

**AGRICULTURE, RURAL DEVELOPMENT, FOOD AND  
DRUG ADMINISTRATION, AND RELATED AGEN-  
CIES APPROPRIATIONS FOR FISCAL YEAR 2012**

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**HEARINGS**

BEFORE A

SUBCOMMITTEE OF THE  
**COMMITTEE ON APPROPRIATIONS**  
**UNITED STATES SENATE**  
ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

ON

**H.R. 2112**

AN ACT MAKING APPROPRIATIONS FOR AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES PROGRAMS FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 2012, AND FOR OTHER PURPOSES

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**Department of Agriculture  
Department of Health and Human Services: Food and Drug  
Administration  
Nondepartmental Witnesses**

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**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2012**

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**THURSDAY, MARCH 10, 2011**

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

The subcommittee met at 2:05 p.m., in room SD-124, Dirksen Senate Office Building, Hon. Herb Kohl (chairman) presiding.

Present: Senators Kohl, Nelson, Pryor, Brown, Blunt, Cochran, Collins, Moran, and Hoeven.

**DEPARTMENT OF AGRICULTURE**

**OFFICE OF THE SECRETARY**

**STATEMENT OF HON. TOM VILSACK, SECRETARY**

**ACCOMPANIED BY:**

**KATHLEEN MERRIGAN, DEPUTY SECRETARY**

**JOSEPH GLAUBER, CHIEF ECONOMIST**

**MICHAEL YOUNG, DIRECTOR, OFFICE OF BUDGET AND PROGRAM  
ANALYSIS**

**OPENING STATEMENT OF SENATOR HERB KOHL**

Senator KOHL. The subcommittee will come to order.

This is our first hearing on the President's fiscal year 2012 budget.

First, I want to welcome our new ranking member, Senator Roy Blunt.

I'd also like to recognize the new members of this subcommittee, Senator Brown, Senator Moran, and Senator Hoeven. We look forward to working with each and every one of the new members of this subcommittee.

And, Mr. Secretary, it's very good to see you again.

I also want to welcome Deputy Secretary Merrigan and U.S. Department of Agriculture (USDA) Chief Economist Joseph Glauber. Also, we have with us today Mr. Mike Young, who is the new USDA Budget Director.

Mr. Secretary, it's obvious that we are faced with tremendous challenges. The Nation is still struggling through economic recovery, while Government spending is being reduced by a big margin.

Here at home, we feel the economic throes of unrest in distant parts of the world as oil supply lines are being shaken and our cost

of energy rises hugely from 1 week to the next. On top of all this, the Federal Government is still operating on a continuing resolution for the current fiscal year. These are the realities.

We all recognize that Government exists for a reason and there are some things that Government must do because it is the job of Government to do. Our food must be safe, our people must not go hungry, our farm and rural economies must remain strong, and we must never lose sight of the impact they have on our national economy. On the other hand, we are going to have to let go of some of the things that, while popular, are not essential. These are indeed days of hard decisions.

The President's budget makes a good start in that direction. Some programs are cut and some are eliminated. At the same time, new initiatives are brought forward and the President is requesting increases in some programs. Our job is to review all of these priorities and make the hard decisions.

The American people rely on USDA every day. The American people also rely on us to make sure their tax dollars are spent wisely. As Government spending declines, the need for wisdom in setting priorities has never been more acute. Mr. Secretary, we will look forward to your guidance on that very important task.

As we continue, I'd like to take note that we have a vote scheduled for 3 o'clock, and so, if we all are brief in our comments, we'll have an opportunity to ask the Secretary the relevant questions.

Mr. Secretary.

#### SUMMARY STATEMENT OF SECRETARY TOM VILSACK

Secretary VILSACK. Mr. Chairman, thank you very much. I appreciate the opportunity to be with you this afternoon.

I will be very short. We have a written statement we'd ask to be part of the record. I'd just simply make two points.

First, we recognize the responsibility to reduce our budget. We started that process last year. We continue it with the budget we propose to you this year, both in the discretionary and on the mandatory side. The reality is that there has to be shared sacrifice, as well as shared opportunity.

The second point I would make is that, in addition to cutting our way to a more balanced fiscal approach, we also have to grow the economy. We have to be focused on jobs. That is certainly true in rural America, where we have had, historically, a much higher unemployment rate than in other parts of the country. Interestingly enough, as a result of the strong agricultural economy, we're seeing the unemployment rate coming down in rural America at a faster rate than the rest of the country. We'll obviously want to continue the momentum.

So, we do indeed focus on an effort to not only reduce our spending, but also to focus it in a way that will advance, strategically, a growth agenda, as well in rural America, and continue the momentum.

#### PREPARED STATEMENT

I understand that you've got a vote. I understand that you really need to have questions directed to us. With that, I will simply conclude and look forward to your questions.

[The statement follows:]

PREPARED STATEMENT OF SECRETARY TOM VILSACK

Mr. Chairman and distinguished members of this subcommittee, I appreciate the opportunity to appear before you as Secretary of Agriculture to discuss the administration's priorities for the U.S. Department of Agriculture (USDA) and provide you an overview of the President's fiscal year 2012 budget. I am joined today by Deputy Secretary Kathleen Merrigan, Joseph Glauber, USDA's Chief Economist, and Michael Young, USDA's budget officer.

In his State of the Union Address, the President laid out some of the challenges America faces moving forward as we compete with nations across the globe to win the future. We need to be a Nation that makes, creates, and innovates so that we can expand the middle class and ensure that we pass along to our children the types of freedoms, opportunities, and experiences that we have enjoyed. We also need to take some serious steps to reduce the deficit and reform Government so that it's leaner and smarter for the 21st century.

The fiscal year 2012 budget we are proposing reflects the difficult choices we need to make to reduce the deficit while supporting targeted investments that are critical to long-term economic growth and job creation. To afford the strategic investments we need to grow the economy in the long term while also tackling the deficit, this budget makes difficult cuts to programs the President and I care about. It also reflects savings from a number of efficiency improvements and other actions to streamline and reduce our administrative costs. It looks to properly manage deficit reduction while preserving the values that matter to Americans.

In total, the budget we are proposing before this subcommittee is \$130 billion, a reduction of \$3 billion less than the fiscal year 2011 annualized continuing resolution. For discretionary programs, our budget proposes \$18.8 billion, a reduction of \$1.3 billion less than the fiscal year 2011 level. These decreases are achieved through reductions and terminations in a wide range of programs as well as proposals to achieve savings through streamlining our operations. These actions will allow us to focus limited resources on programs where we can achieve the greatest impact.

Further, we are proposing legislative changes to target reductions in farm program payments, which would save \$2.5 billion over 10 years, while only affecting 2 percent of participants. The savings would come in addition to savings we have achieved through administrative improvements that reduced the error rate in farm program payments from 2 percent to less than 0.1 percent as well as a partnership with the Internal Revenue Service to eliminate improper payments to wealthy individuals who exceed income eligibility criteria. In addition, legislation will be proposed to reduce premiums for the catastrophic coverage option under the crop insurance program providing a savings to taxpayers of \$1.8 billion over 10 years.

These and other reductions must be made if we are serious about deficit reduction and being able to support the critical investments we need to make to secure our future.

At USDA, we haven't waited to begin reducing our expenditures. Last year, we saved \$6 billion through the negotiation of a new agreement for crop insurance, \$4 billion of which will go to pay down the Federal deficit. Agencies across the Department have looked for ways to reform the way they do business—from reducing the number of visits a farmer has to make to our offices to get conservation services, to saving taxpayer dollars by operating our nutrition assistance programs with historic levels of accuracy.

I would now like to focus on some specific highlights in each of our major goals.

ASSISTING RURAL COMMUNITIES TO CREATE PROSPERITY

Agriculture has generally fared well during the recent economic downturn, with farm income expected to be at almost record levels this year largely due to the productivity and hard work of American farmers and ranchers and growers. Further, agriculture continues to be one of the major sectors of the American economy that has a trade surplus. Our budget preserves a strong farm safety net, including a \$4.7 billion farm credit program, about \$150 million more than the fiscal year 2011 level. As I mentioned earlier, we are also proposing to better target farm payments by reducing the cap on direct payments and reducing over a 3-year period the adjusted gross income eligibility limits. These actions would save \$2.5 billion over 10 years.

Rural America offers many opportunities, but it also faces a number of challenges that have been experienced for decades. Rural Americans earn less than their urban counterparts, and are more likely to live in poverty. More rural Americans are older than the age of 65, they have completed fewer years of school, and more than one-

half of America's rural counties are losing population. In addition, improvements in health status also have not kept pace, and access to doctors and health services has been a key challenge in rural areas.

Within the context of a reduced total funding level, our budget proposes to focus resources on the most effective means to address the long-term challenges facing rural communities and the Nation. A critical element is engaging with public and private partners to revitalize rural communities by expanding economic opportunities and creating jobs for rural residents.

For Rural Development programs, our budget proposes a total program level of roughly \$36 billion supported by \$2.4 billion in budget authority, a reduction of about \$1.6 billion in program level and \$535 million in budget authority. It also reflects the administration's efforts to utilize funding in the most cost-effective manner to achieve our goals.

A number of difficult decisions were made, including a reduction of \$390 million in budget authority from the fiscal year 2011 level in housing programs. The budget eliminates funding for a number of loan and grant programs, including Self-Help Housing grants and low-income housing repair loans. We are also reducing funding for direct single-family housing loans and focusing on maintaining support for single-family housing loan guarantees at a program level of \$24 billion. This level of assistance can be provided with no budget authority by continuing a fee structure that fully supports the subsidy cost of the program. We are also reducing the water and waste loan and grant program by \$62 million in budget authority. Associated with these program reductions, we are reducing administrative funding and staffing levels. These and other actions allow us to focus limited resources on meeting priority investment needs in rural America.

#### *Regional Innovation Initiative*

One of these priority investments is in a new approach we have developed to ensure USDA supports rural communities who choose to engage in regional economic strategies. This approach recognizes that attempting to address the challenges faced by rural communities through a generic approach will not be sufficient. Instead, USDA needs to respond to grassroots local priorities and recognize that each rural region needs a distinctive strategy that reflects its unique strengths, its particular mix of industry clusters, and which integrates its regional economic assets.

In 2010, to support rural communities' efforts to collaborate regionally, USDA used the Rural Business Opportunity Grant program to provide funding to seven identified regions to support plans focused on supporting job creation, local, or regional food systems, renewable energy, capitalizing on new broadband deployment, and the utilization of natural resources to promote economic development through regional planning among Federal, State, local, and private entities. Funding has been provided to multijurisdictional regions in California, Iowa, North Dakota, Oregon, South Carolina, Vermont, and Washington to develop regional plans to enhance economic opportunities. USDA is working department-wide to determine how it can support the priorities of the people in the region. USDA is also working with other Federal partners to ensure that these rural regions have access to other Federal programs that support their regional strategies. By creating a regional focus and increasing collaboration with other Federal agencies, resources can be leveraged to create greater wealth, improve quality of life, and sustain and grow the regional economy.

For 2012, USDA proposes a Regional Innovation Initiative that works through existing programs to fund regional pilot projects, strategic planning activities, and other investments to improve rural economies on a regional basis. USDA would target up to 5 percent of the funding within 10 existing programs, approximately \$171 million in loans and grants, and allocate these funds competitively among regional pilot projects tailored to local needs and opportunities. The approach will support projects that are more viable over a broader region than scattered projects that serve only a limited area. It will also help build the identity of regions, which could make the region more attractive for new business development, and provide greater incentives for residents to remain within their home area.

The fiscal year 2012 budget specifically provides an increase of \$5 million for the Rural Business Opportunity Grant program to foster regional collaboration that encourages regions to engage in strategic regional economic planning that identifies the needs of a defined rural region. In addition, an increase of \$2.1 million is included for the Rural Community Development Initiative to provide technical assistance to communities to develop housing or community facilities projects.



*Facilitating the Development of Renewable Energy*

A major administration priority is continuing to make investments in building a green energy economy. Last year, the President laid out his strategy to advance the development and commercialization of a biofuels industry. At the center of this vision is an effort to increase domestic production and use of renewable energy. Advancing biomass and biofuel production that holds the potential to create green jobs is one of the many ways the Obama administration is working to rebuild and revitalize rural America. By producing renewable energy—especially biofuels—America’s farmers, ranchers, and rural communities have incredible potential to help ensure our Nation’s energy security, environmental security, and economic security. Through investments in energy efficiency and renewable energy sources, farms and rural small businesses across the country can reduce their energy consumption and energy expenses. In 2009 and 2010, USDA has helped nearly 4,000 rural small businesses, farmers, and ranchers save energy and improve their bottom line by installing renewable energy systems and energy efficiency solutions that have produced or saved a projected 4.3 billion in kWh—enough energy to power 390,000 American homes for a year.

In 2012, USDA plans to invest more than \$900 million in discretionary and mandatory funding to improve the entire supply chain of biofuels and bioenergy, from research and development, to production and commercialization. In addition, the budget includes \$6.1 billion for electric loans, which will be used to support renewable energy and the development of clean-burning low-emission fossil fuel facilities to support renewable energy deployment and clean energy technology.

*Promising Market Opportunities*

Developing and supporting market opportunities and outlets for agricultural producers helps to promote jobs and prosperity in rural America. Over the past year, we have supported efforts to build and strengthen regional and local food systems through the “Know Your Farmer, Know Your Food” efforts. Our goal is to build a link between local production and local consumption, which is particularly beneficial to small- and mid-sized farmers.

In fiscal year 2012, USDA will continue to support efforts to expand promising market opportunities with \$9.9 million in funding for the National Organic Program, which will be used to strengthen oversight and enforcement and \$7.7 million for transportation and market development activities that will stimulate development of regional food hubs and marketing outlets for locally and regionally grown food.

Furthermore, USDA, working together with the Departments of Health and Human Services and the Treasury will implement the Healthy Food Financing Initiative (HFFI) to provide incentives for food entrepreneurs to expand the availability of healthy foods by bringing grocery stores, small retailers, and farmers markets selling healthy foods to underserved communities. HFFI will make available more than \$400 million in financial and technical assistance to community development financial institutions, other nonprofits, public agencies, and businesses with sound strategies for addressing the healthy food needs of communities. For USDA, the budget requests \$35 million to support local and regional efforts to increase access to healthy food, particularly for the development of grocery stores and other healthy food retailers in urban and rural food deserts and other underserved areas. In addition, USDA will make other funds available by encouraging and rewarding relevant grant and loan applications through existing Rural Development and Agricultural Marketing Service programs.

*Broadband*

In his State of the Union Address, President Obama established a goal to deploy the next generation of high-speed wireless coverage to 98 percent of all Americans. In the last one-and-a-half years, with funding from the American Recovery and Reinvestment Act (ARRA) we have done more to bridge the digital divide for rural Americans than many ever thought possible. ARRA funding will enable around 7 million rural Americans to connect to 1 of 285 last-mile, 12 middle-mile, or four satellite projects funded by USDA. On top of that, more than 360,000 businesses and 30,000 community service organizations such as hospitals, schools, and public safety agencies will be connected to a high-speed digital future. USDA will continue to build on the success of funding provided through ARRA by making loans and grants under the authorities provided by the farm bill. Our budget continues to provide support for these important efforts with \$17.9 million for grants to support local broadband access in rural communities and funding for loans with balances available from prior-year appropriations.

### *Trade Expansion*

Expanding access to global markets makes a critical contribution to our efforts to enhance rural prosperity by providing opportunities for increased sales and higher incomes. During the past year, we have worked diligently to remove trade barriers and open new markets. Through our efforts, we were able to regain access for our poultry exports to Russia, after Russia introduced a ban on the use of chlorine washes in the processing of poultry. Similarly, we worked to expand market access for pork in Russia and China by addressing residue and disease issues, and we continue to engage China on reopening that market for our beef exports. Also noteworthy, we entered into a memorandum of understanding with China that addresses quality and sanitary and phytosanitary policy issues that will help to facilitate our soybean exports. This is a very significant step as China is now our largest overseas market for soybeans, and the significant growth we have experienced in that market—in soybeans and many other products—has helped China to emerge as our largest agricultural export market.

Our trade promotion activities support the National Export Initiative (NEI), a Governmentwide effort to double U.S. exports over the next 5 years in order to spur economic growth and employment opportunities. Every \$1 billion worth of agricultural exports supports an estimated 8,000 jobs, so we know that when we succeed in expanding markets we are creating real benefits for our workforce. To bolster these efforts, the budget proposes an increase of \$20 million for the Foreign Agricultural Service to support an expansion in trade monitoring and enforcement activities, exporter assistance and education efforts, support for State-organized trade missions, and in-country market access and promotion activities.

### *Ensuring Private Working Lands Are Conserved, Restored, and Made More Resilient to Climate Change, While Enhancing Our Water Resources*

USDA continues to be a major partner in advancing the administration's conservation and environmental agenda through support of the conservation partnership and the strategic targeting of funding to high-priority regional ecosystems. The budget request will ensure that the conservation partnership remains strong among Federal agencies, State and local governments, tribes, industry, and farmers. This broad partnership has proven to be a resilient and effective mechanism for meeting the administration's water policy goals and helping protect the Nation's 1.3 billion acres of farm, ranch, and private forestlands.

The budget requests nearly \$900 million in discretionary funding for conservation activities, primarily technical assistance that provides comprehensive conservation planning for the Nation's farmers, ranchers, and private forest landowners. This reflects a reduction of \$168 million and related staff-years for the elimination of the watershed operations and rehabilitation programs, conservation operations earmarks, and the Resource Conservation and Development program.

The fiscal year 2012 budget advances resource protection by strategically targeting funding to high-priority regional ecosystems and initiatives. This includes \$15 million to implement the Strategic Watershed Action Teams Initiative, which will enhance targeted technical assistance in priority watersheds for a period of 3–5 years with the goal of reaching 100 percent of the landowner base in each watershed eligible for farm bill conservation program assistance. The goal of this initiative is to hasten environmental improvement while keeping production agriculture competitive and profitable.

To improve the delivery of conservation technical assistance, which is a field staff-based activity, the budget includes \$11.3 million to fund the Conservation Delivery Streamlining Initiative. This initiative will develop new business processes designed to simplify the planning process and maximize the amount of time USDA technicians spend in the field helping farmers. These funds will improve how we deliver conservation planning and financial assistance and help farmers with practice installation.

Finally, the budget includes an increase of \$7 million for the Conservation Effects Assessment Project, to enhance the scientific understanding of the environmental effects of conservation practices on agricultural landscapes. This knowledge will help us improve the design and implementation of conservation programs.

The fiscal year 2012 budget also includes \$5.8 billion in mandatory funding to support cumulative enrollment of more than 302 million acres in farm bill conservation programs, an increase of nearly 8 percent more than fiscal year 2011, for conservation programs authorized in the 2008 farm bill, such as the Wetlands Reserve Program, Environmental Quality Incentives Program, and the Conservation Reserve Program.

