Acquisition from 18 to 10 in an effort to better utilize staff and share other resources. This consolidation created organizational efficiencies, while preserving those efficiencies that are evident in a decentralized model of having Contracting Offices in close proximity to the Research and Development (R&D) laboratories and extramural offices. Such efficiencies in a decentralized model foster communication, knowledge and partnership between contracting and program staffs. It enables the contracting staff to gain expertise with their program's requirements.

SAVINGS AND EFFECIENCIES TO BE ACHIEVED

Mr. Obey: What plans do you have to increase such consolidation and what savings and efficiencies do you believe can be achieved? If there are no such plans, do you believe that consolidation would not achieve greater efficiency or economy, or are there other reasons that consolidation is not being pursued?

Dr. Collins: The NIH will continue to aggressively pursue savings via extensions of the above strategies such as:

- Expansion of the NIH Consolidated Scientific Equipment pilot program. As a result of the overwhelming success of the consolidated pilot program initiated in FY 2009, we have expanded our consolidation strategy of scientific equipment in FY10. Each institute and center has been asked to identify FY 2010 equipment requirements, and though it is too early to quantify the cost and time savings, we anticipate the savings will be significant NIH-wide.
- Expansion of NIH wide services through consolidated services contracts. Examples include ongoing efforts in the public communications and information sphere as well as consolidated conference services.
- The NIH Supply Center efforts to award umbrella contracts for commodities and further competition through reverse-auctioning. This will result in lower priced commodities available to the NIH community.
- It is our plan to significantly increase education and outreach throughout the Department and Federal Government, so that awareness of the NITAAC GWACs is increased throughout the Federal Government. As a result, we anticipate that the benefits of leveraging our GWACs to fulfill information technology product and services requirements will result in increased efficiencies.
- As a result of a "spend analysis" and a study of the NIH Supply Center Warehouse operation, an aggressive education and outreach campaign has begun which reaches out to customers to determine requirements, then if

demand dictates, the items are bought into stock at the Center. This has proven beneficial and many stale items, no longer being procured have been removed from stock and new products with higher demand are now being carried. The Supply Center procures in volume resulting in reduced costs for products.

CENTRALIZED FUNDING FOR NLM/NCBI

Mr. Obey: The fiscal year 2011 budget request proposes to centralize funding in the National Library of Medicine for support of public access to research results and the National Center for Biotechnology Information, and includes base adjustments to institute and center funding for fiscal years 2009 and 2010 to reflect this proposed shift. Why does NIH prefer this approach, rather than continued use of its management fund authority to support these assets and activities from the budgets of individual institutes and centers based on their utilization? Doesn't the current approach more accurately allocate costs to the appropriate activities, if not please explain why it does not?

Dr. Collins: The NIH Director and the NCBI Resource Board, which consists of eight NIH IC Directors, have consistently recommended that NCBI's funding needs be built into its base budget. Their recommendation is based upon recognition that NCBI's workload is heavily affected by trans-NIH initiatives such as public access and the growing proportion of genomics-related research in NIH's extramural funding. Only through a stable, appropriated base budget can NCBI anticipate new scientific developments in order to have the necessary lead time to create the databases and tools for these new sources of data. Furthermore, the NCBI Resource Board is considering how to better link the NCBI resource requirements to IC funding priorities.

HARD FUNDS CONTROL

Mr. Obey: The NIH leadership has committed to upgrade its financial computer system to provide "hard funds control", in order to prevent violation of financial management laws (including rules governing reprogramming of funds). Please provided the phased timetable for this upgrade with semi-annual milestones?

Dr. Collins: NIH is committed to implementing reprogramming hard funds control in FY 2013 since it would be most cost effective to do so with the implementation of Oracle v. 12.FSIO. A number of actions are currently underway to assure an optimal installation of this software and these are listed above under "Upgrade NIH Financial Systems". However, until hard funds control for reprogramming is established, actions are being taken to facilitate adherence to the Congressional reprogramming requirements. These include the development of clear NIH-wide budget policies, the development and implementation of an enhanced NIH-wide reporting capability that will allow tracking of obligations by submechanism against authorized levels, and an examination and refinement of extramural policies to

allow implementation of reprogramming requirements while minimizing potential program impact.

NIH BUILDINGS AND FACILITIES

Mr. Obey: What is the estimated dollar value of the backlog of buildings and facilities maintenance and improvement requirements projected for fiscal years 2010 and 2011?

Dr. Collins: The estimated backlog of maintenance and repairs (BMAR) for fiscal year 2010 is $1.313 billion; at the end of fiscal year 2011 it is estimated to be $1.260 billion. The decrease is associated both with current projects underway and with projects expected to start in FY2011.

Mr. Obey: What would be the desirable or appropriate backlog for NIH, given the size, complexity and age of its physical plant?

Dr. Collins: NIH's goal is to achieve a condition index (CI) of at least a 90 for every building in our portfolio. CI is based on the ratio of the total Backlog of Maintenance and Repair (BMAR) to total portfolio Plant Replacement Value (PRV). With a current PRV of $5.15B, the desired backlog of maintenance and repair for NIH is $515M or below.

Mr. Obey: What is the plan to achieve the desirable state for NIH buildings and facilities?

Dr. Collins: In 2002, NIH (as well as all DHHS Operating Divisions) adopted a facility assessment protocol called the Condition Index, which used by many public and private organizations to determine the condition of their real property inventory and create a plan for correcting deficiencies. The Condition Index, which scores a building's health on a scale of 0 to 100 (with 100 being a perfect score) is a useful tool in both forecasting annual budgetary requirements and in prioritizing available funds during the execution year. NIH's stated goal is to achieve a Condition Index of 90 or greater for each facility. Currently, of 280 NIH owned buildings, 123 have a Condition Index of 90 or greater.