PROMOTE AGRICULTURAL PRODUCTION AND BIOTECHNOLOGY EXPORTS AS AMERICA  
WORKS TO INCREASE FOOD SECURITY

USDA works to improve global food security through a wide variety of activities, such as providing food and technical assistance that supports the development of sustainable agricultural systems in developing countries, by facilitating the adoption of biotechnology and other emergent technologies that increase agricultural production and food availability, and by working to advance internationally accepted, science-based regulations that facilitate trade. These efforts are important because more than 1 billion people worldwide face hunger and malnutrition every day, and we know that failing agricultural systems and food shortages fuel political instability and undermine our national security interests.

USDA is an active partner in the administration's global food security initiative—Feed the Future—and we have been working closely with the State Department, the U.S. Agency for International Development (USAID), and others to further its objectives. As an implementing partner, USDA can offer expertise in basic and applied research that benefits both the United States and developing countries; in-country capacity building and technical assistance; and market information and economic analysis. For example, during the past year, USDA has worked with USAID to develop the Norman Borlaug Commemorative Research Initiative, a mechanism designed to increase cooperation and collaboration between our two agencies in managing research strategies and their implementation. Through this mechanism, we will collaborate on targeted, high-impact research priorities, such as wheat rust, legume productivity, livestock diseases, mycotoxins, and human nutrition, which can have far-reaching benefits to farmers worldwide.

An important means to assist developing countries to enhance their agricultural capacity is by providing training and collaborative research opportunities in the United States, where participants can improve their knowledge and skills. The budget provides increased funding for the Cochran and Borlaug Fellowship programs, which bring foreign agricultural researchers, policy officials, and other specialists to the United States for training in a wide variety of fields. Under our proposal, as many as 600 individuals will be able to participate in these programs and bring this knowledge home to benefit their respective countries.

Foreign food assistance programs remain a core component of our efforts to enhance global food security. The fiscal year 2012 budget includes more than \$2 billion of funding for both emergency and nonemergency international food assistance programs carried out by USDA and USAID. Although funding for the McGovern-Dole International Food for Education and Child Nutrition Program is reduced by \$9 million, the program will assist as many as 5 million women and children during 2012.

As the world population grows and the demand for food with it, we must look to new technologies for increasing production, including biotechnology. Biotechnology can expand the options available to agricultural producers seeking solutions to a variety of challenges, including climate change. However, prudent steps must be taken to ensure that biotech products are safely introduced and controlled in commerce. For 2012, the budget includes increased funding to strengthen USDA's science-based regulatory system and ensure that we can provide timely, sufficient review of the expanding volume and complexity of biotechnology applications. During the past fiscal year, USDA continued to see an increase in workload due to this expanding industry. Notably, USDA received 44 percent more requests for field testing of genetically engineered plants than were received in fiscal year 2009.

ENSURING THAT ALL OF AMERICA'S CHILDREN HAVE ACCESS TO SAFE, NUTRITIOUS, AND  
BALANCED MEALS

*Nutrition Assistance*

The budget fully funds the expected requirements for the Department's three major nutrition assistance programs—the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the National School Lunch Program, and the Supplemental Nutrition Assistance Program (SNAP).

National School Lunch Program participation is estimated to reach a record-level again in 2012, 32.5 million children each school day, up from about 31.6 million a day in 2010. The budget proposes an increase of \$9 million to ensure USDA makes progress to decrease the prevalence of obesity among children and adolescents, and to improve the quality of diets. The increase will allow USDA to continue implementing the scientific, evidence-based nutrition guidance and promotion of the 2010 update of the Dietary Guidelines for Americans.

The budget includes \$7.4 billion for WIC, which will support the estimated average monthly participation of 9.6 million in 2012, an increase from an estimated 9.3 million participants in 2011. The request is \$138 million more than the 2011

annualized continuing resolution. This includes an increase for the breastfeeding peer counseling program and a doubling of the breastfeeding program performance bonus funding. WIC State nutrition services and administrative activities are funded at a level sufficient to ensure effective program operations along with increased emphasis on information technology (IT) and electronic benefits transfer (EBT).

Participation in SNAP is estimated to average about 45 million participants per month in 2011, and is projected to fall slightly in 2012. The budget includes more than \$85 billion, including ARRA funding, to fund all expected costs. Legislation will be proposed to extend the ARRA provision that waives time limits for able-bodied adults without dependents for an additional fiscal year. In total, this change would add about \$92 million to recipient benefits and SNAP program costs in 2012. In addition, the fiscal year 2012 budget proposes to maintain the increase for SNAP benefits authorized by ARRA for 5 months, increasing outlays in 2014 by \$3.3 billion.

#### *Food Safety*

The budget includes \$1 billion for the Food Safety and Inspection Service, a reduction of about \$7 million less than 2011. The requested level is adequate to fully fund inspection activities and including an increase of \$27 million to improve our capability of identifying and addressing food safety hazards and preventing foodborne illness. These increases are more than offset by reductions due to streamlining agency operations, reducing lab expenses, and recognizing that implementation of a catfish inspection program will not occur in 2012.

#### *Minimizing the Impact of Major Animal and Plant Diseases and Pests*

To protect agricultural health by minimizing major diseases and pests of food crops and livestock, the budget includes \$837 million, a reduction of \$76 million, in appropriated funds for the Animal and Plant Health Inspection Service (APHIS). We have taken a close look at the APHIS budget and have proposed a number of program reductions and redirections to ensure that scarce resources are being used prudently. The budget achieves savings through a variety of means. It includes decreases for activities where eradication campaigns have been successful, such as cotton pests, pseudorabies, and screwworm, and for pests and diseases where eradication is not likely, such as tropical bont tick. Savings are also possible in the avian health program without affecting overall performance. Further, the budget achieves other savings by acknowledging the role of the producer to engage in best management practices to reduce certain diseases, such as John's disease. These savings allow us to propose increases for selected pests, including the light brown apple moth and the European grapevine moth.

### RESEARCH

Scientific research is essential for our prosperity, health, environment, and our quality of life. By investing in the building blocks of American innovation, we will help ensure that our economy is given all the necessary tools for new breakthroughs, new discoveries and the development of new industries. While progress will not come immediately, our investments today will be a catalyst which leads to answers to problems of national importance, including developing alternative energy sources, improving the nutrition and health of America's children, and developing solutions to the most urgent environmental problems.

The fiscal year 2012 budget requests approximately \$1.2 billion in discretionary funding for the National Institute of Food and Agriculture (NIFA), a decrease of \$141 million from 2011. The budget eliminates \$141 million in congressional earmarks as well as makes selective reductions in ongoing programs, including a reduction of 5 percent in formula funding for 1862 Land Grant Institutions and the elimination of the animal health and disease formula program. The budget continues to move toward the use of competitive grants to generate the solutions to the Nation's most critical problems. A major element in NIFA's research budget is an increase of \$62 million for the Agriculture and Food Research Initiative (AFRI)—the premier competitive, peer-reviewed research program for fundamental and applied sciences in agriculture. This increase, which brings the total AFRI funding to \$325 million, will focus on sustainable bioenergy, global food security, food safety, human nutrition and obesity prevention, and global climate change, while still supporting foundational research.

The fiscal year 2012 budget for the Agricultural Research Service is approximately \$1.14 billion, a net decrease of \$42 million. This reduction is achieved through the elimination of congressional earmarks and other lower-priority projects that total about \$101 million. These reductions help fund program increases totaling approximately \$59 million for high-priority research. Major initiatives include improved genetic resources and cultivars leading to better germplasm and varieties

with higher yields, enhanced disease and pest resistance, and resilience to weather extremes such as high temperature and drought. The budget will also fund several initiatives to support research on breeding and germplasm improvement in livestock which will enhance food security and lead to the development of preventive measures to combat diseases and thereby increase production. These initiatives have great potential to help ensure an abundant, safe, and inexpensive supply of food to meet global demand. Additionally, the budget funds research initiatives that will accelerate the development and deployment of dedicated energy feedstocks, thereby reducing dependence on foreign oil and expanding the opportunities for American farmers. Finally, the budget supports projects that focus on food safety, human nutrition, and obesity prevention.

The fiscal year 2012 budget request for the National Agricultural Statistics Service includes an increase of nearly \$12 million in initiatives, which is offset by \$8.3 million in terminations of low-priority programs. This includes the elimination of a land tenure survey largely comprised of farm operators that are accounted for in the Agricultural Resource Management Survey. The fiscal year 2012 budget includes full funding to support the third year of the 2012 Census of Agriculture's 5-year cycle and to improve the data quality of the County Estimates program which is used within the Department to administer crop insurance programs, as well as crop revenue support programs, emergency assistance payments, and the Conservation Reserve Program.

Finally, \$8.4 million is included for initiatives within the Economic Research Service, including an initiative for behavioral economics that will yield information and analysis that enhances decisionmaking on economic and policy issues related to agriculture, food, farming, natural resources, and rural development. These increases are partially offset by a \$4.9 million reduction from lower-priority projects.

#### MANAGEMENT INITIATIVES

To reform USDA so it is leaner, more efficient and ready for the 21st century, we will support efforts to better streamline operations and deliver results—at lower cost—for the American people. The budget reflects the Department's commitment to increasing program delivery effectiveness by implementing management improvements, administrative efficiencies, and IT systems that modernize the USDA workplace.

A significant streamlining and efficiency measure being proposed is a structured buyout of 504 Federal headquarters and related employees—10 percent—of the Farm Service Agency (FSA). This restructuring effort is expected to result in net savings of \$27 million in 2012 and total savings of \$174 million through 2015. In addition, we are proposing a further savings of \$14.4 million in FSA administrative expenses through efficiencies related to advisory contracts, travel expenses, printing and supplies. It is also critical that we continue to invest in modernizing the FSA IT system to provide a secure, modern system capable of supporting Web-based program delivery.

One of the key components for increasing USDA effectiveness is focused on creating a high-performing and diverse workforce across the Department. Through USDA's Cultural Transformation Initiative, the Department and its workforce are being revamped to increase job satisfaction, training opportunities, and career development possibilities. USDA will focus on improving leadership development, labor relations, human resources accountability, and veterans and other special employment programs. These efforts will greatly improve the productivity of the Department, resulting in better service to USDA constituents and more value for American taxpayers. A \$3 million increase is proposed to strengthen our human resources transformation initiatives and veterans hiring efforts.

USDA also strives to improve the efficiency with which it purchases more than \$5 billion in goods and services annually. These acquisitions support USDA program delivery, including food purchases for the nutrition programs and IT purchases in support of business operations. Regardless of what is being purchased, USDA relies upon a workforce of acquisition professionals to efficiently and effectively procure the goods and services needed to ensure continued service delivery by the Department. As part of a Governmentwide initiative pursuant to the President's Memorandum on Government Contracting, USDA is requesting funding of \$6.5 million for training, workforce development activities, and supporting IT systems. Such efforts will greatly improve the workforce's ability to negotiate more favorably priced contracts and manage contract costs more effectively. These improvements will support USDA's actions to implement its acquisition savings plan that includes a projected 7-percent reduction in noncommodity acquisitions in fiscal year 2011, with additional reductions in the out-years.

We are also taking additional steps to address the unfortunate history of civil rights in USDA. As you know, since coming into office, this administration has made great strides in resolving claims of discrimination by reducing the backlog of complaints and by working to settle lawsuits brought against the Department by Black and Native American farmers and ranchers. USDA has worked closely with the Congress to secure the funding necessary to address the *Pigford II* class action lawsuit. The Department has also been working to resolve other discrimination claims such as those being brought by women and Hispanic farmers and ranchers. In fiscal year 2012, we are requesting funding under the FSA to pay the administrative costs of resolving existing civil rights claims, and to provide settlement for discrimination claims filed under the Equal Credit Opportunity Act where the statute of limitation has expired. The Department remains committed to taking these actions as part of our commitment to create a New Era of Civil Rights in USDA.

Ensuring that the Department and its programs are open and transparent is also a key component of the transformation effort. As a result, USDA is proposing to expand the Office of Advocacy and Outreach (OAO), which was established by the 2008 farm bill, to improve service delivery to historically underserved groups and will work to improve the productivity and viability of small, beginning, and socially disadvantaged producers. The outreach efforts led by OAO will help to ensure that all persons eligible to participate in USDA programs will have the opportunity and the information necessary to benefit from the services delivered by the Department.

The President told us that winning the future will require a lot of hard work and sacrifice from everyone. The President's budget reflects sacrifice, but provides the funding to achieve his vision for a strong America. I look forward to working with this subcommittee to help build a foundation for American competitiveness for years to come so that we pass on a stronger America to our children and grandchildren.

I would be pleased to take your questions at this time.

Senator KOHL. All right. We'll begin our questioning. Thank you so much, Mr. Secretary.

#### FOOD SAFETY AND INSPECTION SERVICE FUNDING LEVEL

As you are aware, we're still in negotiations regarding the fiscal year 2011 bills. H.R. 1 proposes an \$88 million cut to the Food Safety and Inspection Service (FSIS). I've been told this proposed cut would seriously limit FSIS's ability to maintain its inspection force. At what point, Mr. Secretary, would budget cuts at fiscal year 2011 result in a furlough of FSIS inspectors? If that is so, do you have a contingency plan?

Secretary VILSACK. Mr. Chairman, we are obviously hopeful that this matter gets resolved without significant reductions in the FSIS budget. As you probably well know, that budget is predominantly personnel. Any significant cut and reduction in that budget would obviously lead to a very difficult set of decisions we would have to make, relative to our workforce. Most of what our workforce does in that area is to provide inspection services to a number of processing facilities. We would be concerned, obviously, about the impact it would have on those processing facilities and on the markets that are impacted and affected by the work that they do.

We have proposed, in the fiscal year 2012 budget, a reallocation within FSIS. I would simply say that the key here is to give the Department sufficient time to manage difficult choices that you all have to make. If you attempt to squeeze, in a relatively short period of time—i.e., a set of months—a solution to a budget problem that has accumulated perhaps over decades, I think you're going to have difficulty, and I think you're going to make it very difficult for us to manage it properly without someone being hurt. This is one area, in particular, that we have concerns about.

Senator KOHL. All right.

## GAO REPORT ON DUPLICATIVE GOVERNMENT PROGRAMS

Mr. Secretary, the Government Accountability Office (GAO) recently released a report on duplicative Government programs, which I'm sure that you are aware. Duplication in food safety efforts across Federal agencies was a major theme in the report. Can you please respond to the findings of the report regarding overlap in food safety activities? Do you believe the current food safety system is adequately serving the American public? And, how do you believe it can be improved?

Secretary VILSACK. Mr. Chairman, we engaged, at the beginning of the administration, in a workstudy group with the Department of Health and Human Services. It has, in a sense, jurisdiction on food safety issues, as you well know. We handle roughly 20 percent of the food needs of this country. The Food and Drug Administration (FDA) handles the other 80 percent.

What we wanted to be able to do, and what I think you accomplished with the food safety legislation passed last year, was to begin to create parallel tracks, for both the FDA and the USDA, focused on a philosophy of prevention rather than reaction. I think that the food safety proposal that you passed is a very good, significant step forward. We are working with the FDA as they begin the process of implementing that. We've provided staff to assist them in rulemaking, and we'll make sure that we parallel as best we can.

We've also, Mr. Chairman, improved our communication between the two Departments so that we're in a position to know what FDA knows and they're in a position to know what we know, so that we do a better job of regulating the safety of the food supply, particularly as it relates to school lunch purchases and the school lunch program, where we had a problem early in the administration. So, I'm confident that we will be able to do a better job of protecting the food safety concerns of Americans.

There's still work to be done. We are proposing in the budget additional support for the Public Health and Information System, which will provide us data that will allow us to do a better job, within USDA, of determining where there may be potential problems, and address those problems before they manifest themselves into difficulties.

We are also continuing to work on the Uniform Incident Command structure, which will allow us to do a better job of communicating with State and local public health officials. In the event there is a concern or a problem, we'll try to contain it and mitigate it, as best as possible.

We will continue to work, within USDA, on better testing, and more appropriate testing, to ensure that we are catching and identifying pathogens. As the science evolves, so must our testing.

Senator KOHL. Thank you.

We'll turn now to Senator Collins, and then Senator Moran.

Senator COLLINS. Thank you, Mr. Chairman.

First, let me thank you for holding this hearing.

Also, a warm welcome to the Secretary and the members of this panel.

The Department's budget request for the year 2012 is a source of great interest to many Mainers. Farmers across my State, including blueberry growers, potato farmers, and dairy producers, all look to USDA for assistance in the areas of crop research, farm management, and agricultural marketing. But as we know, the Department's mission is much broader than that, than simply fostering agricultural production. And it also plays a key role in spurring economic and infrastructure development in rural communities around the country. I believe that most people would be surprised to learn that roughly three-quarters of USDA's budget actually goes to providing nutrition assistance. That is why I want to take the time today to talk about policies in the Department that appear to be headed toward limiting access to fresh white potatoes within our Federal nutrition programs.

Let me concede a certain bias here. I grew up in northern Maine, and my first job was picking potatoes on a farm during the school recess, for a couple of years, when I was very, very young.

So, I do want to talk about the fact that the white potato is the only vegetable excluded from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)-approved food list. And the Department is proposing to place strict limits on the use of potatoes for the national school breakfast and lunch programs.

So, I have a visual aid here that I want to use to illustrate my point, because if you compare the nutritional content of iceberg lettuce, which is on the WIC list and is not proposed for limitations for the school lunch or breakfast program, with that of the fresh Maine potato, there is quite a difference.

For example, one medium white potato has nearly twice as much vitamin C as this entire head of iceberg lettuce. Per serving, potatoes contain more than four times the potassium as iceberg lettuce, and more potassium than bananas, a fruit that we think of when it comes to potassium. Per serving, potatoes contain twice as much dietary fiber as the iceberg lettuce, and three times more iron than iceberg lettuce, which we know is so important to pregnant women.

So, my question, Mr. Secretary, is, what does the Department have against potatoes?

Secretary VILSACK. Absolutely nothing, Senator. The reality is that when you take a look at the WIC program, it is absolutely supplementing the purchases by the mom or the dad that's using the WIC program. And what we know from research is that moms and dads understand what you have outlined, which is the significant nutritional value, and the dollar value, of purchasing potatoes. And for that reason, they are already purchasing potatoes in great quantity. So, what the WIC program is doing is, it's essentially supplementing those potato purchases with purchases of other vegetables that are not normally purchased or not purchased in the quantity that potatoes are purchased. So, in other words, it's not discriminating against potatoes, it's recognizing that potatoes are already being purchased by WIC recipients.

As it relates to the school breakfast and school lunch programs, we are working—I had a meeting with the Potato Council just recently, and we're willing to take a look at opportunities to look at potato consumption in the school breakfast and school lunch pro-



grams. What we want to do is, obviously, move away from the fried nature of what most schools are preparing. That's essentially the equipment that they have. We obviously want to take a look at ways in which we might be able to provide other alternatives for producing those potatoes so that they are not as caloric—high in caloric content and fat content, because, as you know, we're trying to deal with a significant obesity issue.

So, it's not the potato, it's the way in which the potatoes are being produced or being provided.

Senator COLLINS. Thank you, Mr. Secretary. I hope you will take a look at that.

I would suggest, since my time has expired, that the Government sends a signal when it lists every other vegetable except the potato for the WIC program and when it proposes to limit the use of potatoes in the school lunch or breakfast program. That signal can be perceived as a negative one. I know that's not your intent, but it can be perceived as saying that potatoes are not healthy, when, in fact, when we do that comparison—and I have nothing against iceberg lettuce—

Secretary VILSACK. High value of vitamin K, by the way, that head of lettuce.

Senator COLLINS. I'm sorry?

Secretary VILSACK. It's a high value of vitamin K.

Senator COLLINS. K. Yes, but when you compare it with the fiber, vitamin C, and potassium, it doesn't stack up. I'm not saying this should be banned. I'm saying that neither should this be.

Secretary VILSACK. Right.

Senator COLLINS. So, I do appreciate the fact that you're willing to work with the industry about what you would perceive as more helpful ways of preparing the potato.

Thank you.

Thank you, Mr. Chairman.

Senator KOHL. Thank you very much, Senator Collins.

Before we turn to Senator Moran, I'd like to ask our ranking member to make his statement and ask for questions.

Senator BLUNT. Thank you, Mr. Chairman. I think I'll take my questions in order. Thank you. Sorry to be late for the meeting. I certainly look forward to working with you on this subcommittee, and was pleased to get a chance to visit with the Secretary just a few days ago.

But I am pleased to be here. And I'll take my questions in the order that I arrived. Maybe Mr. Moran will ask better questions than I might have asked, anyway.

So, thank you, Chairman.

Senator KOHL. All right. Very good.

Senator Moran.

Senator MORAN. Mr. Chairman, thank you very much. And thank you, Mr. Blunt.

I'm honored to be a member of the agricultural appropriations subcommittee. I spent the bulk of my time, in the House of Representatives, as a member of the authorizing Committee. Certainly, the jurisdiction of our subcommittee is of great interest to many, many Kansans, and has a huge consequence upon American producers, as well as American consumers.

I welcome the Secretary and look forward to working with him in my current capacity.

And I just want to direct my questions in a couple of areas. First of all, agricultural research. I believe that agricultural research is a significant component of what we can do to be of assistance to agriculture, as well as those who purchase agriculture commodities. USDA has a significant role to play. I think, generally, we've fallen behind in regard to the resources going into agriculture research, as compared to other research. And in particular, I wanted to focus on the competitive grant research program, Agriculture and Food Research Initiative (AFRI). I've tried to find out, in my short 6 weeks of being a Member of the Senate, how that money is spent.

So, Mr. Secretary, my hope is, either today or at an appropriate time, you could give me a list of the Department's priorities, how that money is categorized, and what your suggestions are for increasing or decreasing funding within those various categories, so I can get a better understanding of what the priorities of the Department are, and to, from my perspective, make sure that you continue to focus, or that you again focus, upon production agriculture in the research concepts that you pursue.

Secretary VILSACK. Senator, if you want, I can provide you some background about that today, and supplement it if it's not satisfactory.

We have increased our commitment to competitive grants. We believe this is one way of leveraging additional resources. There are a number of key areas in which we focus these competitive grants.

First, I would say that we have grants that are focused on both commodity and livestock production and protection. That has to do with how do we make farms more efficient, in terms of their capacity to create more production? And how do we protect them against pests and diseases, invasive species and the like, that could potentially cut down on productivity? So, that is one key area.

We are also spending some time and some resources on biofuels, ways in which we might be able to use a wide variety of crops, crop residue, and waste products to be able to produce biofuels to supplement what we're doing with a corn-based ethanol process, to expand beyond that. As we know, the Renewable Fuel Standard requires us to get to 36 billion gallons by the year 2022. To do that, we need substances other than corn, so we're doing some research in that area.

We are obviously focused on food security issues, in terms of our capacity to meet the growing need that we not only have in this country, but, as well, the global need. As you well know, the world population is scheduled to grow to 9 billion-plus by 2050. The question is, how are we going to feed those folks? What is America's role in feeding those folks? How do we maintain security—food security? That's part of the research that is underway with the AFRI grants.

We are also taking a look at ways in which agriculture will have to adapt or mitigate the consequences of climate change that may impact itself in less water, higher temperatures, more opportunities

for drought, more flooding conditions, what we can do to make sure that we don't see a significant decline in productivity.

We are also taking a look at resources in the area of nutrition and obesity, given the very significant impact that we have with a third of our children being obese, and the consequences of that to our national security and educational achievement. We think that's an appropriate place for some resources to go, in terms of our competitive grants.

That gives you a general overview. There's probably more specifics that you'd like, and we'll be happy to provide those.

[The information follows:]

AGRICULTURE AND FOOD RESEARCH INITIATIVE—FOCUS AREAS

[In thousands of dollars]

Focus area	Fiscal year 2010	Fiscal year 2011 <sup>1</sup>	Fiscal year 2012 <sup>2</sup>
Bioenergy .....	\$40,000	\$40,000	\$48,239
Global climate variability .....	55,000	55,000	60,058
Global food security .....	15,000	15,000	31,980
Nutrition and health .....	25,000	25,000	33,520
Food safety .....	20,000	20,000	28,520
Foundational areas <sup>3</sup> .....	80,773	80,773	89,605
NIFA fellows .....	6,045	6,045	11,480
Legislatively authorized set-asides .....	20,664	20,664	21,253
<b>Total, AFRI .....</b>	<b>262,482</b>	<b>262,482</b>	<b>324,655</b>

<sup>1</sup> Fiscal year 2011 annualized level as presented in the fiscal year 2012 President's budget.

<sup>2</sup> These numbers reflect redirection of funding for the Institutional Challenge Grants and the Graduate Fellowships programs into AFRI. Institutional Challenge Grants funding has been equally allocated across the AFRI Challenge Areas. The Graduate Fellowships funding has been added to the NIFA Fellows program.

<sup>3</sup> These are considered investments in each of AFRI's congressionally established priority areas, as follows:

- plant health and production and plant products;
- animal health and production and animal products;
- food safety, nutrition, and health;
- renewable energy, natural resources, and environment;
- agriculture systems and technology; and
- agriculture economics and rural communities.

Senator MORAN. Mr. Secretary, I would love to see the breakdown, in dollars, in each one of those areas, and kind of the trend in which I see the Department going.

GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION RULE

I'm going to try to ask a very brief question, which the answer can be yes or no. I asked the Department, last September, to do economic analysis—Mr. Glauber, to make economic analysis available in regard to Grain Inspection, Packers and Stockyards Administration rules. I'm pleased to know that you're doing that. And I am asking whether or not—once that economic analysis is complete, whether the Department will allow for public comment.

Secretary VILSACK. Senator, if I can, that's not as easy of a question to answer with a yes or no. And the reason is that in order to explain how we went about this process—we solicited comments, as you know, it generated a substantial amount of comments. We're taking those comments into consideration, categorizing them, and they will help to inform the analysis that Joe and his team will do. I've instructed them to do a thorough analysis, a complete analysis. Obviously, we want to make sure that, once we present the final rule for review and for implementation, that it's a solid rule, one that we can justify. And given the extent of the comments, I'm con-

fident in Joe's team, that they'll be able to provide an analysis that can pass muster and that will lead to a good product that we can support and defend.

Senator MORAN. I would encourage you, Mr. Secretary, to allow a very transparent post-economic analysis process at the Department.

Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Moran.

We'll turn to Senator Brown, and then Ranking Member Blunt.

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

Secretary Vilsack, nice to see you.

Mr. Chairman, I know that Wisconsin produces more cheese than any State in the country, but you should know that Ohio produces more Swiss cheese than any State in the country, and that I grew up on a dairy farm, working on a dairy farm, milking Guernseys and Holsteins. So, if you want to know more about Swiss cheese, I'm your guy, right?

I chose this subcommittee, on the Appropriations Committee, for a couple of reasons. One is that one out of seven Ohioans are employed in agriculture—not too different from many other States in this country—but also because of the priorities of this Committee, the subcommittee, under Chairman Kohl's leadership, had been pretty much exactly right—putting food on the table and fighting hunger in America and abroad, about ensuring families don't have to worry about the quality and safety of the food that we buy in supermarkets; about ensuring that our Nation's children grow up strong and healthy, and their mothers have the support and nutritional foundation they need to succeed; and about cutting-edge research to bear on our Nation's most difficult problems. And this subcommittee has pursued those as priorities, and I'm appreciative of that and laud that.

#### BROADBAND

I have a couple of questions, Mr. Secretary. During the 2008 farm bill, several of us worked—in the Agriculture Committee—to rewrite the broadband section of the bill to ensure wider access for communities that are underserved. And you were in Ohio, and worked on that and discussed that and helped to begin the implementation. I understand USDA, today, announced the implementation of the new language for broadband. Could you just briefly give us your thoughts about that?

Secretary VILSACK. Sure. Senator, we certainly agree with the observations contained in the 2008 farm bill, that there needed to be a more focused effort on broadband expansion in unserved and underserved areas. You all basically instructed us to take a look at how to define "rural" with respect to broadband expansion. And the interim rule, the final rule, that we proposed today, we're talking about communities of 20,000 or less that are not located adjacent to, or near, an urban area. We have instructed our folks to take a look at giving priority to unserved and underserved areas.

Our hope is that there are sufficient resources for us to continue the good work that was done with ARRA. ARRA allowed us to fund 330 projects, impacting 7 million Americans in rural areas, poten-

tially 320,000 businesses having access to broadband, as well as 32,000 anchor institutions, like schools, libraries, and hospitals.

We obviously want to continue that, because the Department of Commerce recently put out a map of the United States, showing some of the holes, if you will, in terms of coverage. We want to try to address those with these rules.

So, we've put the rules out. We've put out an application process that will be on the Web, and we're encouraging folks to get comments in, before May 14, on the structure we proposed, and to begin the process of applying for resources.

Senator BROWN. Thank you.

I will submit several questions for the record on topics important to Ohio, especially something we've talked about, the Agricultural Research Station in Wooster, and what we can do on that.

[Senator Brown's questions were not available at press time.]

#### BEGINNING FARMERS

Senator BROWN. And the other question I'd like to ask now is—comment and question, Mr. Secretary—the average age of farmers, as we know, in all of our States, is now 57, and going up—and we all are concerned about what that means, attracting young people into agriculture. How do we better target Farm Service Agency (FSA) loan programs and other USDA assistance, to help launch careers for beginning farmers?

Secretary VILSACK. Senator, we're cognizant of that issue. Thirty percent of our farmers are older than the age of 65, as well. We saw a 30-percent increase in the number of farmers older than 75, and a 20-percent decrease in the number of farmers younger than 25. There are a couple of things.

No. 1, focusing our Beginning Farmers and Ranchers Loan Program, which we have been doing. We've got the Office of Advocacy and Outreach, that is focused on strategies for beginning farmers.

No. 2, I would say that we are doing a better job of using our direct loan capacity. I may be wrong on the percentage of this, but a substantial percentage, maybe up as high as 50 percent of our loans, on the direct loan side, have gone to beginning farmers, as well as about 19 percent going to socially disadvantaged farmers. So, we are making an effort to direct our credit efforts in a way that helps beginning farmers.

But I think there has to be, as we begin the debate and conversation about the 2012 farm bill, I think this is one area that we really need to focus on. We've got some ideas and thoughts. I know my time is up, but I'd be happy to share them with you or the subcommittee, at a later date, relative to how we can identify young people who are interested in farming, how we might be able to use the tax code to encourage farmers who have no relatives to pass the farm on to, to get young people engaged, to get sweat-equity opportunities. There are a whole series of things that need to be done.

Senator BROWN. Thank you.

Thank you, Mr. Chairman.

Senator KOHL. Thank you very much, Senator Brown.

Senator Blunt.

## PREPARED STATEMENT

Senator BLUNT. Thank you, Mr. Chairman. Again, I look forward to working with you on this subcommittee.

I'll have a statement for the record and some written questions, I'm sure, as well.

[The statement follows:]

## PREPARED STATEMENT OF SENATOR ROY BLUNT

Good afternoon. Thank you Chairman Kohl for holding today's hearing on the U.S. Department of Agriculture's (USDA's) fiscal year 2012 budget request, and thank you to our witnesses for being here today.

This is my first hearing as ranking member of the Agriculture subcommittee, and I look forward to working with the chairman and other members of the subcommittee as we determine funding levels for the Department during an era where we must show restraint, and everything must be on the table.

While we are still working to get our fiscal house in order for fiscal year 2011, we are looking forward to fiscal year 2012. The task that has been placed before us, Mr. Chairman, is not ideal. How we respond to this responsibility is important for the taxpayers and our economy as a whole. We're at a crucial moment in our Nation's history, and the decisions we make now will define who we are going to be as a country.

We are all aware of the current state of our economy. Americans are gravely, and rightfully, concerned about the size of the national debt and the budget deficit. As we begin to formally review the administration's budget request, we have to recognize that every \$1 we appropriate will be borrowed and must be repaid with interest. The Government must start operating under the same rules that families across America face every day when balancing their checkbook.

Last week, the Government Accountability Office released a report on duplicative efforts throughout the Government that highlighted more than 30 programs at USDA. The President's budget also proposes a series of program consolidations and terminations at the Department. Both of these proposals should be thoughtfully and seriously considered.

While tackling these difficult funding decisions, we do so with an understanding of the important role that agriculture plays in our economy. We should invest taxpayer dollars wisely in agriculture programs that will increase our agricultural communities' competitiveness here and abroad because agriculture is a leading driver in our economic recovery.

For example, research supports more efficient, higher-quality agricultural production and the continued development of new and existing biofuels. That same research also supports American farmers and rural communities by giving them the tools to be more competitive in the global economy.

Agriculture products remain the one highlight in our export portfolio. The Secretary notes in his written testimony that every \$1 billion worth of agricultural exports supports an estimated 8,000 jobs. Agriculture exports from Missouri alone support more than 37,000 jobs.

We have to continue to expand access to foreign markets because a thriving agriculture industry is key to our economic recovery. It's time to move forward with the free trade agreements with South Korea, Columbia, and Panama.

Mr. Secretary, I look forward to hearing your thoughts on these important issues. Again, thank you Chairman Kohl for holding today's hearing.

## CROP PRODUCTION

Senator BLUNT. I may have missed it, but, in your response to Senator Moran's question about agricultural research, I didn't hear as much as I would hope to hear about plant research, about having better results from less and less acreage, or on the same amount of acreage as we struggle to feed a growing world. I know that's one of your priorities, but I'd like to hear your thoughts on that.

Secretary VILSACK. Senator, I did—I actually started with the first area of emphasis, in terms of our competitive grant program,

is on crop and livestock production and protection, which is precisely to your point of how—

Senator BLUNT. Actually, I thought that was more the implementation of things we thought might work than trying to develop what might work, which was my point.

Secretary VILSACK. No, no—the question was about competitive research grants. And this has to do with developing new ways to produce, to become more efficient, more effective. It's precisely the point that I'm making.

Senator BLUNT. Good.

Secretary VILSACK. As well as on the food security side, how do we learn from our experiences in other countries that may be drought-stricken, may be struck with floods? How can we create, potentially, new products that would be more inclined to be productive in very adverse weather conditions? That's part of the research, as well.

#### TRADE AGREEMENT

Senator BLUNT. Good. On the "other countries" front, we have three trade agreements. I understand they could mean an additional \$2.3 billion in meat and poultry exports alone. That could add almost 30,000 new jobs in our economic recovery. What is the position you and the Department are taking on each of those three agreements?

Secretary VILSACK. We are very supportive, obviously, and hope to have quick ratification, of the Korean Free Trade Agreement, which has been completed. That will basically allow 60 percent of the tariffs on about \$5 billion of agricultural products to be removed immediately; the other 40 percent, over a period of years. You're correct, it will increase opportunities for us and make us far more competitive. We want it to be done quickly, because, obviously, we risk the possibility of Korea making a deal with Australia and other countries, where we could potentially lose market share.

It's my understanding that Ambassador Kirk has been instructed to complete the discussions and negotiations on the Colombian and Panama Free Trade Agreements, and we're excited about that opportunity, as well. We hope that the Korean Free Trade Agreement's passage will provide momentum for the passage of the other two free trade agreements.

It's not just those bilateral agreements, it's also the multilateral discussions that are taking place—the Transpacific Partnership, which the President is very interested in embracing—as well as our efforts at USDA in the Foreign Agricultural Service to reduce barriers to trade. We've seen a lot of that happen, in part because of the growing trade surplus that we're experiencing in agriculture. We project it to be \$47.5 billion this year, which will be a record, in terms of sales, by almost a \$20 billion increase more than last year's record. Every \$1 billion of agriculture sales creates 8,000 to 9,000 jobs. So, we are certainly supportive of this, and encouraging quick action.

Senator BLUNT. Very good.

On the other two agreements, not for today, but I'd like to know what you think, for Colombia and Panama, the best markets are. For example, wheat or other markets that might benefit.

Regarding the beef market, and again, I think your point is well made, that if we don't get to those markets before other people do, you allow patterns to establish that are often hard to reverse. And I think the beef area still needs some work, but it's moved some since Ambassador Kirk has worked on it, as he has.

GAO REPORT ON DUPLICATIVE PROGRAMS

There was a GAO duplication report that came out after you submitted your budget, and I wonder if that's given you a chance to go back and look at things to find some savings by bringing programs to your Department that would be better done there than somewhere else, or figuring out how to better accomplish some of the programs that are duplicative.

Secretary VILSACK. I had a conversation with the President, earlier today, about the whole issue of trade—as you well know, that there are a number of agencies that are involved and participate in trade. The challenge is to make sure that the opportunities and the tremendous advantage that we have in agriculture, in whatever structure, whatever ultimately comes about, in terms of restructuring or reorganization, is not impacted negatively. This is a good-news story. This is a positive story. It's one we want to build on, we want to continue. We've got really good people working at Foreign Agricultural Service, breaking those barriers down. We want to continue that.

We are constantly looking for ways in which we can restructure and reorganize within the USDA. We have a Process Improvement Program underway, which is identifying efficiencies and savings. As we deal with difficult budgets, as we deal with decisions you all will make, they will obviously impact personnel. Our only request is that you give us sufficient time in which to manage it properly.

As I said earlier, if we try to shoehorn in a solution to budget problems that have accumulated over a number of years into a short period of time, it makes it much more difficult for us, as managers, to do an effective job and to minimize the negative impact that it may have on the American public. We don't want that. You don't want that. We just simply need appropriate time.

I haven't had a chance to look at the GAO report in its totality. I know that there are issues concerning food safety. And as we are working with the FDA to make sure that we are coordinating our efforts so that we have, in a sense, a virtual food safety agency, in terms of its capacity, in terms of its philosophy, focused on prevention, as opposed to just reacting. We want to be able to be proactive. We want to prevent problems from occurring before they happen.

Senator BLUNT. I remember one point in that report was that FDA is responsible for the safety of shell eggs, and USDA is responsible for the safety of processed eggs.

Secretary VILSACK. That is a good example, Senator, but, maybe a better example is the pizza example, that, if it's a cheese pizza, with respect to Senator Brown or the chairman—

Senator BLUNT. Particularly if it's a Swiss cheese pizza.