THIRD PARTY COLLECTIONS

Mr. Obey: NIH has the authority to seek reimbursement from insurance companies for the cost of clinical services provided to insured patients who receive care at the NIH Clinical Center.

To what extent has NIH used this authority to seek third-party reimbursement for Clinical Center care, or plans to do so in the future? If the authority is not being fully used, why not? Doesn't failure to achieve maximum third party collections have the

effect of subsidizing insurers and reducing resources available for research? Explain if NIH believes recent health changes will impact any earlier analysis?

Dr. Collins: The NIH Clinical Center has not sought third-party reimbursement from its patients, for a variety of reasons discussed further below. However, it is a concept that has been repeatedly examined as environmental and technological factors evolve.

The most important factor of note is that the NIH Clinical Center's mission and statutory authority is to conduct research, not to provide health services. . Research costs are not reimbursable by insurers. The most recent comprehensive NIH Clinical Center third-party reimbursement feasibility study, conducted in 2005, estimated the net achievable annual income from implementation of third party billing at ~$10M annually. The proposal was rejected as the risks listed below were determined by the previous NIH Director, with input from the NIH Advisory Board for Clinical Research, to outweigh the financial benefit.

Relationship with patients: Currently the NIH Clinical Center has a partnership relationship with patients who volunteer to participate in clinical studies. Past surveys of physician investigators have revealed concern that relationships with patients would change to consumer-provider affiliations, altering the nature of the research mission at the NIH Clinical Center. In the 2005 study, 23% of patients indicated they would not continue to participate in research if their insurance were billed. However, this may have changed with the health care reform legislation since there is no longer a life time cap on reimbursement and a patient cannot be denied coverage based on previous diagnosis.

Competition with outside providers: Introducing a business model of third party collection will place the NIH Clinical Center in competition with academic medical centers and referring physicians, possibly negatively impacting the patient referral stream, especially the referral of local patients who represent about half of the NIH Clinical Center patient population.

Complexity and cost of billing at the NIH Clinical Center: As a national hospital, with patients admitted from every state, the NIH Clinical Center would have to manage scores of insurance companies from across the country, not just the local providers as is the situation with other hospitals. This would add substantially to the administrative workload to meet the requirements of each payer.

Additionally, since every NIH Clinical Center patient participates in a clinical protocol involving participation in complex research processes, the majority of services provided are not considered health services or standard of care. Identification of health services (standard of care) versus research services is a manual process, for which no automated commercial products are currently available. As such, the NIH Clinical Center would need a team to institute a system to separate these costs.

Finally, the implementation of billing services would affect the Clinical Center's status as a HIPPA- exempt organization, resulting in significant additional expense to become HIPAA-compliant.

• Clinical investigator retention. The clinical investigators who work at the NIH Clinical Center come often for a fraction of the salary they would receive at academic medical centers, because of the scientific opportunities relatively free of administrative hassle. Implementation of a third-party payer system will impose a new administrative burden on these clinical scientists and, based on a survey of our clinical scientists, many say they would leave because the cultural change would be significant and the advantages for staying at NIH will be compromised.

THIRD PARTY COLLECTIONS

Mr. Obey: Dr. Collins, NIH has the authority to seek reimbursement from insurance companies for the cost of clinical services provided to insured patients who receive care at the NIH Clinical Center.

Please explain how NIH has or plans to examine ways in which third party collections authority has been used by other Federal organizations, such as the Department of Defense, the Department of Veterans' Affairs, or the Indian Health Service?

Dr. Collins: As part of a comprehensive feasibility study conducted in 2005, an examination of third party collections at other federal agencies was performed to frame the billing and collection of third party reimbursement revenues in the context of federal authorities. Interviews were conducted with federal organizations that collect revenues designed to elicit insights on infrastructure, processes, tools, culture and other components required to maintain collections within a federal agency. The federal agencies interviewed included amongst others the Department of Veterans Affairs, Food and Drug Administration, Indian Health Service, and the Air Force Medical Command.

There are several key differences between the NIH Clinical Center and these Federal organizations that must be addressed when considering third party collections.

Mission: Patient care at other Federal organizations is focused on standard medical care for treament of illness and disease. In contrast, at the NIH Clinical Center, the focus is on clinical research and standard patient care for treatment of illness and disease is coincidental. At the VA and DoD, patients seek established therapeutic treatment of known diseases whereas at the NIH Clinical Center only patients enrolled in research protocols are admitted and participate within the paramaters of the protocol on a journey of discovery of new innovative treatments for diseases, both known and previously undiagnosed.

Economies of scale: The patient population at the NIH is small compared to our Federal counterparts. We are one, 234-bed hospital; the VA and IHS have a network of hospitals and clinics. An example of the differences in scale: the VA expects to see over 6,000,000 patients in 2011, which is exponentially larger that the NIH Clinical Center population of approximately 7,000 inpatient admissions (~60,000 patient days) and 100,000 outpatient visits. The projected net cost recovery is $10M, after taking into account the impacts of infrastructure to support third party collections. Potential revenue estimates have to be weighed against the negative impact to patient recruitment and staff retention from billing. When all factors were considered, NIH decided that the negative impacts to the Institution's mission and culture were greater than the potential financial benefits.

Billing eligibility: Only IHS is able to recover costs for Medicare/Medicaid covered individuals; this represents approximately 15-20% of our patient population. If the NIH were to bill patients, it would be important to obtain specific legislative authority to enable recovery of costs from CMS.