Secretary VILSACK. That might be tough. But if it's a cheese pizza, basically, FDA does it. But if there's one pepperoni slice on it, it's ours. And I think that there are, obviously, ways.



But in order to do this, I think the first thing is, you've got to build a foundation. And the way you build a foundation is to make sure that the philosophies are the same. I think what we had was a philosophy, because of the quantity that FDA had, of being reactive to circumstances, to try to mitigate the impact. And we at USDA—because of our niche, we were looking more to preventative measure. I think preventative is now what you all have been able to do with the food safety legislation that passed last year. You've got us all on the same track, which I think is very, very important, and I think it's going to result in improved food safety.

Senator BLUNT. I did ask the Housing Secretary the other day, at a hearing like this, if they had the infrastructure to handle the rural housing component. They may or may not have. And what we don't want to do is eliminate programs if your Department can uniquely serve a purpose that others would have to create additional infrastructure to do. So, we want to be careful about it, but we also want to be sensible about it, in trying to eliminate duplication wherever we can.

Secretary VILSACK. Also, I think that there's a real desire to avoid—we had this with the U.S. Agency for International Development, in terms of overlapping jurisdiction and responsibilities and confusion.

There's a difference, if I can, between rowing and steering. Steering is the policymaking aspect of this. There should be consistency. There should be, clearly, somebody in charge of the steering apparatus. But the implementation—it's a different set of skills, and somebody ought to be—that ought to be a separate lane. And if you start confusing the steering and rowing, you end up not going anywhere.

#### BROADBAND

Senator BLUNT. That is absolutely true. Not for an answer today, but on broadband, which we're all interested in seeing that people have access to, I'd like you to come back to me with a definition of what “underserved” means. I know what “unserved” means. I don't know what “underserved” means, and I think you get into a really interesting competitive environment, where you go in and assist somebody to compete with someone who has gone in and already put infrastructure in, themselves, without taxpayer help.

Secretary VILSACK. I think the answer to that may be in the interim final rule that we presented today. We'll get you and your staff a copy of that.

[The information is available as follows:]

*See* Federal Register, Monday, March 14, 2011, Vol. 76, No. 49, pgs 13770–13796, Rules and Regulations at <http://www.gpo.gov/fdsys/pkg/FR-2011-03-14/pdf/FR-2011-03-14.pdf>

Senator BLUNT. Good. I'd like to see it.

Thank you.

And thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Blunt.

We'll listen, now, to Senator Nelson, then Senator Hoeven, and then Senator Cochran.

Senator Nelson.

Senator NELSON. Thank you, Mr. Chairman.

And, Mr. Secretary and your colleagues, it's good to have you here. We appreciate this opportunity to go over some very important issues.

#### NATIONAL DROUGHT MITIGATION CENTER

Mr. Secretary, as you know, the National Drought Mitigation Center at the University of Nebraska, Lincoln, performs a number of valuable services: monitoring and forecasting drought, planning for drought, and developing means of mitigating drought. It's extremely important for farmers and ranchers for understanding trends that affect food production and for planning by a number of businesses and individuals. And the widely used Drought Monitor is published on Thursdays, I believe. As we all know, these are extremely important.

For a number of years, a number of these beneficial programs were supported by earmarks. In the absence of earmarks, do you have any plans for sustaining the National Drought Mitigation Center through—and its activities—in your fiscal year 2012 budget?

Secretary VILSACK. Senator, what we have suggested is that there really does need to be a priority-setting process. There are a number of projects that have received earmarks over the course of a number of years. All of them have, I'm sure, appropriate justification, including the one that's located in your area, in Nebraska.

I think it would helpful for us to, basically, do a review of all of those proposals and all of the existing facilities to determine, what are the highest priorities? When we are dealing with difficult budgets, it is, at the end of the day, about choices and priorities. We want to make sure we can justify whatever decisions are made.

So, there is a priority-setting process in place. I can't tell you, today, where the Nebraska project is, specifically, in that process, because it hasn't been completed.

Senator NELSON. I might point out that the project might exist in Nebraska, but it's nationwide in its implications, and is used by a number of other entities, as well. Unfortunately or fortunately, depending upon your point of view, drought is not just unique to Nebraska. So, others have focused on it, and I think it's, obviously, a worthwhile project. And I want to make a pitch for it. Perhaps we can follow up after the hearing.

And relating to trying to find a way to make a budget work in difficult and trying economic times, I understand the challenge that you face. I think it's important for the American people if we—consider it this way, that if you like importing 70 percent of your oil, you'll love importing 70 percent of your food.

#### AGRICULTURAL PRODUCTION

What I'm getting at is, your agency and the programs under your agency and programs—new farm program and everything we move forward on, will be designed to try to sustain American agriculture so we can continue to produce, here at home, our own food for our own needs: food, fuel, fiber, and feed.

So, I hope that, as we look at cuts, we'll be judicious and, as you say, prioritize, so that, at the end of the day, agriculture is not left hanging without a safety net. In anticipation of bad times, we need

to be sure that we are protecting against those bad times. And it's harder to do it—in good times, in terms of commodity prices. But in tough budget times, as we do that, we have to be very judicious and have very strong prioritization so that we don't end up having people talk us out of continuing to support agriculture in advance of the bad times.

Secretary VILSACK. I'm not sure if I have time to respond to that, Mr. Chairman.

Senator, we obviously agree. We're certainly pleased with the fact that we have a strong agricultural economy today, but recognize full well the nature of agriculture could be difficult tomorrow. There does need to be a strong safety net. We do have to have shared—as the President says, shared sacrifice and shared opportunity, and it has to be proportional. We think our budget reflects those—that balance. We think it maintains a strong safety net, through a variety of mechanisms: additional market opportunities, crop insurance, as well as the payment structures that are in place. We are suggesting some changes to the payment structure which we think are legitimate. But we're happy to tell the agricultural community that we are aware of the need for a strong safety net.

Senator NELSON. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

Senator KOHL. Thank you, Senator Nelson.

Senator Hoeven, Senator Cochran.

Senator HOEVEN. Thank you, Mr. Chairman.

Secretary Vilsack, good to see you again. You've been up here a lot, and I know how demanding your schedule is. So, it's good to have you here.

#### AGRICULTURAL RESEARCH

First thing I want to touch on, for just 1 minute, is a follow-up to both my colleagues, Senator Moran and Senator Blunt, in emphasizing the importance of agricultural research. I think it pays incredible dividends. And obviously, we're going to have to tighten up on these budgets. We have a spending issue. And from what I've seen, agriculture will certainly take its share of the load. Some of us may feel it's even taking more than its share of the load. And I think that's borne out by some of the percentages I've seen so far.

But good farm policy is important to every single American and people all over the globe, as you well know. We have the lowest-cost, highest-quality food supply, not only in the world, but in the history of the world, thanks to our farmers and ranchers.

But I'm wondering if there's some flexibility that we could give you, in your budget, that would help. And a couple different areas. Agricultural research. I think that's incredibly important. If you have some ability to move dollars around, that might help us do more through our universities and extensions, so forth, to do a good job on agricultural research. Biofuels development. Also, even in the area of, with the Rural Utilities Service (RUS), some of the new clean coal technologies, which actually comes under your purview through RUS.

Is there something we can do with flexibility, in these times when there are going to be less dollars, that can really help, in

terms of doing the job—make your budget go further for agriculture?

Secretary VILSACK. On the research side, Senator, we're trying to do that by increasing, over what we had last year, the competitive grant program. We think that that is a way in which we can more effectively leverage scarce Federal resources to partner with private resources and the land grant universities to extend our research opportunities.

#### ENERGY PROGRAMS

You mentioned RUS. We are proposing, in this budget, the capacity to use a portion of \$6 billion in loan authority to be able to better assist existing facilities that might be fossil fuel-based, as they look for new renewable opportunities for peak production, for efficiencies and improvements, and more flexibility in being able to use those resources to help assist in the development of those improvements. That would be something that could be helpful.

Senator HOEVEN. So, that is something we could work with your people, in terms of your budget, that—clean coal technology, the RUS loan program is a great example. How do we make sure—same thing in biofuels—second-generation cellulosic development for ethanol, other—and biodiesel.

Secretary VILSACK. Well, the biofuels—

Senator HOEVEN. We need to get that creativity going in the private sector.

Secretary VILSACK. You're right.

Senator HOEVEN. We need to get your dollars into those projects.

Secretary VILSACK. On the biofuels side, I think the Congress and the President have been of one mind, in terms of getting the energy title of the farm bill implemented. And we are attempting to do that with new biorefineries that are being financed with the Biomass Crop Assistance Program, with advanced biofuel producer assistance. All of that is underway. So, I think we're doing a pretty good job on that. But we're certainly willing to work with you in other ways.

I will tell you that I have a deep concern—this is a little far afield from your question, but I have a deep concern about the cliff that some folks want to create, in terms of the incentives that are currently in place for the biofuel industry. I think, if you create a cliff, what you're going to see is a drop in production. You're going to see a loss of jobs. I think it would be much better to have a glidepath towards ultimate elimination of those incentives—but, a glidepath. And perhaps a redirection of those incentives in a way that helps blender pumps, helps build greater demand with flexible fuel vehicles. That kind of thing could be very helpful to us.

So, I think there are a number of ways in which we can help.

Senator HOEVEN. Blender pumps, flex-fuel vehicles, higher-blend standard, working with the Environmental Protection Agency—I think we can transition to some of those measures that can still help the industry grow, but that don't create a cost, necessarily, for the Federal Government.

Secretary VILSACK. Right. Or reduce the cost that we've been incurring over time.

Senator HOEVEN. Right. Thank you.

Senator KOHL. Thank you, Senator Hoeven.

Senator Cochran.

Senator COCHRAN. Mr. Chairman.

Mr. Secretary, welcome to the subcommittee. We appreciate your cooperation with us in attending the hearing.

#### CATFISH INSPECTION PROGRAM

While we understand that the Department has been considering releasing some catfish inspection regulations and beginning to implement a program, we've not seen any final action taken, or specific requests for funding, for enforcement of the program. What is the status of that issue, if you know, particularly as it relates to aquaculture activities?

Secretary VILSACK. Senator, we just recently put forward for comment and consideration, specifically as it relates to catfish, a responsibility that was given to us statutorily, a new inspection program. We expect and anticipate that there'll be quite a bit of comment, relative to precisely how extensive that inspection process should be, in terms of the varieties of catfish that should be included.

I didn't know how many different varieties of catfish there were until I got this job. I just thought there was one kind, out in the Mississippi River. But I find that that's not the case. There are quite a few more.

So, our view is that it's going to take some time for us to sort of get our hands around precisely what we will be regulating. Therefore, it would be a bit premature this year to ask for resources for an inspection process, or enforcement process, when we don't have the program in place. We anticipate it will take us a little time to get it in place.

Senator COCHRAN. We would encourage you to move ahead on it. We hope you don't do like we do here in the Senate sometimes, and just kind of filibuster, talk, talk, and nothing really happens. We hope the administration will cooperate with this subcommittee, and collaborate on defining a new regime, and then let us provide the funds to pay for it.

Thank you, Mr. Chairman.

Senator KOHL. Thank you very much, Senator Cochran.

#### FARM SERVICE AGENCY LOAN PROGRAMS

Mr. Secretary, for the past 2 years, private credit markets provided insufficient credit to support farmers and ranchers, due to the recession. As a result, this subcommittee had to increase support for FSA loan programs. Wisconsin is the largest user of these programs, with a loan portfolio of more than \$1.3 billion. And they are particularly important for the dairy industry. This budget cuts those programs by 6 percent. Can you give us some assurances that private credit markets will provide adequate credit for farmers and ranchers in fiscal year 2012?

Secretary VILSACK. Mr. Chairman, I think the most significant reduction in the loan programs is a program that provided not just a loan, but also interest assistance. Given the difficult times, our feeling was that there obviously are priorities, and our priorities

should be on the direct loan and the guaranteed loan programs without interest assistance.

We are seeing a better credit circumstance, in terms of the capacity to get credit. That's probably in part because farm prices are better. It's in part because we're seeing fewer defaults. We're seeing fewer efforts to restructure or ask for additional time in which to pay. Therefore, we're fairly confident that the numbers we've provided should be adequate to meet the credit needs of our farm community, given the circumstances as they exist today. But as you know, things could change in the next 3 or 4 months. We're keeping an eye, obviously, on energy costs. That may have an impact on all of this. But at this point in time, we're confident that we'll be able to meet the need with what we proposed.

#### GOVERNMENT SPENDING CUTS

Senator KOHL. Mr. Secretary, as we've all been trying to find ways to reduce Government spending, we received from the Office of Management and Budget (OMB) a list of suggested places to cut spending across the entire Government. That list included 38 items, of which 12 out of the 38 were from USDA. Those USDA programs included cuts of \$1.5 billion, from a total of \$6.5 billion on the entire OMB list.

So, can you explain why OMB seems to be focused so much on USDA spending? Are these USDA programs really not that important? Does USDA simply have too much money these days, or does the administration have huge amount of regard and respect for your ability to create efficiencies?

Secretary VILSACK. I'd like to think it's the latter, Mr. Chairman. But in all seriousness, we at USDA recognize the responsibility because of the people that we work with and represent and work for—the folks in rural America, who I think, themselves, understood something about that long ago, which is one of the reasons why the agricultural economy is probably a little bit stronger than other parts of the economy, because there wasn't quite as much debt. We're seeing, right now, an 11.3-percent debt-to-asset ratio in farm country, which is a solid ratio.

So, we stepped up last year, with a \$4 billion savings on the crop insurance. We were asked to identify, consistent with the President's instructions, a number of reductions that would take place within a reduced discretionary spending number. We've provided those to OMB. And I think what you see is a reflection of OMB's efforts to accelerate what we have identified in the fiscal year 2012 budget as a way of assisting the Congress in trying to finalize the fiscal year 2011 budget.

Will these reductions be easy? No. If I had my druthers, I'd like to live in a world where we had unlimited resources and we didn't have to deal with these issues. But the reality is, American families are dealing with them, and they expect their Government to do the same. And we want to be reflective of that value.

Senator KOHL. All right. Senator Pryor, we'll turn to you.

Senator PRYOR. Thank you, Mr. Chairman.

Secretary Vilsack, always good to see you. Thank you for being here today.

Let me start by picking up on something that Senator Cochran said just a few moments ago. And that is that catfish is an important industry, of course, but even more than that, it's an important food source for people, and it's important that consumers know what they're eating and can be assured that it's safe to eat. So, I hope that the USDA will continue to move down the tracks with your new catfish rule.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

Let me, though, ask a question about the National Institute of Food and Agriculture (NIFA). I have a question, generally, about the administration's decision to recommend some of these cuts, because as some of my colleagues have said already, agriculture is a fairly strong sector of the U.S. economy. I think you just mentioned that. And we are not doing well, when it comes to exports. We have a huge trade deficit. The President has come out and said he wants to double exports within so many years. It seems to me that we're a world leader in exporting of agriculture products, and so I'm not sure why we should be cutting that. We want to see economic recovery. We want to see a more stable, more robust economy in this country. And really, the foundation of rural America's economy is agriculture.

So, I was going to ask about NIFA. But just generally, why are you recommending some of these cuts? And particularly with NIFA, which is agricultural research and is doing great things all over the country. Why are we cutting now? I understand we're in a difficult budget environment, but tell me the administration's thought process.

Secretary VILSACK. I would say two things.

First of all, as it relates to exports, I want to make sure I make our budget clear, Senator. We are proposing, actually, in that area of the budget, an increase of \$20 million. And we believe that that increase—based on experience, every \$1 we spent on export assistance last year netted \$35 of trade. So, that's actually an increased item on our budget.

Senator PRYOR. Right.

I think it's great. That's why we need the product in the pipeline.

Secretary VILSACK. It can create economic opportunity.

As it relates to NIFA's budget, basically, we are increasing the competitive grant program within NIFA. Our belief is that, by increasing that part of NIFA, of AFRI, we will be able to leverage an equal or greater amount of overall dollars within research. So, while it obviously is, in total, less money, we think by increasing a part of that budget, we can make up for whatever reductions may take place in other parts of the research budget.

And it's primarily in the areas of formula funding, a small reduction in formula funding, an increase in competitive grants, because competitive grants, we believe, have the greater potential for accessing additional dollars into research. This administration has been a supporter of research, and has been proposing additional resources for research, over the last couple of years.

Senator PRYOR. Thank you, Mr. Chairman.

Senator KOHL. Thank you very much, Senator Pryor.

Senator Blunt.

Senator BLUNT. Thank you, Chairman.

#### DISCRETIONARY FUNDING LEVELS

What is the fiscal year 2010 number that you're working under now, the fiscal year 2012 number, and the fiscal year 2008 number? If somebody could give me the bottom line. I don't expect you to know that, without looking it up, but you might.

Secretary VILSACK. I know that the net discretionary appropriations for fiscal year 2010, enacted, was \$26 billion. In the fiscal year 2011 budget, what we proposed was a little more than \$25.5 billion. And the fiscal year 2012 number is less than—

Senator BLUNT. This is net discretionary, right, Secretary?

Secretary VILSACK. Yes.

Senator BLUNT. The other number I'd like to know is what the 2008 number was for net discretionary.

Secretary VILSACK. The fiscal year 2012 budget number is almost \$24 billion—\$23.8 billion. The fiscal year 2008 number is \$21 billion.

Senator BLUNT. Okay, that's helpful. Thank you.

#### BUDGET PRIORITIES

What are the three top priorities that you have for the year for the Department? And why would those be your three top priorities?

Secretary VILSACK. That is a really difficult question, given the scope of what we do at USDA.

First and foremost, we obviously want to continue the momentum that's been building in rural America, in terms of job growth and economic opportunity. We've got a strong agricultural economy. We want to continue to build on that. We have a strategy of expanding broadband, of making sure the biofuels industry is supported, of doing a good job of using our conservation resources in a way that builds outdoor recreational opportunities, which we think can help build the rural economy. And the ability to build local and regional food systems creates job opportunities. So, that's one.

Second, we've got a good trade story to tell. We obviously want to increase the momentum there.

Then we have a responsibility to make sure that safe and nutritious food is available to every American. So, that gets into the food safety area. It also gets into the nutrition programs that are important, with particular emphasis on implementation of the recently enacted Healthy and Hunger-Free Kids Act of 2010, a historic opportunity for us to improve, significantly, the school lunch and school breakfast programs, given the obesity and hunger issues we face.

Now, there are a multitude of other responsibilities we have. Invasive species are a big issue, often not discussed in a context of this budget, because, in terms of dollars, it may not be the largest part of our budget, but it's extraordinarily important to crop production and productivity.

There are issues relative to homeownership, that we discussed briefly earlier. That's an issue.



The credit needs of farmers is an issue. The beginning farmer. I mean, there are just a lot of issues that you deal with in this Department.

And asking which of those, of all my priorities, is sort of like asking which of my two sons I love the most. I love them all. And we want to work hard to try to advance all of these priorities.

Senator BLUNT. Thank you, Secretary.

I think that is it for my questions, Mr. Chairman.

Senator KOHL. Senator Cochran.

Senator COCHRAN. I have no further questions.

Senator KOHL. Senator Hoeven.

Senator HOEVEN. I have one other question, Mr. Chairman.

#### CROP INSURANCE

Mr. Secretary, crop insurance is incredibly important for our producers. It's going to be incredibly important in the next farm bill. I see, in the budget proposal you put forward, you're reducing funding for crop insurance by \$1.7 billion. That follows about a \$4 billion reduction this past year. But I think crop insurance is really going to be a cornerstone of our safety net. It will be a cornerstone of our safety net for our producers in the new farm bill. How do we improve crop insurance?

Secretary VILSACK. If I can, let me explain why we're proposing the reduction. The \$4 billion reduction was, in part, a result of us doing a historical study of appropriate returns on investment for the insurance industry to provide stability in the crop insurance arena. What we determined was, a 12-percent return on investment would be sufficient to promote and ensure stability. What we did with the crop insurance agreement was to come down from the 17-percent to a 14-percent return. So, we think that there is stability and security.

The proposal we're making this year is in one narrow area of crop insurance: catastrophic insurance. And the reason we're doing this is because the loss ratio, not the premiums, but the relationship with the insurance industry was based on a 1.0 loss ratio. When in reality, historically, it's been far less than that. So, there are ways in which we can reduce the exposure to the taxpayers, not increase the cost to producers, and make the product still available. That's what we're proposing.

We are expanding crop insurance. We have 14,000 additional customers in our crop insurance program, as a result of the program improvements we made last year in range and pasture and forageland areas. We're looking at a series of organic crops that could potentially be covered, as well. We're reducing surcharges on a variety of citrus products, which may not impact North Dakota, but—

Senator HOEVEN. That's funny.

Secretary VILSACK [continuing]. Are obviously important to folks in the South. So, there are steps that we are taking.

We are also creating a premium refund program for good producers, those who have historically good records. We've identified about \$75 million that could be returned, if you will, to producers.

So, I think we're looking—always looking for ways in which we can expand coverage and create a better program.

Senator HOEVEN. I think it's going to be absolutely key that we work together, particularly as we go into this next farm bill, on crop insurance. I think that's going to be just a key, key component. And we have such a good case to make with it, too, for our producers.

Secretary VILSACK. You're right, Senator. I don't disagree with that.

Senator HOEVEN. Thank you.

Senator KOHL. Senator Pryor, you have a question?

Senator PRYOR. I do, Mr. Chairman. Thank you.

#### THE NATIONAL AGRICULTURAL LAW CENTER

This may seem like a parochial matter, but it really isn't; it's of national importance. And that is, University of Arkansas School of Law has the National Agricultural Law Center housed there. It offers a master of laws in agricultural law, which I think is the only program in the country that does that. But even more than that, it is really a clearinghouse for all kinds of information. Last year, they had 430,000 visitors to their Web site, wanting to know about agriculture law.

It reminds me—I just finished a book on healthcare—there's now a new field of economics, called "healthcare economics." Agriculture is complicated enough, where there is a legitimate field of agriculture law.

But the Web site also had well more than 1 million hits. And 20 percent of those—this is just last year's numbers—20 percent of those were Federal employees.

So, this is a real resource that's available to everybody. Even our own Federal Government relies on it heavily. There's a lot of very constructive and positive things I could talk about with the National Agricultural Law Center. In fact, in your shop, Janie Hipp and Doug O'Brien are former directors of the center.

Nonetheless, I'm curious to hear your explanation about why the program is proposed to be terminated and how we might overcome the adverse effects of a termination.

Secretary VILSACK. Senator, this is just a reflection on the concern that has been expressed by the President and others, in terms of specific earmarks. This is a process that we need to undertake within the USDA, that we are undertaking within USDA, to establish a priority listing of things that need to be maintained and things that need to be continued, and to be able to explain and justify why they need to be continued. We're undertaking that. And in lieu of that, our budget reflects an elimination of all of those earmarks.

Senator PRYOR. Mr. Chairman, I'm not sure I agree with y'all's definition of "earmark," but that's something that we should talk about further, and maybe not in this context. But I do think it does provide a national service.

Thank you.

#### ADDITIONAL COMMITTEE QUESTIONS

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

## QUESTIONS SUBMITTED BY SENATOR HERB KOHL

## BROADBAND

*Question.* A recent Washington Post article called the U.S. Department of Agriculture (USDA) Rural Broadband Loan Program one of the “worst ideas in Washington.” The loan program is eliminated in your fiscal year 2012 budget, but there will still be money available from previous years to carry it out.

How do you respond to criticism that the program hasn’t focused on rural America?

*Answer.* The program is focused on rural America. The issues raised in the Washington Post article addressed concerns from the USDA inspector general that the program did not reach the most rural communities. USDA has used the statutory definition of “rural” for its Broadband program that was enacted through the 2002 farm bill and then revised the Broadband program in 2008. USDA had no authority to change the statutory definition and was pleased that the Congress enacted the inspector general’s recommendation to amend the definition of “rural” in 2008. This new definition of rural was used for the American Recovery and Reinvestment Act’s (ARRA’s) Broadband Initiatives Program (BIP) and is used today in our revised farm bill Broadband Loan program. I am also pleased to report that no farm bill broadband infrastructure loans to new borrowers were made under this administration using the old definition of “rural.” I am also pleased to report that the Rural Utilities Service (RUS) has addressed all Office of Inspector General (OIG) recommendations on the farm bill Rural Broadband Loan Program and as of March 24, the OIG has now closed the audit. If the Congress has concerns with the current statutory definition of rural for our Broadband program, we would be pleased to work with the subcommittee to draft a new standard.

*Question.* When will rural America truly be served by high-speed broadband, which is important for economic development?

*Answer.* Under ARRA, USDA received more than \$28 billion in applications for BIP. With our \$2.5 billion in budget authority, we were pleased to leverage these funds into 320 awards totaling in excess of \$3.5 billion. In Wisconsin, USDA made 15 BIP awards totaling in excess of \$90 million. For example, USDA provided a \$15.5 million loan and \$15.5 million grant to Chequamegon Communications Cooperative, Inc. (CCC) to offer high-speed broadband to 31 rural communities in northern Wisconsin. CCC’s network will bring high-speed fiber to more than 3,000 new customers including several community anchor institutions. To further leverage this BIP award, CCC partnered with the State of Wisconsin on another ARRA project to bring high-speed Internet to schools and libraries in the area. The project will create or save 66 jobs.

Regrettably, we did not have sufficient resources to reach every unserved area in rural America. To help reach families and business in areas unserved by BIP or the Department of Commerce’s Broadband Technology Opportunities Program (BTOP), USDA made \$100 million in awards to satellite service providers to lower the cost of installation and monthly broadband service to areas that remain unserved after all BIP and BTOP awards were made.

Finally, USDA has other broadband programs to assist with bringing broadband to rural areas. Our Community Connect Grant program is specifically targeted to rural communities that have no broadband service. The 2008 farm bill Rural Broadband Loan Program offers loans to bring broadband to underserved and unserved communities. Both programs are operating under carryover funding this fiscal year and were part of the President’s fiscal year 2011 budget request. The President’s fiscal year 2012 budget did not request funds for the farm bill loan program but did request an additional \$17.8 billion for the Community Connect Grant program. The fiscal year 2012 budget did not request additional funds for the Broadband program because it anticipated sufficient carryover funding would be available.

## RENEWABLE ENERGY

*Question.* USDA was given a clear and urgent mandate to promote the development and expansion of renewable energy, to help diminish the Nation’s dependence on fossil fuels. Recent oil price volatility has caused us to refocus on this charge. Substantial mandatory funding was included in the farm bill for this purpose. This subcommittee needs to know what USDA has done with this mandate and the funding you received. Specifically:

Please describe the current state of implementation of USDA’s renewable energy programs.

Answer. The interim rules for the Advanced Biofuel Payment Program and the Repowering Assistance Program were published in the Federal Register on February 11, 2011. The interim rule for the Biorefinery Assistance Program was published in the Federal Register on February 14, 2011. Notices of funds availability and a notice contract of proposal for these programs were published in the Federal Register on March 11, 2011. The interim rule and Notice of Funds Availability for the Rural Energy for America Program (REAP) are expected to be published in the Federal Register by April 14, 2011. The Rural Energy Self Sufficiency Initiative was not implemented because no funds have been appropriated for this program.

*Question.* What are the timelines you envision for bringing new energy sources on line to reach consumers?

Answer. New energy supplies from biofuels currently being developed by the Biorefinery Assistance Program will take 3–5 years to allow for plants to be built, ramped up, and for supplies to reach consumers. Less complex renewable energy and energy efficiency projects involving known technologies are being completed anywhere from a few months to a few years.

*Question.* What challenges are slowing achievement of your goals?

Answer. Interest in our programs has never been greater. In terms of market concerns: the availability of private-sector capital and investments necessary to develop new biofuels and biorefineries is a challenge. Some lenders are risk averse and the Department has worked closely with the industry and the investment community to address this issue.

*Question.* We need to know which of these programs work and which do not. How are you measuring success and what can you tell us about successes and failures?

Answer. All of our programs are working, very popular, and in the case of REAP, producing measurable results. While awards have been made, none of the construction projects have been completed. In terms of applicants: REAP had 2,400 successful applicants in 2010; it helped to provide an investment of \$159 million in renewable energy and energy efficiency projects in rural America with less than \$84 million of Government grants and helped to produce or save more than 2,900 megawatt hours of energy. The Bioenergy Program for Advanced Biofuels is providing incentive payments for the production of advanced biofuels. The program made payments of \$19 million to 140 recipients that produced advanced biofuel during fiscal year 2010. We measure success of our programs by the geographic diversity of the program funds, funding a wide range of project technologies, jobs creation, energy production, energy conservation, leveraging other funds with program funds, and by providing loan guarantees for the development of new fuels that will meet the energy demands of our Nation. Upon request, the Rural Business Service (RBS) will provide summary data for all of the title 9 RBS programs.

*Question.* Please describe how you are coordinating the energy initiatives within USDA, and with land grant universities' research efforts.

Answer. USDA is working within the Department and with other Federal departments and organizations, including the land grant universities, on furthering renewable energy initiatives and programs. Efforts include the following intra-/inter-governmental panels, councils, working groups, and boards.

As an extramural research, education, and extension agency, the National Institute of Food and Agriculture (NIFA) works directly with land grant universities and others to implement sustainable bioenergy strategies. These extramural groups carry out the needed work to advance programs. This is further coordinated with NIFA review of the State plans of work for noncompetitive funding. Competitive funding typically brings together university faculty, Federal scientists, industry, and others to meet national needs related to advancing bioenergy. This leverages and coordinates Federal, State, and private funding in most cases.

The USDA Energy Council mission is to advance the contribution of agriculture and forestry in rural America in promoting the Nation's achievement of energy security through the efficiency and effectiveness of the Department's numerous energy-related programs and initiatives. Chaired by the Secretary of Agriculture and consisting of the Under Secretaries and other senior managers, the Energy Council leads the Department in policy development and efforts to reach all audiences to inform them about USDA energy programs and regulations. The council ensures that these audiences are aware of the Department's comprehensive energy program and also understand how it fits into the United States' overall energy policy.

The USDA Energy Council Coordinating Committee consists of staff from all USDA mission areas who work on energy issues, coordinates energy-related activities among USDA agencies and performs duties as assigned by the Secretary as the Energy Council chair, or the Energy Council as a whole.

The Biomass Research and Development Board is co-chaired by USDA and the Department of Energy (DOE). The board coordinates the Governmentwide research

initiatives and activities for the purpose of promoting the use of bio-based products, power, and biofuels. Members of the board also include the National Science Foundation (NSF), the Environmental Protection Agency (EPA), the Departments of the Interior and Defense, and the Office of Science and Technology Policy.

The Biomass Research and Development Advisory Committee is a group of approximately 30 individuals from industry, academia including land grant universities, and State government. The committee is responsible for providing guidance to the Biomass Research and Development Board on the technical focus of the Biomass Research and Development Initiative.

The National Agricultural Research, Extension, Education and Economics Advisory Board's Renewable Energy Committee was created by the Congress in 2008. This committee annually submits to the advisory board a report that contains its findings and any policy recommendations to the USDA in preparation for the annual budget. The committee also consults with the Biomass Research and Development Technical Advisory Committee.

*Question.* How is USDA coordinating efforts with other Federal, State, and private entities to make sure the most efficient use of public dollars is taking place?

Answer. We coordinate with DOE, using their environmental reviews when available for biorefinery assistance projects and we are working with DOE grant recipients, where we guarantee loans to build biorefineries that will help to end our dependence on foreign sources of petroleum. The USDA works closely with DOE to provide the best energy expertise to our field staff and ensure that all of our project loans and grants are awarded in accordance with the highest professional standards. We work closely with EPA to ensure that their expertise is utilized as well as their efforts to promote anaerobic digester technology. We ensure that applications for assistance are selected on a basis of competition using priority scoring so that applicants selected have a project that is meritorious. REAP provides a grant for no more than 25 percent of eligible project costs, up to a maximum amount to an eligible applicant; and the majority of funds are invested by the applicant who put their own money into the project. Our programs succeed by utilizing State incentive programs, renewable portfolio standards, utility incentives, and local and national lenders making solid investments in partnership with applicants throughout the Nation.

*Question.* What is your evaluation of the Department's success in meeting its renewable energy mandate?

Answer. Based on the purpose of the program and the results tracked, we determine whether the program is successful. In fiscal years 2009 and 2010, REAP helped nearly 4,000 rural small businesses, farmers, and ranchers save energy and improve their bottom line by installing renewable energy systems and energy efficiency solutions that will save a projected 3 billion in kWh—enough energy to power 390,000 American homes for a year. In 2010, the Biorefinery Assistance Program provided a conditional guaranteed for \$55 million private loan to the advanced bioenergy producer Sapphire, once completed the facility is expected to generate 72 million kWh in renewable energy, once the biorefinery is built. In 2010, the Bioenergy Program for Advanced Biofuels provided \$18.5 billion in support of the generation of 53 billion BTUs, and the Business and Industry Guaranteed Loan program provided \$43.4 billion in support of renewable energy infrastructure.

#### PLANT/ANIMAL HEALTH

*Question.* More than \$830 million is requested for protection against invasive species, pests, and diseases. However, there is no indication in the budget what the real costs of these various threats are, in terms of market disruption, lost income, diminishment of producers' capital, etc. It is also unclear what the value is of the Department's strategies implicit in this request. This budget asks the subcommittee to make decisions regarding allocating discretionary resources absent any cost/benefit framework.

This subcommittee needs to know what are the costs facing the economy of these different threats.

Answer. Invasive pests and diseases can cause huge losses and control and eradication costs. For example, we estimate that a half-week delay in finding an animal disease outbreak can increase cleaning, disinfection, depopulation, and quarantine costs by \$70 million per incident (on average). The light brown apple moth (LBAM) attacks more than 2,000 types of plants and trees found throughout the United States and we estimate that it has the potential to cause production losses ranging from \$700 million to \$1.6 billion annually if it spreads. The Asian long-horned beetle's total potential economic impact on industries in New York and New England is estimated at \$1.1 billion in annual losses.

*Question.* In addition, what are the benefits that accrue from expenditures on the various programs?

*Answer.* The benefits of Animal and Plant Health Inspection Service's (APHIS') pest and disease programs generally include the prevention of damage to the commodity or resource at risk, reduced control costs over time, and continued trade opportunities. For example, the Asian long-horned beetle (ALB) program protects forest resources and urban trees nationwide, as roughly 30 percent of U.S. trees are potential ALB hosts. If urban areas across the United States were infested with ALB, the estimated potential national impact would be a loss of 35 percent of the canopy cover and almost \$815 billion in compensatory value. The benefits of the program include protecting these trees in neighborhoods and parks across the country as well as preventing the spread of the pest into New England's hardwood forests, which support the timber, tourism, and maple syrup industries. The LBAM program prevents the spread of the pest through regulatory and control efforts. Without the regulatory program to prevent LBAM from spreading, U.S. trading partners would restrict, if not ban, imports of U.S. fruits, vegetables, and nursery stock into their countries.

*Question.* What basis did the administration use to determine the priorities implicit in the request?

*Answer.* Our main focus was to determine those programs where we could have a positive impact on the health of American agriculture and where we could best contribute to reducing losses caused by pests and diseases. Recognizing the need to restrain Federal spending, we reviewed our programs to determine where we could do things differently. In some areas, the agency was able to take advantage of program successes to realize savings (examples include the decreases requested for the cotton pests, screwworm, pseudorabies, and avian influenza programs). APHIS also identified programs that could be reduced since eradication or control of agricultural pests or diseases are no longer considered feasible (such as emerald ash borer), or where we will request greater contributions from partners or those that directly benefit from program efforts (such as the potato cyst nematode program).

*Question.* Please identify the administration's priorities within these components.

*Answer.* Ensuring our ability to prevent the entry of exotic pests and diseases, quickly detect those that do enter the United States, and respond in a timely way remain our highest priorities. Our budget proposes to maintain our strong infrastructure of highly skilled employees and cooperative relationships with States and industry. Additionally, there are several emerging needs for which we request more funding.

APHIS developed the National Animal Identification System in 2004 to enhance the United States' capability to minimize the spread of foreign and domestic animal diseases of concern. Since then, USDA has obtained input from stakeholders to develop a more efficient traceability system. Detecting a disease before many animals have been exposed to it limits the spread and allows for more timely eradication and management efforts. The proposed funding level for fiscal year 2012, which includes an increase of \$8.85 million for a total of \$14.15 million, more accurately reflects how much the program needs to carry out essential activities and retain advances made to date.

APHIS faces a growing workload in the area of genetically engineered (GE) plants. The requested increase for our Biotechnology Regulatory Services (BRS) program, while significant, is needed to implement improvements, expand our regulatory program for biotechnology, and resolve the challenges currently faced by the program.

The agency is responsible for enforcing the Animal Welfare Act (AWA). APHIS' Animal Welfare program carries out activities designed to ensure the humane care and treatment of animals. USDA's Office of Inspector General (OIG) recently conducted a review of APHIS' inspections for AWA compliance, specific to problematic dog dealers who have committed repeat and serious violations. OIG concluded that APHIS should shift its compliance efforts from an education focus to an enforcement focus, improve inspection performance, and seek legislation regarding the Internet sale of dogs. APHIS is responding to the audit and needs additional resources to address the improvements noted in the OIG audit.

The fiscal year 2012 budget also includes increases for programs that target specific pests, such as the Asian long-horned beetle (ALB) and the European grapevine moth (EGVM). The ALB program has eradicated two ALB outbreaks (in Chicago, Illinois, and Hudson, New Jersey) and has successful tools and strategies to attack this pest. The program is now addressing a large outbreak near Worcester, Massachusetts, that threatens New England's hardwood forests. With adequate resources, the program can prevent ALB from spreading into the valuable forests and ultimately eradicate it. APHIS is also addressing EGVM (detected in fiscal year 2009)

in California. With a strong early response, APHIS and State and industry cooperators have greatly reduced EGVM populations. Continued resources are necessary to ensure that the pest is eliminated.