SCIENTIFIC MANAGEMENT REVIEW BOARD

Mr. Obey: The NIH Reform Act of 2006 requires establishment of a Scientific Management Review Board to advise the NIH Director. Please provide an update on the activity of this Board, including the anticipated schedule for issuing its first recommendations.

Dr. Collins: As of the end of May 2010, the Scientific Management Review Board (SMRB) has met in full session four times. In addition, three working groups have been formed and have met numerous times.

The Working Group on Deliberating Organizational Change and Effectiveness has prepared a draft report outlining a process for considering organizational change at NIH, the principles that should guide the consideration of change, and the underpinning attributes of the process. The Working Group on Substance Use, Abuse and Addiction has been considering whether organizational change within NIH could further optimize research into substance use, abuse and addiction. The Working Group on the NIH Intramural Research Program and Clinical Center has been exploring whether organizational changes are needed to improve the fiscal sustainability and utilization of the NIH Clinical Center. The working groups have conducted systematic analyses of their respective issues, received extensive briefings from internal and external experts and stakeholders, and examined a broad range of possible options to address each issue.

At the Board's next meeting May 18-19, 2010, the SMRB will consider the draft report on organization change and explore public and stakeholder perspectives on the deliberations of the Working Group on Substance Use, Abuse and Addiction, and the Working Group on the NIH Intramural Research Program and Clinical Center. A fifth SMRB meeting will be scheduled in the summer of 2010 to consider recommendations

for a reorganization strategy for the agency to optimize NIH conducted or supported research on substance use, abuse and addiction and a new vision, budget model and governance structure to support utilization and fiscal sustainability of the NIH Clinical Center.

CONFLICT OF INTEREST REGULATIONS

Mr. Obey: Section 219 of the fiscal year 2010 appropriations legislation for the Department of Health and Human Services requires amended regulations to be issued by May 1, 2010 governing financial conflicts of interest among extramural researchers receiving support from NIH. Have such regulations been issued? If not, when will they be issued and what is the reason for the delay?

Dr. Collins: As the first step in the rulemaking process, NIH published an Advanced Notice of Proposed Rulemaking (ANRPM) on May 8, 2009 for public comment. The ANPRM asked for input in six broad areas related to how institutions manage conflicts of interest and whether the regulations should be amended to strengthen NIH oversight. The public comment period closed July 7, 2009. The many comments we received from universities, members of the public, scientific research organizations, and patient advocacy groups were carefully analyzed. The findings and recommendations of recent reports issued by the Department of Health and Human Services Office of Inspector General (DHHS OIG), the Institute of Medicine, and professional associations were also reviewed.

NIH has drafted a Notice of Proposed Rulemaking (NPRM) that outlines proposed changes throughout the regulation with a focus on three broad areas, disclosures by investigators; information that must be submitted to NIH; and information that is to be made public. The NPRM was published in the Federal Register on May 18 for a 60-day public comment period. After the comment period ends, the comments will be analyzed and final regulations drafted. We are proposing that the final regulations will be ready for HHS and OMB review in September 2010, and that the final regulation will be published the following month.

OUTSTANDING CACRS

Mr. Obey: Please provide a table listing all reports requested from NIH by the House Appropriations Committee that have not yet been provided, showing the date by which they were requested and the expected completion date.

Dr. Collins: At this time all outstanding CACRs have been submitted to the Department for review. The Department is working to ensure that future CACRs are submitted in an appropriate and timely manner. The table follows:

IC	Requestor	Report Name	Due to Committee	Target Submission Date
FY 2008 HOUSE REPORTS				
NIMH/NIA		Geriatric Mental Health, p. 158	10/1/2008	Sep-2010
FY 2009 HOUSE REPORTS				
OD/OBSSR	House	Basic Behavioral Research, p. 166	3/1/2009	Sep-2010
OD	House	Clinical and Translational Science Awards (CTSA) clinical research, p. 167	8/1/2009 annually	Aug-2010
NINDS	House	Parkinson's Disease, Udall Ctrs prog, p. 147	6/1/2009	Aug-2010
NINDS	House	Peripheral Neuropathies, p. 147	3/1/2009	Jul-2010
NHLBI	House/Senate	Lymphatic Disease	3/1/2009	Aug-2010
OD/NCMHD	House	Translating NIH Research to Address Racial and Ethnic Disparities, p. 174	3/1/2009	Aug-2010
FY 2010 HOUSE REPORTS				
NCI	House	Cancer Information Service Partnership Program (CIS), p. 108	2/1/2010	Jul-2010
OD	House/Senate	Discretionary Funds (3rd Quarter), p. 129	Quarterly	Sep-2010
OD	House/Senate	Discretionary Funds (4th Quarter), p. 129	Quarterly	Nov-2010
NIAMS	House	Musculoskeletal Conditions, p. 124	9/30/2010	Oct-2010
NCI	House	Pancreatic Cancer, p. 110	60 days of occurrence	TBD
NCI	House	Pediatric Cancer, p. 110	6/1/2010	Aug-2010
OD/NCMHD	House	Translating NIH Research to Address Racial and Ethnic Health Disparities	TBD	TBD
FY 2011 HOUSE REPORTS				
OD/NIAAA	House	Underage Drinking and Adolescent Brain Development, p. 139	10/1/2011	Oct-2011

ANTIMICROBIAL RESEARCH

Mr. Honda: Although I support your efforts to focus on obesity, HIV, and rare diseases, multiple and extreme drug resistant staph, tuberculosis, gonorrhea, and syphilis are all on the rise — in some cases there are alarmingly high rates of infections and we are only one drug away from being powerless against these extremely common bacteria/microorganisms. Still, research and development on new antibiotics to treat these and other infections and diseases lags alarmingly behind the reality of these infections.