*Questions.* In the future, this subcommittee requests that this segment of the budget (at least) be supported by a rigorous cost-benefit analysis, to better focus the Department's plans and strategies, and to equip this subcommittee with adequate tools to make the most effective decisions.

*Answer.* We will make every effort to provide this information with our budget request in the future.

#### GENETICALLY MODIFIED ORGANISMS

*Question.* GE or genetically modified organisms (GMOs) were in the news again last week—specifically, GMO alfalfa and GMO sugar beets. Obviously, there are a variety of concerns surrounding the proliferation of genetically modified (GM) species.

What assurances can you provide that new GM crops will not result in drift-related problems, contaminating nearby species?

*Answer.* Before a GE crop can be commercialized, APHIS thoroughly evaluates it to ensure there is no plant-pest risk, thereby enhancing public and international confidence in these products. Crops being field tested must be grown under a permit or notification depending on the type of crop and its potential risk. APHIS imposes confinement measures for field trials of regulated GE organisms to safeguard against the unintended release of GE materials into the environment and also limit gene flow. Safeguards can include surveying for local wild relatives; removing plant reproductive structures (detasseling); cleaning equipment; and bagging flowers to contain pollen. APHIS also conducts thorough inspections of field trials to ensure that biotechnology organizations are adhering to APHIS regulations and permit conditions. Once APHIS has made a determination of nonregulated status, the GE organisms do not fall under APHIS regulatory purview and can be moved and planted freely in the United States.

*Question.* Does this budget request, for instance for BRS, provide sufficient resources for the Department to meet marketplace demands and ensure public safety regarding GMOs?

*Answer.* The fiscal year 2012 budget request for the BRS program includes an increase of \$12,072,000 to, among other things, enhance APHIS' compliance program and improve the petition process for nonregulated status. Specifically, the increase will allow BRS to inspect additional field test permit acreages, develop emergency response plans for APHIS to rapidly respond to incidents involving regulated GE organisms, enhance port of entry inspection procedures and processes, increase the ability to respond to emerging technologies, and fully implement the Biotechnology Quality Management System, a voluntary program that helps participating biotechnology researchers and companies develop sound management practices that enhance compliance with regulatory requirements for field trials and movement of regulated GE organisms. APHIS has also requested funding in the fiscal year 2012 budget to begin a multiyear gene flow status and trends monitoring program. This program will develop information about the extent, scale, and measurement of gene flow in major agricultural regions in the United States.

#### RESEARCH

*Question.* Mr. Secretary, the budget proposes to decrease funding for the two USDA research agencies, the Agricultural Research Service and NIFA, by \$180 million. In NIFA alone, nearly 20 programs are eliminated.

I understand and appreciate the need to consolidate or eliminate programs, especially in this budget environment. How did you determine which programs to eliminate and which to protect? Are you trying to steer people towards competitive funding?

*Answer.* The administration strongly believes that peer-reviewed competitive programs that meet national needs are a more effective use of taxpayer dollars than earmarks that are provided to specific recipients. The fiscal year 2012 budget proposes to eliminate these targeted earmarks. Within necessary budget constraints, it is critical that taxpayer dollars be used for the highest quality projects, those that are awarded based on a competitive peer-reviewed process to meet national priorities. Therefore, some broad aspects of many research topics currently addressed by earmarked projects can be included in the scope of the Agriculture and Food Research Initiative (AFRI) program in fiscal year 2012. Other topics will be addressed under other broader based, competitively awarded Federal programs supported with non-Federal funds administered by State-level scientific program managers.

## AGRICULTURE AND FOOD RESEARCH INITIATIVE

*Question.* In AFRI specifically, over the past few years, have you received more qualified applications than you have been able to fund? How do you coordinate with other Federal and State research agencies to prevent duplication?

*Answer.* There are always more qualified applications for AFRI than we are able to fund. In fiscal year 2009, the first year of the AFRI program, NIFA received 2,424 applications, of which 835 ranked well enough in the peer review process to qualify for funding. Funds were available to support 470 of those applications. For fiscal year 2010, funds are available to support the applications processed to date.

NIFA has increased discussions in recent years with agencies such as NSF, the National Institutes of Health (NIH), and others to ensure coordination and lack of duplication. NIFA is actively partnering with these agencies to offer joint programs in areas of common interest, creating greater visibility and impact for agricultural issues. For example, NIFA has recently partnered with NIH to offer a program entitled, "Dual purpose with dual benefit: Research in biomedicine and agriculture using agriculturally important domestic species." This program allows NIFA to leverage its scarce dollars while engaging a broader research community in work relevant to NIFA's mission.

## RESEARCH

*Question.* Is there concern about the long-term effects that occur from stopping or significantly reducing agricultural research projects mid-stream? Typically, do the researchers stay in agriculture research, or do they move on to something else?

*Answer.* While the administration proposes to eliminate earmarks and emphasize peer-reviewed competitive programs, we do expect earmark projects funded in fiscal year 2010 to fully meet research goals and objectives outlined in the proposals submitted to and approved by the agency. The majority of these projects included multiyear funding that would allow for the orderly completion of the specific research outlined in these proposals. The agency has encouraged recipients of earmarked projects to submit proposals to the competitive grant programs of the agency. Researchers generally continue to stay in agricultural research but may also look to alternative sources to support their work.

## SETTLEMENTS OF DISCRIMINATION CASES

*Question.* Recently the Department announced settlement processes for discrimination cases involving Hispanic and women farmers and ranchers.

Please summarize the current status of the *Pigford*, *Love*, *Garcia*, and *Keepseagle* cases.

*Answer.* On February 18, 2010, USDA worked with the Department of Justice (DOJ) to enter into a settlement with Black farmers for \$1.25 billion, known as *Pigford II*. And on December 8, 2010, President Obama signed legislation that will provide \$1.15 billion in funding for this settlement beyond the \$100 million provided for in the 2008 farm bill. When this settlement receives final approval by a Federal court, we look forward to bringing closure, once and for all, to the long-standing litigation brought by Black farmers against USDA.

On October 19, 2010, USDA and DOJ announced the settlement of a class action lawsuit filed against USDA by Native American farmers (*Keepseagle*) alleging discrimination by USDA. The settlement, which received preliminary approval by a Federal court, ends litigation concerning discrimination complaints from Native Americans generally covering the period 1981–1999. Under the settlement agreement, \$680 million will be made available from the Judgment Fund to eligible class members to compensate them for their discrimination claims, and tax relief. An additional \$80 million will be provided by USDA for the forgiveness of existing farm loan program debt.

On February 25, 2011, USDA and DOJ announced a unified claims process for Hispanic and women farmers and ranchers who allege discrimination that occurred between 1981 and 2000. Under the plan, the United States will make available at least \$1.33 billion from the Judgment Fund to eligible claimants to resolve their discrimination claims. USDA will provide an additional \$160 million in debt relief to successful claimants with eligible farm loan program debt. USDA is presently conducting outreach across the country regarding the claims process and is in the process of procuring an independent administrator and adjudicator to carry out the claims process. Once the administrator and adjudicator are in place, the opening of the 180-day period for filing claims will be announced.

*Question.* Are there other situations involving groups of aggrieved applicants that remain unresolved?



Answer. On March 15, 2011, a group of *Garcia* plaintiffs filed a complaint challenging the voluntary claims process. This complaint has been referred to the judge presiding over *Garcia* and the Government will argue for its swift dismissal. We are moving forward to fully implement the Hispanic and Women Farmers and Ranchers Claims Process and the new lawsuit has no impact on our outreach and preparation. USDA is confident that the court will uphold the legality of the voluntary claims process.

*Question.* What processes have you implemented to ensure equal public access to all farm credit programs?

Answer. The Farm Service Agency (FSA) has more than 2,400 offices located throughout the country. While not all of the offices have credit officials permanently stationed in them, FSA employees are cross trained to provide basic information on credit programs and arrange an appointment with the credit official if needed. Each FSA office delivering credit programs has developed a marketing/outreach plan to ensure programs are marketed to all sectors of the served communities. FSA credit forms have been streamlined to make the application process less daunting. Currently FSA is working on a "plain language guide to FSA loans" that when completed will provide for a layman's guide to obtaining credit.

#### RENEWABLE ENERGY

*Question.* REAP has been in existence, in some form, since the fiscal year 2002 farm bill. Substantial mandatory and discretionary funding has been spent on this program over the years. This budget seeks to supplement the \$70 million of mandatory funds available in 2012 with an additional \$37 million of discretionary dollars. Why is additional funding needed for this specific program?

Answer. The demand for REAP far exceeds the funds available in this program. In 2010, more than 300 eligible applications did not receive funding. This program encourages investment; and successful applicants make tangible investments in more energy conservation, more renewable energy production, and a more productive economy.

*Question.* In the past, the bulk of this funding was used for on-farm activities such as grain dryers. Is this the best use of this funding?

Answer. Through the interim rule the agency is limiting equipment replacement to similar size or capacity equipment. The change is designed to provide an equitable distribution among a range of technologies and balance our portfolio without giving any project type an undue advantage.

*Question.* Would utilizing these funds in alternative energy programs be more effective in moving the United States toward energy independence?

Answer. REAP is geared towards rural areas and small businesses. Achieving energy independence is a goal that requires a comprehensive effort and will involve every community in America, rural and urban. Energy efficiency has played a major role in reducing our demand for energy and most experts predict we will continue to do more with less energy in the future. Providing the mechanisms for energy efficient rural communities must be part of achieving energy independence. While we aren't going to totally replace fossil fuels in the near term, we need to rapidly grow our ability to use alternative advanced biofuel and rural communities are on the frontlines of that effort. The investment in REAP and other USDA Energy programs is a sound investment with real dividends for America.

#### WATER AND WASTE DISPOSAL PROGRAM

*Question.* The second largest source of budget authority expenditures in the USDA Office of Rural Development (RD) is the Water and Waste Disposal program. Projects are typically funded through loan/grant combinations, with the loan component averaging 65–70 percent of the project cost.

Have you given thought to requiring communities to rely even more heavily on loans?

Answer. RD Water and Waste Loan and Grant activities are exclusively focused on rural water and waste infrastructure needs, working with only rural areas with populations of 10,000 or less. Most RD projects serve areas well less than a 10,000 population. Applicants must demonstrate that they need Federal assistance because they cannot obtain credit from commercial lenders or investors, and they have urgent needs for water or wastewater improvements. While some communities are able to take on additional loan debt, many of our applicant communities are not. The average cost for water and waste disposal service in rural America has increased as the cost of construction, operation, and maintenance of water and waste disposal systems has increased. The average cost per equivalent dwelling unit was

\$43 per month for water service and \$45 per month for waste disposal service for the projects we funded in fiscal year 2010.

The program is a needs-based program, where loan and grant funds are combined based on a strict underwriting process to keep rates reasonable for rural residents. That underwriting process considers the cost of the project, the current ability of a community to take on additional debt, and the level of reserves that are needed for replacement of short-lived assets (i.e., motors, pumps, etc.), as well as other factors necessary to ensure that the project is feasible.

In fiscal year 2010, RD obligated 1,052 loans of which 315 (30 percent) were cases where the loan component was greater than 70 percent of the funding provided.

*Question.* Can this be done such that grant funding is conserved for the most remote and low-income rural communities?

*Answer.* Grant funding is currently conserved for the communities with the greatest financial need. We continue to implement our funds through an underwriting process that determines the loan and grant mix needed to fund the project. Grant levels are subject to the availability of funds and we are not always able to provide the level of grant funding a community has requested. Therefore, we encourage and often facilitate the partnering of our funding with that of other Federal, State, and local programs to keep the user rates as reasonable as possible.

#### HOUSING

*Question.* This budget announces a fee change in administration policy regarding rural housing support. Many long-standing rural housing programs are eliminated, and the flagship Single-Family Housing Direct Loan program is slashed. The following housing programs are eliminated:

- Very Low-Income Housing Repair Loans;
  - Multifamily Housing Guaranteed Loans;
  - Credit Sales of Acquired Property;
  - Self-Help Land Development Loans;
  - Mutual and Self-Help Housing Grants;
  - Housing Preservation Grants; and
  - the Multifamily Housing Revitalization and Preservation Program.
- And the Single-Family Housing Direct Loan Program is reduced from an historic annual level of \$1.1 billion to \$211 million. This loan program, for very low- and low-income rural households, will fund fewer than 1,700 houses nationwide.

What is your vision of the future role the Federal Government will play regarding providing support for rural housing?

*Answer.* Housing is a vital economic pillar in rural America for creating wealth for communities and homeowners. USDA realizes that rural populations tend to be more economically challenged with lower incomes and fewer housing choices than their suburban and urban counterparts, and therefore we continue to offer a no-down payment homeownership program through both the Single-Family Housing Guaranteed and Direct programs. Providing credit in areas that lack private investment is a critical function of USDA RD. To address the need for credit—particularly in the rural housing market—RD has dramatically increased the Single-Family Housing Guaranteed Loan Program in recent years, doubling the Government's investment from \$12 billion in 2010 to \$24 billion in 2011. A fee structure that is consistent with other Federal housing agencies has eliminated the requirements for additional budget authority.

*Question.* What evidence do you have that private housing credit markets have recovered sufficiently to meet credit needs in rural America?

*Answer.* RD's section 502 guaranteed loans have taken on a greatly increased role in providing adequate housing credit in rural America. The program increased from 31,000 guarantees for \$3 million in fiscal year 2006 to 133,000 guarantees totaling nearly \$12 billion in fiscal year 2010. The market has clearly demonstrated a need for USDA's home loan program as lenders have increased activity in rural areas. We expect this growth to continue.

The private housing credit markets have never fully met the needs in rural America. These credit markets have changed, with RD stepping in to play a crucial role to help assure adequate credit will be available to rural Americans and stabilize mortgage availability. The situation would be worse without the USDA program.

The private housing credit markets for affordable rental loans guaranteed through the section 538 program have not changed the past several years. RD has maintained its relationship with the Government National Mortgage Association (Ginnie Mae) to secure loans guaranteed under the section 538 program. Through this relationship the vast majority of the loans guaranteed under the section 538 program

prior to the credit crisis and after the crisis have been purchased by private investors as pooled loans in Ginnie Mae securities.

*Question.* Does it make sense to have a nationwide housing loan program that serves fewer than 1,700 families?

*Answer.* The Single-Family Housing Direct Loan Program provides subsidized mortgages to low- and very low-income families, who cannot obtain credit elsewhere, so that they can own modest, decent, safe, and sanitary homes in rural areas. In some instances, qualified borrowers can reduce the interest rate to 1 percent. The fiscal year 2012 budget provides funding to support the needs of rural America's neediest homeowners. The funds are targeted to very low-income borrowers who would not be eligible for private-sector financing. The Direct Loan program enables these borrowers the opportunity to purchase a home.

While it's true that the Single-Family Housing Guaranteed Loan Program performance from 2010 shows that 30 percent (more than 40,000) of the loans were to low-income home buyers, there will always be a segment of the population that will not qualify for the guaranteed program because of the need to qualify for private-sector credit. It is USDA's intent to meet that need, however large or small, to the extent possible given our budget constraints.

*Question.* In the face of eliminating the multifamily revitalization program, how does USDA plan to protect the Government's interest in its large multifamily housing portfolio?

*Answer.* The USDA plans to protect the Government's interest in its large multifamily housing portfolio through a proposed budget increase in the Section 515 Direct Rural Rental Housing Program for fiscal year 2012. Traditionally, the way to fund revitalization has been through the section 515 program with rehabilitation loans. The fiscal year 2012 budget proposes to increase the section 515 program from \$69.5 million to \$95 million.

*Question.* For years USDA has cultivated the expansion of Self-Help Housing grantee organizations across the country. What assistance can the Department provide to these organizations now that you are eliminating grant funding?

*Answer.* USDA intends to continue a partnership in the immediate future with the Self-Help Housing Technical and Management Assistance (T&MA) contractors to provide guidance to Self-Help Housing grantees. As we transition out of a program that we recognize has made major contributions to rural housing, we will no longer have the ability to fund the administrative costs associated with Self-Help Housing due to budget constraints. Together with the grantees and T&MA contractors, USDA will identify other means for grantees to garner fees for their services and address regulations that will accommodate new ideas.

#### RENTAL ASSISTANCE

*Question.* Please describe in detail the forecasting methodology used to develop contract renewal estimates (number of contracts and costs) for the President's budget.

*Answer.* In 2004, the RD Program Office and Chief Information Office developed a rental assistance forecasting tool that incorporated the Office of Management and Budget's (OMB's) inflation rate to forecast the exhaustion of funds from all the rental assistance contracts. The forecasting methodology reviews actual rental assistance usage over the last 3 years, develops an average usage rate, and applies the inflation factor to determine the amount needed in the contract based on the number of units with rental assistance. The methodology was reviewed by the Government Accountability Office (GAO), which provided comments on the inflation adjustment that were incorporated in the tool in 2005.

*Question.* How do you determine inflation factors for utility increases, etc.?

*Answer.* Inflation factors are determined within the forecasting tool using the OMB inflation rate.

*Question.* Is the same methodology used for section 515 and farm labor housing?

*Answer.* The same methodology is used for section 515 and farm labor housing.

*Question.* Has this methodology been reviewed by either OIG or GAO?

*Answer.* This methodology was reviewed by GAO in 2005.

*Question.* If so, what were their comments and what changes were implemented based on those comments?

*Answer.* GAO suggested a change in the inflation adjustment to add the inflation factor one time, rather than for each year in a contract. The change was incorporated.

*Question.* Please provide, by year since 2008, the total President's budget request, including the number of contracts and average costs.

*Answer.* [The information follows:]

Fiscal year	Budget request (millions)	Appropriation (millions)	No. of units under contract	Amount obligated (millions)	Average per year
2008 .....	\$567	\$478.7	121,568	\$478.7	\$3,937
2009 .....	997	997.0	210,618	902.5	4,285
2010 .....	897	980.0	219,231	980.0	4,470
2011 .....	966	980.0	211,111	252.8	4,340
2012 .....	906	.....	204,500	.....	.....

*Question.* Also provide the appropriated amount, the number of contracts actually funded and the average cost.

*Answer.* [The information follows:]

Fiscal year	Budget request (millions)	Appropriation (millions)	No. of units under contract	Amount obligated (millions)	Average per year
2008 .....	\$567	\$478.7	121,568	\$478.7	\$3,937
2009 .....	997	997.0	210,618	902.5	4,285
2010 .....	897	980.0	219,231	980.0	4,470
2011 continuing resolution .....	965	980.0	58,237	252.8	4,340

*Question.* For each year since 2008 please provide the average actual duration of contracts funded.

*Answer.* Starting in fiscal year 2008, Rental Assistance contracts were funded for a 1-year period. In fiscal year 2009, of the contracts funded in fiscal year 2008, approximately 9.5 percent of the contracts exhausted funds prior to the end of the 1-year period. In fiscal year 2010, of the contracts funded in fiscal year 2009, approximately 3 percent of the contracts exhausted funds prior to the end of the 1-year period.