What is NIH doing to focus research on better understanding and new treatments for antibacterial and antimicrobial therapies?

Dr. Collins: The National Institute of Allergy and Infectious Diseases (NIAID), the lead Institute of the National Institutes of Health (NIH) for research on infectious diseases, conducts and supports basic research to identify new antimicrobial targets and translational research to apply this information to the development of therapeutics; to advance the development of new and improved diagnostic tools for infections; and to create safe and effective vaccines to control infectious diseases and thereby limit the need for antimicrobial drugs. This includes efforts to advance our knowledge of microbial genetics and genomics that can bolster our understanding of antimicrobial resistance, reveal vulnerable areas in a microbe's genome that could be potential drug targets, and aid in the development of better diagnostic tests. NIAID funds research and development of diverse products through a variety of mechanisms, including grants and contracts to academic laboratories and to small and large companies. NIAID also is conducting studies to inform the rational use of existing antimicrobial drugs or alternative therapies to help limit the development of antimicrobial resistance. As part of the federal government's comprehensive efforts to combat the problem of antimicrobial resistance, NIAID oversees a major effort built upon a foundation of basic research to understand the biology of microbial pathogens, the interactions between these pathogens and their human hosts, and the biological mechanisms by which pathogens develop resistance to antimicrobial drugs.

To complement these collaborative research efforts, NIAID developed an innovative program that provides a broad array of pre-clinical and clinical research resources and services to researchers in academia and industry designed to facilitate the movement of a product from bench to bedside. By providing these critical services to the research community, NIAID can help to bridge gaps in the product development pipeline and lower the financial risks incurred by industry to develop novel antimicrobials..

Mr. Honda: How much of NIH resources as a percentage of your total budget is devoted to this type of research?

Dr. Collins: NIAID funding for antimicrobial research in FY 2009 was $750M, or 15% of the total NIAID budget of $4.703B. The total for antimicrobial research includes basic research as well as applied research for drugs, diagnostics, and vaccines for a range of microbes, including drug-resistant bacteria and viruses such as HIV.

ENDOCRINE DISRUPTERS

Mr. Honda: Endocrine disrupting chemicals are found in plastics, pesticides, flame retardants, flooring, and many other items that make up our modern environment. They have been linked to mutations, decreased fertility, cancers, menstrual problems, behavioral changes, early puberty, impaired immune functions, and a range of other problems. In addition, tap water, as well as treated and raw sewage water released into our oceans and waterways, frequently contain relatively high levels of chemicals and hormones humans excrete every day.

How is NIH working with EPA to better study and understand the effects of these chemicals on our health?

Dr. Collins: The National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP) have been active partners with the Environmental Protection Agency (EPA) in supporting research to understand health effects of exposure to endocrine disrupting chemicals. NTP scientists have provided important information to EPA throughout the development of EPA's Endocrine Disruptor Screening Program. The Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), with NTP support, reviewed endocrine disruption screening test methods, recommended standards for assay validation, and is currently conducting an international validation study of one of the receptor-based assay methods, while also consulting on the study protocol for a second method.

The NTP High-Throughput Screening Program, in partnership with EPA and the National Human Genome Research Institute's (NHGRI's) NIH Chemical Genomics Center, is working on the Tox21 program, a new approach to toxicological testing. This approach consists of using in vitro assays targeting the key pathways, molecular events, or processes linked to disease or injury, including endocrine pathways, and incorporating them into a framework of research and testing using more traditional methods. The researchers are using quantitative high throughput screening assays to test a large number of chemicals, among which are a number of endocrine disrupting chemicals. The resulting data are being deposited into publicly accessible relational databases. Analyses of these results will set the stage for a new framework for toxicity testing.

Finally, the NTP, through an interagency agreement with EPA, is supporting research to determine how well the outcomes from exposures to combinations of endocrine disrupting chemicals are predicted based on our current assumptions of how these chemicals may interact. This research program currently focuses on a single class of commonly used chemicals in plastics and cosmetics called phthalates but may soon

expand to evaluate different classes of chemicals that appear to target similar biological processes.

DIVERSITY IN BIOMEDICAL RESEARCH

Mr. Honda: The chronic underrepresentation of minorities and women in the sciences is a well known and undisputed fact. Diversity in grant review panels, among researchers, and in the leadership of the various institutes is critically important to bring new perspectives to biomedical research.

What are you doing to improve diversity on NIH review panels and to encourage individuals from underrepresented minorities and women to enter and stay in biomedical research?

Dr. Collins: NIH is committed to ensuring the diversity of peer review panels. At the end of 2009, 27 percent of peer reviewers were members s of ethnic minority groups and 33 percent were women. According to NIH policy NIH advisory councils are to be ethnically diverse and geographically balanced. In keeping with this policy, every nomination slate and advisory committee roster is carefully reviewed to ensure their diversity. If slates lack ethnic representation, NIH staff is responsible for managing peer review panels and advisory councils are required to outline plans for rectifying the problem. These efforts are tracked centrally by the Office of the Director, NIH.

NIH also is committed to encouraging underrepresented minorities and women to enter careers in biomedical research. NIH has developed a number of policies, programs, and initiatives to promote careers in science among minorities and women. These include:

- NIH policy encourages diversity in all institutional research training, fellowship, career development, and research education project awards. The policy is included in funding opportunities for these programs and is part of the peer review considerations for all institutional training programs.
- The Research Supplements to Promote Diversity in Health-Related Research program encourages investigators with active grants to provide mentoring and learning experiences in research to individuals from diverse backgrounds.
- The NIH Director's ARRA-Funded Pathfinder Award to Promote Diversity in the Scientific Workforce encourages exceptionally creative scientists to develop innovative approaches for promoting diversity in the biomedical workforce.
- The Research on Causal Factors and Interventions that Promote and Support the Careers of Women in Biomedical and Behavioral Science and Engineering grant program examines factors that contribute to women entering and staying in the biomedical workforce.

- The amount of paid parental leave for Ruth L. Kirschstein National Research Service Awards trainees has been doubled to sixty calendar days or eight work weeks.
- The NIH reentry supplement program, which provides opportunities for fully trained researchers to reenter careers in science after a hiatus due to family or other responsibilities, has been expanded to include postdoctoral researchers (http://grants.nih.gov/grants/guide/pa-files/PA-08-191.html).
- To enable more parents with young children and others to attend scientific conferences, NIH now requires applicants for NIH Conference Grants (R13/U13) to describe a plan for identifying family care resources so that conference attendees with child care needs or other types of family support needs can make the necessary arrangements.

DIVERSITY NIH STAFF

Mr. Honda: Are you making any internal administrative efforts to diversify NIH staff?

Dr. Collins: Promoting and increasing diversity of the NIH workforce, and particularly tenured and tenure track scientists in NIH's intramural research programs, is a priority for the agency. In particular, the NIH is placing special emphasis on recruiting minority scientists to increase the applicant pool of candidates for tenure and tenure track positions. NIH has developed a plan to enhance diversity and promote the inclusion of under-represented scientists within these ranks. Elements of this plan include:

- Reaching a diverse pool of applicants by notifying the diversity specialists at Association of American Medical Colleges accredited medical schools, and program directors at NIGMS Minority Opportunities in Research Programs of all tenured and tenure track vacancies and soliciting their assistance in reaching prospective applicants.
- Reaching a diverse pool of applicants by conducting targeted outreach to individuals as well as organizations known to have diverse individuals with the requisite skills.
- Preparing NCMHD loan repayment recipients to compete for NIH tenured and tenure track positions by providing the Disparities Research Education Advancing our Mission intramural postdoctoral training program.
- Conducting focus groups to learn about any barriers that may inhibit the employment and retention of diverse groups, and develop strategies to remove any identified barriers.

In addition, for the entire NIH workforce, not just the intramural research programs, there is strategy to recruit and retain Hispanic employees. Elements include:

- Targeting outreach to University of Texas, Texas A&M, University, University of New Mexico and University of Puerto Rico.
- NIH institutes participating in conferences which target Hispanic audiences
- NIH conducting focus groups to learn more about the workforce's perceptions of the reasons for the limited numbers of Hispanics in the workforce.

Similarly, for all positions at NIH, there is a plan to recruit individuals with targeted disabilities. Elements include:

- The Disability Program Manager providing training sessions on special hiring authorities, reasonable accomodations and the Americans with Disabilities Act Amendments to educate managers and supervisors

BIODEFENSE RESEARCH

Mr. Tiahrt: Please provide a list of each grant funded by the $304,000,000 that was transferred from the BioShield Special Reserve Fund to the National Institute of Allergy and Infectious Diseases in fiscal year 2010. In your response, please include the title of the grant, when it was initially funded, the amount to be provided in fiscal year 2010 and the specific countermeasure the advanced biodefense research NIAID is funding is intended to address. For funds that have yet to be awarded, how does NIAID intend to ensure that the research addresses the specific biodefense needs identified by the Biomedical Advanced Research and Development Authority?

Dr. Collins: In the Consolidated Appropriations Act of 2010 (P.L. 111-117), $304 million was transferred from the Project BioShield Special Reserve Fund (SRF) to the NIAID, the lead Institute of NIH for biodefense research, primarily as an offset for other budget authority. The total combined appropriation for NIAID in FY 2010 is over $4.8 billion, of which NIAID estimates it will spend nearly $1.7 billion, including the transferred funds, for research on biodefense and other emerging infectious diseases. For example, one of the new activities to be supported in FY 2010 are projects solicited under a Broad Agency Announcement (BAA) entitled, "Development of Technologies to Facilitate the Use of, and Response to, Biodefense Vaccines." Other new activities to be supported in FY 2010 include research and development of broad spectrum antibiotics and filovirus vaccines.

A description of NIAID's plans for the nearly $1.7 billion in funding for biodefense and emerging infectious diseases research can be found in the FY 2010 NIAID budget justification: http://www.niaid.nih.gov/about/whoWeAre/budget/Documents/fy2010cj.pdf. The $304 million in transferred funds has been included in, and is making a substantial contribution to, the overall biodefense and emerging infectious diseases program for NIAID in FY 2010.

NIAID's biodefense research is guided by the Institute's Biodefense Research Agendas and its Strategic Plan for Biodefense Research, which align with the Department of Health and Human Services (HHS) Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan. In coordination with BARDA, NIAID aligns its funding strategies for biodefense research with the research priorities set out in these plans. NIAID anticipates that candidate products successfully developed through its Biodefense and Emerging Infectious Diseases Research Program will transition to BARDA for late-stage advanced product development and future acquisition under Project BioShield.

BIODEFENSE RESEARCH

Mr. Bonner: Director Collins, It is my understanding that National Institute for Allergy and Infectious Diseases serves as the source of basic biodefense research and development where BARDA provides funding for advanced R&D. Is this correct?

Dr. Collins: Yes, with regard to biodefense, NIAID supports basic and applied research and early product development. The Biomedical Advanced Research and Development Authority (BARDA) supports advanced product development and eventual procurement.

Mr. Bonner: I also understand that a not insignificant amount of the funding provided following the Anthrax attacks and in subsequent appropriations cycles has either been provided directly to NIH for medical countermeasures against biological attack or epidemic concerns such as H1N1 or transferred from within BARDA for the same reason. Can you provide the subcommittee with the exact amount of funds either directly appropriated or transferred from BARDA for biodefense and medical countermeasure since the anthrax attacks?