*Question.* Please describe how RD controls the escalation of rental assistance costs.

*Answer.* The Housing Act of 1949 requires that borrowers under Section 515 Rural Rental Housing and Section 514 Farm Labor Housing programs submit a budget annually to demonstrate the costs associated with operating rental housing. This includes requests for rent increases, which must be justified by the borrower. Since rental assistance provides some of the operating income to support operations, the Rural Housing Service (RHS) field staff work closely with borrowers and management agents in reviewing the budget and determining appropriate costs.

#### MULTIFAMILY REVITALIZATION INITIATIVE

*Question.* Please describe in detail all of the tools available in the Multifamily Housing Revitalization Initiative toolbox, and how RD utilizes this mix of options to sustain affordable housing in rural areas.

*Answer.* The Multifamily Housing Revitalization Demonstration Program uses four tools to financially restructure these affordable rural rental properties. These tools are a modification of the existing section 515 loan, a zero-interest rate section 515 loan, a soft second section 515 loan (a second loan that has its interest and principal deferred to a balloon payment) and a revitalization grant. In addition, there are two other programs which, although not technically revitalization, are funded from the same account. They are the Preservation Revolving Loan Fund and RD vouchers. The properties are reviewed and underwritten to determine the property's financial needs, after which a combination of tools are used to ensure the property is financially sound and remains in the affordable housing portfolio for many years. In addition to these section 515 revitalization tools, direct loans are available to support revitalization activities of the portfolio as well. The section 538 loan guarantee has also been used in the past to address immediate capital repair needs; however, funding for section 538 is not requested in the fiscal year 2012 budget. Many revitalization projects also use third-party funding, such as low-income housing tax credits, as additional leverage for revitalization of section 515 properties.

*Question.* By year, for the life of the initiative, please provide the President' budget request, the appropriated amounts, and how those funds were used.

*Answer.* [The information follows:]

[Dollars in millions]

Fiscal year	Budget request (budget authority)	Appropriated (budget authority)	Number of deals	Soft second loans	Grants	Deferrals	Zero-percent section 515 loan	Presentation revolving loan fund	Vouchers
2006	\$214.00	\$18,976	76	\$4.5	\$0.2	\$48	\$0,280	\$6,415	\$0,620
2007	74.25	18,853	87	2.8	0.5	56	2,561	9,151	3,000
2008	27.80	27,804	135	13.0	0.4	100	12,649	13,793	6,205
2009	.....	27,714	94	5.3	0.2	50	15,021	15,398	6,751
2010	26.62	43,191	142	21.5	0.3	117	5,057	20,897	7,595
2011	18.00	43,191	8	3.7	.....	.....	0.391	7,061	4,557
Total	342.67	179,730	536	50.8	1.6	371	51,030	80,820	28,730

*Question.* For vouchers specifically, please provide by year the President's budget request, the amount appropriated, the number and amount of vouchers offered (distinguishing between new and renewals), the number and amount of vouchers accepted (also distinguishing between new and renewals), and how surplus voucher funding was utilized.

*Answer.* [The information follows:]

**RURAL DEVELOPMENT VOUCHER PROGRAM**  
[Dollars in millions]

Fiscal year	President's budget	Appropriated	Dollars obligated	Vouchers issued		Total issued
				New	Renewals	
2006	.....	\$16,000,000	\$620,000	211	.....	211
2007	\$74,250,000	15,840,000	3,000,000	1,098	.....	1,098
2008	27,800,000	4,965,000	6,205,375	1,013	1,088	2,101
2009 <sup>1</sup>	.....	4,965,000	6,751,534	811	1,251	2,062
2010	4,965,000	16,400,000	7,595,644	764	1,481	2,245
2011 <sup>2</sup>	18,000,000	16,400,000	3,610,843	563	577	1,140
<b>Total</b>	.....	.....	24,783,396	4,460	4,397	8,857

<sup>1</sup>Indicates the President's budget did not request funds for this program and proposed a \$20 million rescission from carryover balances.

<sup>2</sup>Fiscal year 2011 obligations are as of March 31, 2011.

Carryover funding that was not used for vouchers in the appropriated fiscal year was used to fund the Multifamily Preservation and Revitalization Program, for voucher administration contracting payments, and for information technology upgrades.

*Question.* What percentage of voucher recipients move from their original place of residence?

*Answer.* RHS experience in the program as of October 2010 is that 12.6 percent of the former section 515 tenants receiving vouchers move from their original apartment after the property leaves the section 515 program.

*Question.* Please describe the information systems RD utilizes to manage the voucher initiative. What socioeconomic data do you collect on voucher recipients?

*Answer.* USDA maintains a database system on all tenants in section 515 and section 514 housing developments. As a borrower prepays the section 514 or 515 mortgage, or a foreclosure action occurs, tenant information is used to advise tenants of the availability of the voucher program. Once a tenant chooses to accept a voucher, USDA utilizes the services of a contractor, who has developed a Workflow Management System that houses landlord and voucher holder information. In addition, RHS is currently in the process of replacing and upgrading its current accounting database, which will manage the voucher certification and payment processes.

The agency collects demographic and income data on voucher holders at the time of issuance of the voucher. The tenant characteristics are captured in the Multifamily Information Systems database.

*Question.* Are vouchers always renewed for the same amount or have you instituted procedures whereby voucher amounts can be increased?

*Answer.* Generally, vouchers are renewed for the same amount. There are exceptions where the original amount of the voucher may have been reduced from the maximum amount available because the voucher amount exceeded the amount of the voucher holder's rent. If the voucher holder moves to another apartment where the rent is higher, the voucher amount is adjusted upward, not to exceed the maximum amount available. USDA has not instituted a cost of living or annual adjustment increase.

#### MICROENTERPRISE PROGRAM

*Question.* What is the status of implementation of the Microenterprise Program?

*Answer.* Rural Development, Rural Business-Cooperative Service published a final rule in June 2010 and began funding loans and grants during the fourth quarter of fiscal year 2010. Additionally, on July 19, 2010, the agency published a technical correction to the interim rule (1 CFR, part 4280, subpart D).

*Question.* Is this program showing success as you expected?

*Answer.* Yes, in fiscal year 2010, the Rural Business-Cooperative Service funded 63 direct loans in the amount of \$24,982,500, 62 automatic technical assistance grants in the amount of \$5,356,349, and 12 technical assistance only grants in the amount of \$1,289,500. It is anticipated that the intermediary will revolve the Rural Microentrepreneur Assistance Program loan funds twice in the 20-year term; and each ultimate recipient loan will assist one business and save a minimum of one job. Each loan to an ultimate recipient is expected to average \$15,000 to \$20,000. This equates to an estimated minimum 40 businesses assisted and 40 jobs created/saved per \$100,000 of Loan Budget Authority.

*Question.* At this stage of implementation, isn't it premature to request additional discretionary funding to supplement the mandatory funding that is available?

*Answer.* The program has already experienced success based on the overwhelming interest in the program, as a result of the 2010 Notice of Funds Availability (NOFA). The majority of available discretionary and mandatory funding has been provided during the first round of solicitation in 2010. To date, \$34.9 million has been awarded to 82 microlenders in 38 States.

The reduced level of funding included in 2011 will be fully utilized when the 2011 NOFA is published. Already, there are 60 applicants requesting \$17.1 million in programmatic funds in the funding cue. This compares to the approximate \$16 million program level provided for 2011. If the Congress determines that additional discretionary funds are needed, it would meet the demand of rural small businesses.

*Question.* How are you measuring success?

*Answer.* We measure success of our programs by the number of jobs created/saved, businesses assisted, geographic distribution, and addressing communities with the greatest need.



## AGRICULTURAL EXPORTS

*Question.* The budget request includes an increase of \$20 million for the National Export Initiative (NEI). According to USDA, agricultural exports are forecast to hit a record of \$135 billion, this is \$9 billion more from the November forecast and higher than the previous record set in 2008.

Given the current budget atmosphere and ever shrinking resources, please explain why you believe this request is justified at this time.

*Answer.* The \$20 million request for NEI in fiscal year 2012 supports additional activities and staff positions that are necessary to reach the President's goal of doubling U.S. exports by the end of 2014. The Foreign Agricultural Service (FAS) will use these funds to enhance our activities in defending market access as well as expanding market access for U.S. agricultural products. Competitive opportunities around the globe are rapidly changing, as more and more countries enter into trade agreements and preferential arrangements. Although U.S. agricultural exports are currently strong and increasing, these changing international relationships will pose ever-increasing challenges to U.S. export competitiveness. We must also help educate more agricultural businesses on the benefits of exporting and provide technical assistance on reaching foreign customers.

To expand FAS export assistance efforts, \$18 million will be used to provide technical assistance and trade facilitation, both in the United States and in overseas markets, in order to strengthen the ability of U.S. producers and related agribusinesses to increase exports to a wider range of foreign markets. Domestic outreach efforts will include a special outreach to educate and support small- and medium-sized enterprises, which are a key focus of NEI. The remaining \$2 million will be used to bolster FAS's trade monitoring and enforcement efforts. This work will focus on key countries such as China, the European Union, Indonesia, Canada, Mexico, Japan, as well as on prospective Free Trade Agreement partners such as South Korea, Colombia, and Panama. With continued growth in exports come new and more complex opportunities for trade barriers and irritants, especially on sanitary and phytosanitary issues, and other technical issues. The additional resources will enable FAS to better support U.S. challenges to foreign actions that harm U.S. agricultural interests, as well as support U.S. defenses against trade cases brought against us, such as under the World Trade Organization.

## HUMANITARIAN FOOD ASSISTANCE

*Question.* News events daily remind us of a chaotic world where chronic and acute hunger threatens the lives of millions of people. As we have seen over the past few months, rising food prices around the world have caused instability in some of the most vulnerable places. Your budget includes level funding for Public Law 480 title II grants, which often provides the only meal a person will have during the day.

Given the current worldwide economic situation, do you believe your request is sufficient to meet the ever increasing demand for food assistance?

*Answer.* Although USDA is not responsible for administering the title II program, we understand the importance of food aid programs and appreciate the Congress' support in our efforts to alleviate hunger. Rising food prices do have an impact on hunger and certainly lead to political and economic instability worldwide.

Given competing priorities and current deficit-reduction strategies, we believe that amounts requested for fiscal year 2012 are sufficient. If unanticipated emergencies arise, the Bill Emerson Humanitarian Trust is available to supplement title II resources.

## FARM BILL CUTS

*Question.* The farm bill provides mandatory spending for a number of programs. Over the last several budget cycles the administration has proposed to limit several of these programs.

Can you discuss why the administration believes these limitations are needed and how you decide which programs to target?

*Answer.* The President believes that if we are to promote economic recovery, invest in our long-term competitiveness, and create opportunities for all Americans a comprehensive, balanced deficit reduction framework must be part of that strategy. The President's vision of "shared sacrifice" requires that mandatory programs be included in the comprehensive deficit reduction framework. There are a number of factors that have influenced which mandatory programs have thus far been targeted for reductions in the President's annual budget requests as well as how those reductions have been proposed. For example, President Obama made a campaign promise to eliminate farm program payments to wealthy individuals. Accordingly, since

taking office, the President's budget requests have consistently proposed reductions to mandatory farm programs to eliminate payments to wealthy individuals and better target the farm safety-net payments to individuals who need the assistance. These proposals have provided budgetary savings consistent with the President's campaign promises while preserving the basic structure of the farm safety-net programs so that the future of the farm program policies can be debated in the context of the next farm bill.

THE SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS, AND CHILDREN

*Question.* Mr. Secretary, the budget request includes an increase of \$138 million for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). According to the Economic Research Service, food prices are expected to increase 3–4 percent this year. Often times, when we see food prices rise, we also see a corresponding rise in WIC participation levels. Food becomes more expensive and so more people need assistance.

In light of food price increases, do you believe your request of \$7.4 billion is sufficient to cover the demand for this program?

*Answer.* The amount requested for WIC in the President's budget was based on estimates for the program derived from the most current data available at that time. However, the Food and Nutrition Service (FNS) recognizes that circumstances can change, and we constantly monitor food costs and participation in the program.

*Question.* The budget does not include new monies for the contingency fund. What is the current availability in the contingency fund? Given the current economic situation, do you envision the need for the contingency fund?

*Answer.* FNS constantly monitors program performance in WIC, including participation trends and food costs, and would consider seeking apportionment of the \$125 million in WIC contingency funds if needed to support participation because program costs are unexpectedly higher than anticipated.

PUBLIC HEALTH INFORMATION SYSTEM

*Question.* For fiscal year 2012, the budget proposes to decrease funding for the Food Safety and Inspection Service (FSIS) overall slightly, but includes significant increases for the Public Health Information System (PHIS), which will help FSIS track information in a more streamlined, real-time manner.

Can you discuss how the testing of PHIS went and what benefits you expect it to provide when fully implemented.

*Answer.* FSIS conducted multiple rounds of user acceptance testing with field personnel as well as several extensive dry-run training sessions with District Office representatives from around the country in order to make PHIS the best possible tool for FSIS personnel. They provided critical feedback that was utilized to refine the system for implementation and finalize clear and concise training for inspection program personnel.

The goal of the PHIS is to improve the agency's ability to collect, analyze, and communicate data to protect public health. The system will integrate FSIS' data sources to support a comprehensive, timely, and reliable data-driven approach to FSIS inspection, auditing and scheduling. This system will be flexible, user-friendly, and Web-based. It refines and replaces many of FSIS' stove-piped legacy systems (e.g., Performance-Based Inspection System (PBIS)), automates paper-based business processes (e.g., export certification), and can accommodate changing needs.

PHIS will better identify food safety risks to help prevent outbreaks or recalls. Using multiple FSIS data sources, analysts will be able to identify trends and anomalies, including the relationship between pathogen test results and inspection findings.

Using PHIS' predictive analytics component, the agency will be able to monitor establishment data in near real time and have built-in alerts for anomalies such as a large number of incomplete inspection activities or high rates of noncompliance in an establishment.

PHIS will also streamline the agency's export program by automating paper-based processes, including establishment applications for approval for export, applications for export certificates, and the issuance of export certificates. The system will enable automatic edit-checks to ensure that certificates properly reflect a foreign country's import requirements.

Finally, the system will allow for faster and more effective communication between FSIS personnel at headquarters and the more than 8,000 FSIS personnel protecting public health nationwide in approximately 6,200 federally inspected establishments and elsewhere on the front lines. It will also allow for improved collabora-

tion with stakeholders and Federal, State, and local public health partners to improve contaminant tracing and prevent foodborne illness outbreaks.

*Question.* What will the effects be if the Congress is unable to provide the level of funding you are requesting for PHIS?

*Answer.* The agency will seek to manage the effects in such a way as to minimize the impact on PHIS. FSIS considers PHIS a critical food safety regulatory tool for inspection program personnel.

The goal of the PHIS is to better protect public health by improving the agency's ability to collect, analyze, and communicate data. The system will integrate FSIS' data sources to support a comprehensive, timely, and reliable data-driven approach to FSIS inspection, auditing, and scheduling. Through improved data quality, more consistent reporting, enhanced management controls, and efficient, effective use of FSIS data, PHIS will enable FSIS to respond more quickly to threats. Integration and analysis of the data will also help us to predict negative public health outcomes and pinpoint vulnerabilities so that FSIS can rapidly respond to the hazards at all points and prevent problems. The system will also allow FSIS to coordinate effectively within FSIS and with stakeholders and other agencies, improving investigations and contaminant tracing.

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#### QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

##### FOOD SAFETY AND INSPECTION SERVICE

*Question.* For fiscal year 2011, the administration requested an \$18 million increase more than fiscal year 2010 levels for the Food Safety and Inspection Service (FSIS) to support initiatives to improve public health infrastructure, speed up investigations and response to outbreaks, conduct a baseline study on the prevalence of pathogens, and expand sampling. Rather than this increase, FSIS would suffer an \$88 million cut over the remainder of the year if H.R. 1, passed by the House of Representatives becomes law.

Please describe any progress you were able to make on the initiatives described in the fiscal year 2011 budget and describe how the fiscal year 2012 budget builds on that. If no progress was made, did we in fact lose a year of progress on improving public health?

*Answer.* In addition to inspection, verification, enforcement, and other activities directly related to FSIS' food safety mission, during fiscal year 2011, FSIS has continued to develop its Public Health Information System (PHIS). The agency conducted multiple rounds of user acceptance testing with field personnel as well as several extensive dry-run training sessions with District Office representatives from around the country, who provided critical feedback that was used to make PHIS the best possible tool for employees. FSIS refined the system based on this feedback; began training inspection program personnel on March 14; and plans to launch the system on a staggered basis, as employees are trained, in April 2011. FSIS will continue implementation and enhancement of PHIS into fiscal year 2012.

During fiscal year 2011, FSIS has also implemented policy initiatives, such as revised salmonella performance standards and new campylobacter performance standards aimed at reducing the prevalence of these pathogens in young chickens and turkeys. However, FSIS did not fund these initiatives as they were proposed in the President's fiscal year 2011 budget, since FSIS is operating with an annualized fiscal year 2011 continuing resolution funding.

*Question.* What impacts would the proposed \$88 million cut have on food safety programs, and how would those impacts be addressed in fiscal year 2012—even assuming the Congress provides at least the full FSIS budget request for fiscal year 2012?

*Answer.* Under the proposed plan to mitigate an \$88 million reduction, the agency would seek to manage the effects in such a way as to minimize the impact on the agency's regulatory responsibilities, on industry, and ultimately the consumer.

If FSIS funding for fiscal year 2011 were reduced further, we would have to review our options for achieving efficiencies for fiscal year 2011 and fiscal year 2012. I would point out, however, that 85 percent of the FSIS budget is for personnel; therefore, a reduction of this magnitude would likely have an effect on the FSIS workforce.

*Question.* Can you describe what is new in the food safety initiatives proposed for fiscal year 2012 and what is a carryover from last year's request?

*Answer.* For fiscal year 2012, the FSIS request totals \$1,011,393,000, a net decrease of \$7,127,000 (0.7 percent) compared with the annualized fiscal year 2011 continuing resolution amount of \$1,018,520,000.

The fiscal year 2012 budget for FSIS includes the following increases for food safety initiatives:

- \$16.6 million to continue the deployment and enhancement of the FSIS public health information infrastructure, including \$13 million to allow for the purchase of critical equipment and improvement of information gathering systems to enhance access of inspection personnel to centralized, mission-critical systems (fiscal year 2011 request); and \$3.6 million to pay for staffing requirements associated with the implementation of PHIS (fiscal year 2012 request).
- \$700,000 to support regulatory testing for strains of non-O157 Shiga-toxin producing *E. coli*, motivated by increasing awareness that these strains are causing human illnesses (fiscal year 2012 request);
- \$5.5 million to expand regulatory sampling for key pathogens and conduct an additional baseline study. Expanded sampling will help FSIS better estimate food safety risks and focus its resources most effectively and efficiently (fiscal year 2011 request);
- \$4.3 million for strengthening the Public Health Epidemiology Program, which will support the agency in responding more quickly to the current public health needs, including rising frequency of multijurisdictional foodborne illness investigations (fiscal year 2011 request).