Dr. Collins: NIAID represents over 90% of NIH's biodefense research effort. Within its annual appropriation since the anthrax attacks, NIAID has allocated the following amounts for biodefense and emerging and infectious diseases research and development of medical countermeasures

FY 2003	$1.162B
FY 2004	$1.600B
FY 2005	$1.658B
FY 2006	$1.632B
FY 2007	$1.596B
FY 2008	$1.602B
FY 2009	$1.641B
FY 2010 (est.)	$1.679B

In addition to these funds, BARDA developed interagency agreements (IAAs) with NIAID for it to continue certain biodefense research and development activities that NIAID had initiated. In these IAAs, BARDA provided NIAID the following amounts:

FY 2007	$98.8M
FY 2008	$58.1M
FY 2009	$25.8M

Lastly, the following amounts have been appropriated to the NIH Office of the Director for research and development of medical countermeasures for radiological/nuclear and chemical threats:

	Radiological/Nuclear	Chemical
FY 2006	$46.5M	$49.5M
FY 2007	$46.5M	$49.5M
FY 2008	$45.7M	$48.6M
FY 2009	$47.6M	$49.1M
FY 2010 (est.)	$47.6M	$49.1M

Mr. Bonner: There is some concern that this funding has not only been used on the development of medical countermeasures but also to fill the funding gaps of NIH elsewhere to the detriment of our national preparedness. Can you provide this subcommittee a better understanding here today and then much more specifically in a follow up: 1) how that funding has been spent?

Dr. Collins: Through its Biodefense and Emerging Infectious Diseases research program, NIAID has supported and will continue to support a comprehensive and robust portfolio of basic and applied research in order to facilitate the milestone-driven development of vaccines, therapeutics, and diagnostics for NIAID Category A, B, and C Priority Pathogens. This research has included investigator-initiated basic research, Small Business Innovation Research (SBIR) grants, and solicited grants and contracts for applied research and early product development for a variety of countermeasures against NIAID priority pathogens, including the microbes that cause anthrax, smallpox, botulism, and the viral hemorrhagic fevers. Recently, NIAID began focusing on new efforts for the development of broad-spectrum platforms and technologies for next-generation therapeutic agents directed toward biodefense threats and agents of public health concern.

Within its Biodefense and Emerging Infectious Diseases research program, NIAID has built and maintains a comprehensive infrastructure to respond rapidly to newly emerging microbial threats such as extensively drug-resistant tuberculosis and the novel 2009 H1N1 influenza. For example, NIAID has built a national network of Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs), which support research focused on countering threats from bioterror agents and emerging infectious diseases and provide core facilities for NIAID biodefense researchers in the region. The network of RCEs is complemented by the NIAID National and Regional Biocontainment Laboratories, which also will be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism or infectious disease emergency. In addtion, NIAID provides a broad array of pre-clinical and clinical research resources and services to researchers in academia and industry designed to facilitate the movement of candidate medical countermeasures through early development.

NIAID anticipates that candidate products successfully developed through its biodefense and emerging infectious diseases research program will transition to BARDA for late-stage advanced product development and future acquisition under Project BioShield.

With regard to funds provided by BARDA to NIAID through interagency agreements in FY 2007 through FY 2009, NIAID has used these funds to support a variety of development activities for medical countermeasures for biological threats, including pandemic influenza, nuclear/radiological threats, and chemical threats.

Mr. Bonner: What progress has been made in the basic development of countermeasures?

Dr. Collins: NIAID supports a comprehensive and robust portfolio of basic and applied research in order to facilitate the milestone-driven development of medical countermeasures—vaccines, therapeutics, and diagnostics—for NIAID Category A, B, and C Priority Pathogens. Examples of these candidate medical countermeasures include:

- Smallpox therapeutics: NIAID has supported and continues to support the development of the antiviral drug, ST-246. A Phase II/III clinical trial was recently completed.
- Smallpox vaccine: NIAID supported the development of Modified vaccine Ankara (MVA) vaccine, which was recently transitioned to BARDA. NIAID supported Phase III clinical trials.
- Anthrax vaccine: NIAID supported the development of recombinant protective antigen (rPA) vaccine, which has now been transitioned to BARDA. NIAID is supporting vaccine enhancement activities for Anthrax Vaccine Adsorbed (AVA).
- Botulism monoclonal antibodies: NIAID is supporting the development of therapeutic antibodies that are entering Phase I clinical testing.
- Plague antibiotics: NIAID supported the development of a plague nonhuman primate model which allowed the completion of studies of three licensed antibiotics. Data on the antibiotic ciprofloxacin for treatment of plague has been submitted to the Food and Drug Administration.
- Ebola/Marburg viruses: NIAID is supporting the development of vaccine candidates and therapeutics against Ebola and Marburg viruses.

Mr. Bonner: if funds been redistributed to other areas of research?

Dr. Collins: NIAID has not redistributed appropriated funds from its allocation for biodefense and emerging infectious diseases to other areas of research. Nor has NIAID redistributed funds transferred from BARDA through interagency agreements for biodefense research and development activities to other areas of research.

Mr. Bonner: What means has NIH used to prioritize and award funds for biodefense and medical countermeasure research?

Dr. Collins: NIAID's biodefense research is guided by the priorities set out in its Biodefense Research Agendas and its Strategic Plan for Biodefense Research NIAID also coordinates with the Department of Health and Human Services (HHS) Public

Health Emergency Medical Countermeasures Enterprise (PHEMCE) , which includes partners with BARDA, CDC, FDA, and the Departments of Defense, Homeland Security, and Veterans Affairs.

EPSCOR

Mr. Bonner: Director Collins, Alabama is blessed to be home to the University of Alabama Birmingham, a first class medical school and research university. UAB's expertise in a broad variety of medical research areas makes it a center for innovation and it also means UAB has access to millions of dollars annually in NIH grants.

This is great, except that it means Alabama's other universities cannot take advantage of another potentially promising program, the Experimental Program to Stimulate Competitive Research, or EPSCOR. EPSCOR grants from NIH would allow UAB and other Alabama universities like the University of South Alabama in Mobile to work together to do the innovative and groundbreaking medical research everyone on this subcommittee wants to see pursued.

- The EPSCOR program at NIH is subject to a limit which denies funding to states which receive above a certain amount of overall NIH funding. UAB's NIH grants put Alabama over that limit.

- EPSCOR programs at other agencies, like the Department of Defense, the Department of Energy, the National Science Foundation, and others, do not use similar limits in awarding their grants.

Why does the NIH impose this limit, when other agencies do not?

Dr. Collins: Both the NIH Institutional Development Award (IDeA) Program and the NSF Experimental Program to Stimulate Competitive Research (EPSCOR) determine eligibility based on funding received by each state respectively. IDeA eligibility is based on a five-year average of NIH funding. States are eligible for the IDeA Program if the average NIH support is less than $120 million or the application success rate is less than 20 percent. NSF EPSCOR bases its eligibility on a three-year average of NSF support. States are eligible if their funding level is less than 0.75 percent of the total NSF funding. Alabama meets the EPSCOR eligibility criteria at NSF but its level of NIH support exceeds the NIH criteria for participating in the IDeA Program. Other federal agencies with EPSCOR or EPSCOR-like programs base eligibility either on the NSF eligible list or have their own eligibility criteria.

PEDIATRIC CANCER

Mr. Cole: Director Collins, as you know, about 2,300 children die of cancer each year. Cancer is the number one kills more children than asthma, cystic fibrosis, AIDS, and diabetes combined. Public Law 110-285, the Caroline Pryce Walker Conquer Childhood Cancer Act, was passed unanimously by the House and Senate. We all understand fiscal constraints, so please understand that this statement and the following questions come with that knowledge and consideration. It's been said that we are judged by those we help who cannot help themselves. These children cannot take action on their own therefore we elected and appointed officials must take action. So there is the human element of this -the prevention of the pain and suffering through identifying cures for cancer- but there is also a very real fiscal benefit to such funding. The funding generated through the 2,300 lives saved each year, lives of children who turn into productive citizens.

The Caroline Pryce Walker Conquer Childhood Cancer Act, authorized $150 million over five years to increase funding for pediatric cancer trials to address pediatric cancer research.

Would you please inform me if you take into consideration this law when planning future funding for cancer research?

Dr. Collins: The Caroline Pryce Walker Conquer Childhood Cancer Act sent a strong message from the Congress that all that can be done to help children and families who are affected by pediatric cancer must be done. We at the NIH fully agree with this message and are working aggressively to incorporate the spirit of the law into our future plans. We are fully committed to meeting and exceeding the directives in the Act through a robust research effort led by the National Cancer Institute (NCI). The NCI has identified pediatric cancer as one of its highest priorities and has developed an ambitious research strategy designed to bring the most promising new technologies and ideas to the efforts of developing effective therapies and other interventions to help children with cancer, including research on the special issues associated with surviving childhood cancer.

Mr. Cole: Further, in a recent letter (attached to brief) to one of my colleagues from OMB Director Orszag, it is indicated that NIH will provide $215 million for the conditions and needs of children with cancer in FY10. However, in a document recently distributed by NCI, only $196.3 million will be provided for such research.

Can you provide me with some clarity as to how much funding will actually go to pediatric cancer research this year and what you anticipate out-year funding for that research to be?

Dr. Collins: NIH has not set its tracking system on disease spending to be able to capture estimates for childhood cancers or pediatric cancer research funding across all of NIH. However, these estimates are available for research funded by NCI. The

estimated funding level in Director Orszag's letter reflects the NCI-projected FY 2010 funding level for pediatric research (approximately $215 million), which is a broader research category than childhood cancer alone, and includes research related to child health, childhood cancers, birth defects, multiple sclerosis, etc. In FY 2011, NCI expects to fund pediatric research at $223.7 million. NCI also projects funding in the category "childhood cancer research", which is a subset of pediatric research and includes only childhood cancer research (such as childhood leukemia and neuroblastoma). The National Cancer Institute (NCI) estimates it will spend $196.3 million in FY 2010 and $202.7 million in FY 2011 on childhood cancer research. This is the funding level that was provided in the recent NCI document. The key difference between these two categories of research is pediatric research is a broader category that includes research related to child health in general, whereas childhood cancer specifically deals with cancers affecting children.

NCI's Pediatric Research and Childhood Cancer Funding, 2007 – 2010 (dollars in millions)

Year	2007	2008	2009	2010 (estimate)
Pediatric Research	243.2	235.4	240.8	215.0
Childhood Cancer	172.7	189.7	192.9	196.3

IOM CANCER STUDY

Mr. Cole: We know that research undertaken through clinical trials has been instrumental in the advancement of treating and preventing cancer. The Federal Government had the foresight to create the Clinical Trials Cooperative Group (background info on the group is below) in the 1950s and is now considered a primary method for identifying and curing pediatric cancer and early-stage cancers in adults.

On April 15, 2010 the Institute of Medicine (IOM) issued a report, "A National Cancer Clinical Trial for the 21st Century," that states "...many stakeholders have expressed concerns that the program is falling short of its potential to conduct the timely, large-scale, innovative clinical trials needed to improve patient care." The report identifies the cooperative group clinical trials are an essential component of a robust cancer research program. And the report makes recommendations to improve efficiency of the trials process. Among those findings the report indicates that there is severe inadequacy of NCI funding to support clinical trials.

Given these findings do you agree that this is a good opportunity to begin to appropriately support trials, starting with pediatric trials and using the authorized funds under the Conquer Childhood Cancer Act to increase the current per case reimbursement rates from $2000 to say $5000?

In addition, The IOM report contained a short history called the "Overview of Creation of Children's Oncology Group" by Dr. Sharon Murphy (page 149). In it she describes the challenges of bringing the several sectors of research, government, and industry together to successfully coordinate pediatric cancer research. One sentence stands out:

"This process of working with industry was inherently challenging, because the pharmaceutical industry had relatively little interest in developing and licensing drugs for childhood cancers because of the small market."

I raise this point because the sentence illustrates the task we in Congress have to ensure that proper attention is paid to those who cannot advocate for themselves. In this case it is the children afflicted with cancer and their families. The Conquer Childhood Cancer act was Congress' acknowledgement that there is a disparity between adult cancer research and childhood cancer research.

Dr. Collins: Recognizing the changing understanding of the biology of cancer and the critical need to incorporate this into clinical trials, the NCI requested that the Institute of Medicine (IOM) assess the current state of cancer clinical trials review the NCI Cooperative Group Clinical Trials Program and provide recommendations for improvement. The IOM report, entitled, "A National Cancer Clinical Trial for the 21st Century," recognized the work of NCI's Operational Efficiency Working Group and noted that this group's recommendations had similar goals to those described in the IOM report.

Specifically, the IOM report validated the importance of the Cooperative Group Clinical Trials program as an essential component of a robust cancer research program. This is especially true in the childhood cancer setting, as the pediatric clinical trials program supported by NCI is optimally placed to prioritize the most compelling research questions for clinical evaluation in children with cancer and then to conduct these clinical trials in a clinically and scientifically sound manner. NCI is increasing per case reimbursement rates from $2000 to $5000 for Cooperative Group phase 2 studies, and additional funding beyond the standard $2000 is being provided for selected phase 3 trials based on their complexity.

Mr. Cole: I would like to hear your thoughts about, and your Institute's commitment to the long term funding for pediatric cancer research.

Dr. Collins: NIH is committed to the wise investment of funds in opportunities that will lead to a reduction in the cancer death rate for children. We share your hope for a future in which no parent will endure the grief of losing a child to cancer. The National Cancer Institute (NCI), which leads our pediatric cancer research effort, supports a comprehensive pediatric cancer research program that extends from basic biology research and preclinical testing to identifying new therapeutic targets, as well as an extensive clinical trials program. Pediatric research in the laboratory includes studying the genetic and other mechanisms related to tumor formation and metastasis.

For example, NCI's Childhood Cancer Therapeutically Applicable Research to Generate Effective Treatment (TARGET) Initiative applies high-throughput genomic analysis methods to identify novel therapeutic targets for childhood cancers. The Pediatric Preclinical Testing Program (PPTP), an NCI-supported research contract begun in 2005, generates preclinical data that informs decisions about prioritizing new agents and combinations of agents for study against specific types of childhood cancers. NCI supports several consortia of institutions to perform clinical trials of novel agents and treatments, thereby allowing preclinical discoveries to rapidly move to the clinic and be studied by experienced pediatric oncology investigators. The Children's Oncology Group (COG) develops and coordinates cancer clinical trials available at over 200 U.S. and international institutions. The clinical trials conducted by COG, NCI, and other NCI-supported consortia play key roles in evaluating new treatment approaches.

An important feature of the NCI research program is its work addressing the special issues faced by childhood cancer survivors. Initiated in 1993, the NCI-funded Childhood Cancer Survivor Study (CCSS) is a collaboration of 27 institutions which seeks to increase knowledge of the late effects of childhood cancer treatment. With an original cohort of 20,000 childhood cancer survivors diagnosed between 1970 and 1986, the CCSS began recruiting an additional 14,000 individuals treated for cancer as children between 1987 and 1999 to allow for the evaluation of late effects of newer types of cancer treatment.

More than 12 million cancer survivors are alive in the United States, at least 270,000 of who were originally diagnosed when they were under the age of 21. Although there has been some increase in the incidence of all forms of invasive pediatric cancer over the past 20 years, from 11.5 cases per 100,000 children in 1975 to 14.8 per 100,000 children in 2004, death rates have declined dramatically and five-year survival rates have increased for most childhood cancers during this same time. Advances in cancer treatment have meant that today, over 80 percent of children diagnosed with cancer are alive at least five years after diagnosis, compared to about 58 percent in the 1970s. These advances have averted an estimated 38,000 childhood cancer deaths in the U.S. between 1974 and 2006. This improvement in survival rates can be attributed to the large proportion of patients participating in clinical trials and to significant advances in treatment, resulting in a cure or long-term remission for the majority of children with cancer.

It is important to note that the basic research on cancer mechanisms done by NCI, as well as most of the other Institutes and Centers at NIH, also contributes heavily to the understanding of all cancer mechanisms including pediatric cancers. That research and the dollars spent on basic cancer mechanisms are not reflected in the above mentioned programs that are specific to pediatric cancers. However, the importance of broad research on molecular mechanisms of cancer cannot be overstated as they inevitably funnel seminal basic research discoveries into specific studies and clinical trials in pediatric as well as other cancers.

WITNESSES

INDEX

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