Increases in the fiscal year 2012 budget request for FSIS are partially offset by reductions in funding for:

- The Catfish Inspection Program, given the investment to date and the need for considerable stakeholder engagement and regulatory development before adoption and implementation of the program (–\$15.3 million) (combined fiscal years 2011–2012 request);
- Cooperative agreements with the 25 State and local partner laboratories in the Food Emergency Response Network (FERN). In conjunction with the capabilities of the FSIS laboratories, this funding will maintain surge capacity throughout the FERN laboratory system should a terrorist attack on the food supply involving meat, poultry, or egg products take place (–\$4.1 million) (fiscal year 2011 request); and
- FSIS laboratory capacity-building. Since fiscal year 2002, FSIS has worked to improve the overall security and capacity of its three regulatory sampling laboratories. We have completed the capacity-building phase of these efforts and have begun the maintenance and operational phases, which require considerably fewer resources (–\$5.6 million) (fiscal year 2011 request).

In addition, FSIS will achieve significant savings by streamlining agency operations (–\$4.5 million); achieving broadband efficiencies (–\$3.5 million) and laboratory sampling efficiencies (–\$1 million); and reducing laboratory sample shipping costs (\$400,000) (fiscal year 2012 requests).

*Question.* The inspector general for the U.S. Department of Agriculture (USDA) found that the current sampling program lacks a statistical precision that is reasonable for assuring food is safe. Would you describe how the program in your budget for fiscal year 2012 addresses the concerns raised by the inspector general?

*Answer.* FSIS agrees that a strong sampling program is an important part of inspection activities performed by the agency. We believe that to ensure food safety, FSIS must verify that establishments have identified hazards likely to occur and have put in place processes to minimize or eliminate those hazards. Verification includes a variety of inspection activities, of which sampling is just one example.

The focus of the Office of Inspector General (OIG) report is the sampling method that FSIS uses to test for *E. coli* O157:H7 in beef products. Overall, our current beef sampling strategy appears to be working, because ground beef is no longer the leading source of foodborne-based *E. coli* illnesses.

Still, the agency is continually considering new approaches to further reduce the incidence of *E. coli* O157:H7, testing being one of our many strategies. Testing alone will not ensure the safety of products in the marketplace. Food safety is achieved by ensuring that the appropriate safeguards are in place at every step along the process.

That is why the agency is working to ensure that our sampling programs have the greatest possible impact on public health. We want to explore what improvements can be made in our sampling programs, and the OIG report will inform and help drive our efforts.

As referenced in the report, FSIS will develop a plan for prioritizing and performing *E. coli* O157:H7 baseline studies of beef to improve our verification systems, and will develop new verification tasks for inspection program personnel to perform as part of their hazard analysis verification and their verification of sanitary dressing.

*Question.* The fiscal year 2012 budget request estimates savings of \$34 million from restructuring, eliminating positions, and introducing efficiencies. If FSIS inspection is inadequate, we risk massive recalls, plant closures, and of course, heightened food safety risks to consumers.

Please describe what safeguards would be in place with respect to the proposed savings to ensure that they don't result in inspection failures with serious adverse consequences?

*Answer.* The proposed \$34 million in savings for fiscal year 2012 from restructuring, eliminating positions, and introducing efficiencies will not affect our front line inspection workforce. For example, FSIS has identified 37 full-time equivalent positions that can be eliminated by refraining from backfilling open positions resulting from attrition, restructuring functional areas to streamline operations, and consolidating staff and resources to eliminate redundant positions, saving the agency an estimated \$4.5 million. However, none of these positions are in the field.

The agency does not anticipate a change in its regulatory requirements and activities, and would seek to minimize any effect on the enforcement of its regulatory responsibilities. For example, FSIS inspection program personnel will continue to be present at all times for slaughter operations and once-per-shift per day for processing operations. In addition, FSIS personnel will continue to perform humane handling verification and enforcement activities at all slaughter plants.

#### SCHOOL FOOD SAFETY

*Question.* The Healthy, Hunger Free Kids Act sets some new requirements for USDA to improve food safety in America's schools. Specifically, the bill requires you to improve the communication and effectiveness of communication from the Federal level to the States about food safety holds and recalls.

How do you intend to improve that communication? Have you considered a Rapid Alert System similar to the one used in Europe, which uses technology to ensure rapid dissemination of critical information?

*Answer.* The Food and Nutrition Service (FNS) currently uses a Rapid Alert System to communicate with State agencies about food safety recalls that affect USDA foods. The Rapid Alert System uses telephone, email, text message/SMS, and fax to repeatedly contact the State recall coordinators until they acknowledge receiving the message.

USDA has conducted an evaluation of the needs of State agencies during food emergencies such as recalls, and is setting criteria and exploring means to improve their capabilities. The President's fiscal year 2012 budget request proposes \$1.75 million to fund State information technology enhancements to assist State agencies in fulfilling their responsibility to quickly identify and inform recipient agencies that receive recalled product. These enhancements would provide for improved communication with recipient agencies about recalled foods; enable Web-based information posting; and include both a rapid alert notification system and a self-registration notification service. Currently, FNS communicates with State agencies through the Electronic Commodity Ordering System (ECOS), but a similar system reaching from State agencies to local school districts and schools is not widely available. Provided funds are available, phase two of this initiative would enable the same rapid communication between State agencies and recipient agencies.

*Question.* Are you considering reorganizing responsibility within the Department for oversight of food safety in schools, which is now shared among FSIS, the Agricultural Marketing Service (AMS), and FNS, I understand?

*Answer.* No, at this time the Department has no plans to reorganize the oversight of food safety activities within schools.

Ensuring safe food for our school children is a collaborative effort among a number of USDA agencies which have unique authorities that span the farm to table food safety continuum, from inspecting the product when it is produced, to setting procurement standards, managing the distribution of the product to schools, and inspecting the school cafeterias in which the product is served.

In February 2010, Secretary Vilsack announced several new initiatives to assure the safety and quality of food purchased by USDA for the National School Lunch Program and these initiatives have moved forward. For example, in July 2010, after a detailed, ongoing review by USDA's FSIS and the Agricultural Research Service (ARS), AMS finalized tougher new standards for ground beef purchased for Federal food and nutrition assistance programs including the National School Lunch Program. The new standards guaranteed that USDA purchase standards meet or exceed major private-sector buyers of ground beef.

In addition, USDA has increased its information sharing between agencies to better monitor vendor performance and identify potential food safety issues in the proc-

ess. For example, information on FSIS in-plant enforcement actions, positive pathogen test results, and recall notifications are being shared directly with AMS.

Also, as Secretary Vilsack had requested, the National Academy of Sciences completed a review of the testing procedures and requirements of USDA purchased ground beef for the National School Lunch Program. The review confirmed America's school children are receiving a safe ground beef supply.

Collectively, these changes and ongoing scientific reviews of AMS commodity procurement specifications is ensuring, and will continue to ensure, that the food USDA distributes to school children and others meets the highest quality and safety standards.

#### DAIRY POLICY REFORM PROPOSALS

*Question.* There is a significant amount of work being done to develop proposals for modifying and reforming Federal dairy policy. The Congress will consider a number of important considerations relating to the ramifications of any changes to Federal dairy policy. In addition to the key objective of enhancing income protection and prospects for dairy farmers, the Congress will also be examining expected impacts of policy on milk and dairy product markets and prices, consumer prices, and costs to the Federal budget both for the dairy programs and for nutrition programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children.

Will you ensure that USDA includes all of these considerations and potential impacts in its analysis and review of proposals for dairy policy reform and that the Department completes and provides to the Congress such review and analysis in time for it to be available to the Congress in its examination of legislative options for dairy policy reform?

*Answer.* The USDA looks forward to working with the Congress in evaluating proposals for dairy policy reform. We will strive to provide comprehensive information on the impacts of significant reform proposals in a timely manner.

#### QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

##### DAIRY

*Question.* Years 2009 and 2010 were catastrophic for our Nation's dairy farmers. Over supply and chronically low prices led to an unprecedented loss of farm equity and the closure of more than 4,500 dairies nationwide. In response, the U.S. Department of Agriculture (USDA) spent more than \$1 billion on dairy support programs and the Congress appropriated an additional \$350 million to help farmers weather the hard times. These private-sector losses and public-sector expenditures were untenable, and the lesson was clear: Federal dairy programs must be reformed.

What is the Department doing to facilitate meaningful reforms in the dairy support system?

*Answer.* The Secretary formed the Dairy Industry Advisory Committee (DIAC) which was made up of 17 milk producers, processors, retailers, and academic members. The DIAC has worked over the past year to develop a set of recommendations for dairy policy reform. The Department is currently reviewing those recommendations. The recommendation of the DIAC can be found at: [http://www.fsa.usda.gov/Internet/FSA\\_File/diac\\_final\\_rpt\\_0302.pdf](http://www.fsa.usda.gov/Internet/FSA_File/diac_final_rpt_0302.pdf).

*Question.* Do you believe that a supply management system will help stabilize dairy prices? And if so, will the market stabilize at a level that is sustainable for both producers and processors?

*Answer.* Developing and administering a supply management system to stabilize dairy prices at a level that is sustainable for both producers and processors could prove to be a tremendous challenge. Finding the correct balance between producer and processor price desires in an ever changing domestic and international marketplace could be difficult. While the DIAC recommended that the Federal Government should adopt a growth management program by a narrow margin, the subcommittee was not prepared to endorse a specific plan or agree on whether better coordinating milk marketings with milk usage over time in order to reduce milk price volatility should be a public or a private endeavor.

#### DAIRY INSURANCE PROGRAM

*Question.* Crop insurance has been a great asset to row crop farmers across the country looking to manage their risks, but to date the dairy insurance program, Livestock Gross Margin for Dairy (LGM-Dairy), has not seen the same successes.

Is a new dairy insurance program needed to ensure that farmers have a bona fide safety net and a sound financial management strategy?

Answer. The Risk Management Agency (RMA) has administered the LGM-Dairy pilot program since 2009. Until this year, the pilot program experienced very low participation. During summer 2010, the Federal Crop Insurance Corporation Board of Directors approved two program changes that have had a significant impact on participation. The board revised the date that premium is due from the producer until the end of the coverage period, and instituted a graduated producer premium subsidy. These changes went into effect for the December 2011 sales period, and RMA saw a significant jump in participation. Participation in the LGM-Dairy policy has continued to grow each month since then, until program funding was exhausted during the March 2011 sales period. (The Federal Crop Insurance Act limits funding to not more than \$20 million for administrative costs to cover all livestock pilot programs, which generally include any premium subsidy and administrative and operating expenses. There are currently eight livestock pilot programs available, and LGM-Dairy was allocated approximately \$16.2 million with the remaining amount left to fund the other livestock programs based on their historical rate of spending.) During this short period of sales time reflecting the new program changes, private companies wrote and RMA will reinsure about 44 million cwt. of milk, representing about 2.5 percent of the market. Thus, dairy producers have responded to these changes indicating they believe the LGM-Dairy program has become a viable risk management strategy.

*Question.* If every dairy farmer in the country were to opt in to the existing LGM-Dairy program, what would be the annual expected cost to the Federal Government? If we found a way to reduce the volatility of the dairy market, how would this annual expected cost change?

Answer. If every dairy farmer were to use the LGM-Dairy product, USDA estimates it would need approximately \$715 million to support this program, based on the recent market conditions and purchasing patterns of dairy producers. If the volatility in the dairy market were reduced, both the cost to dairy producers and the amount of premium subsidy paid to dairy producers would decrease, but it is not possible to provide any meaningful estimates as to how much savings that might entail given the wide range of potential scenarios to consider.

#### INVASIVE PESTS

*Question.* California farmers, unlike farmers in many other States, pride themselves on receiving very little by way of Federal subsidies. But what I do hear is that they need assistance in finding ways to control invasive pests that come across the border from Mexico or through our international ports. The European grapevine moth, just discovered last year, already has the potential to devastate the \$3.2 million California grape and wine industry. The red palm weevil, just discovered this year, threatens the date industry and poses a serious public safety threat. And of course, the Asian citrus psyllid, which has been found in San Diego, Imperial, Orange, Riverside, and Los Angeles counties is poised to overwhelm citrus producers in California, just as it overwhelmed the Florida producers only 3 years ago.

Simply put, U.S. agriculture is facing threats from foreign pests and diseases like never before, and the USDA must do more to help growers address these bugs.

The Congress included section 10201 in the 2008 farm bill which authorized funding for States and localities to address invasive pest problems in new and unique ways, but the funding for this program is in question because the Commodity Credit Corporation (CCC) will not release the funds to pay for these activities. What are you doing to ensure that this funding goes out in a timely manner?

Answer. We recognize your concern about the threats that U.S. farmers face from invasive pests and diseases and the potential for section 10201 programs to help with early detection and control of new infestations. The Animal and Plant Health Inspection Service (APHIS) has taken steps to improve the process for allocating section 10201 funds and worked with a variety of stakeholders, including the National Plant Board, specialty crop stakeholder groups, State partners, and others, to develop criteria for evaluating proposals for the funds.

The Commodity Credit Corporation Charter Act (15 U.S.C. 714i) limits the availability and use of section 11 CCC funds for salaries and related expenses, including technical assistance, associated with the implementation of farm bill programs. Language was included in the American Recovery and Reinvestment Act of 2009 that allowed APHIS, and certain other USDA agencies, to utilize the funds of CCC to administer certain 2008 farm bill programs in fiscal year 2009 and fiscal year 2010. However, this authority expired at the end of fiscal year 2010 and without this authority to use CCC funds to administer farm bill programs going forward, APHIS and other agencies would have to reduce discretionary program funding and use appropriated funds to carry out mandatory farm bill programs.

For fiscal year 2011, USDA requested language be included in the full-year appropriations bill that would allow section 11 funds of CCC to be available for salaries and related administrative expenses associated with the implementation of certain farm bill programs without regard to the limitation contained in section 11 of the CCC Charter Act. The fiscal year 2012 budget includes \$50 million for section 10201.

*Question.* What authorities and resources can APHIS use to address emerging pests and diseases prior to congressional approval of the action?

*Answer.* Under section 442 of the Plant Protection Act, the Secretary of Agriculture may transfer funds from other appropriations or funds available to the agencies or corporations of the USDA in connection with emergencies in which a plant pest or noxious weed threatens any segment of U.S. agriculture. For example, USDA released \$16.9 million from CCC for the European vine moth in fiscal year 2011. APHIS can also use its appropriated Contingency Fund to address small-scale outbreaks.

*Question.* I was pleased to see that the President's budget included \$44.8 million for the Citrus Health Research Program because this program is critical to ensuring that the citrus industry has a future in our country. Can please update me on what progress has been made in developing citrus trees that are resilient to the Huanglongbing disease carried by the citrus psyllid?

*Answer.* Industry-led research to develop citrus greening-resistant trees began in 2007. The company that developed the trees is currently conducting field trials under a permit from APHIS on genetically engineered (GE) trees that have shown disease resistance in a laboratory setting. If the trees perform well in the field, the company will likely petition APHIS to determine the GE trees' regulatory status so that they can be commercialized.

APHIS is working to coordinate and accelerate research efforts to identify tools that can assist producers with sustainable management of citrus greening, including development of disease-resistant trees. USDA has established the Citrus Research Coordination Group, a collection of representatives from USDA agencies, universities, States, and citrus industry organizations. This group is coordinating the comprehensive research being conducted by more than 150 scientists dedicated to finding the necessary tools and solutions for citrus greening. The research efforts focus on several critical areas, including: crop improvement by developing disease-resistant trees; horticulture management strategies designed to maintain productive trees, even if they are infected with citrus greening; early-detection technology to find the disease; and tools to track infectious citrus psyllid populations and limit their encroachment into citrus production areas.

#### ANTIBIOTICS

*Question.* I remain concerned about the routine use of antibiotics in the food and water of animals that are not sick. While I understand that these antibiotics may improve feed efficiency, it also facilitates the development of antibiotic-resistant bacteria.

The President's fiscal year 2012 budget request announces that the Agricultural Research Service (ARS) plans on launching a biotherapeutic discovery program to find alternatives to antibiotics in animal agriculture. Can you provide more details on this initiative and when you plan on implementing this program?

*Answer.* The incidence of antibiotic resistance in pathogenic bacteria is rising. This presents one of the greatest threats to human health in the 21st century. Public health concerns with antibiotic resistance are driving new proposed regulations and policies to restrict the use of antibiotics in animal production. Developing alternatives to antibiotics is therefore becoming a critical issue for food animal medicine. The ARS Animal Health Research Program is using new information emerging from the rapidly expanding "omic" technologies (e.g., animal genomics, metagenomics, transcriptomics, proteomics, metabolomics) to discover new molecules with antimicrobial activity that can be developed as alternatives to antibiotics. The ARS Animal Health National Program plans for fiscal year 2012 include launching a biotherapeutics discovery program that will focus initially in the following strategic areas:

- innate immune molecules with antimicrobial function;
- bioactive phytochemicals (herbal extracts and volatile oils); and
- demonstrated synergistic approaches that could both reduce costs and increase efficacy while reducing the risk of drug resistance development.

This animal health initiative cross-cuts other national programs, such as the ARS Food Safety Research Program, which includes research on alternatives to anti-



biotics, microbial ecology, and the effect of processing environments on antibiotic resistance prevalence.

*Question.* Should the USDA and ARS receive funding less than the President's fiscal year 2012 request, will this inhibit the program?

*Answer.* If ARS receives funding less than the fiscal year 2012 request, this will prevent the launch of the proposed animal health alternatives to antibiotics research program.

*Question.* Are you working with the Food and Drug Administration (FDA) in relation to its proposed draft guidance regarding the use of antimicrobials in food-producing animals? When can we expect to see this guidance implemented on the farm?

*Answer.* ARS provided significant input to the development of the draft guidance document. USDA has collectively drafted a response plan to FDA's latest guidance document on the voluntary reduction of growth promoters in agriculture. APHIS is the lead agency for USDA interactions and any timeline for on-farm implementation.

#### ORGANIC

*Question.* Organic agriculture is one of the fastest growing segments of the rural economy. It creates nearly 150,000 jobs and provides farmers with lucrative market opportunities.

But Federal investment in organic research and market data has lagged behind its fair share—organic agriculture makes up about 3.7 percent of the total industry, but research in this new and promising area only makes up 2.6 percent of the total USDA research budget. I was pleased to see the agency's plan to spend \$20 million in the Organic Agriculture Research and Extension Initiative (OREI) and an additional \$5 million in the Organic Transitions program, but I believe more must be done to help ensure the continued growth of this industry.

What additional resources can be made available to help organic farmers discover and understand the best ways to address invasive pests and diseases?

*Answer.* In the 2011 OREI, research and extension to develop and improve systems-based Integrated Pest Management (IPM) programs for organic crops was one of the seven priority areas. Specifically, we requested systems-based evaluations that could include the safety and efficacy of allowable pest management materials and practices. Special emphasis was given in the 2011 request for applications to research relating to management of diseases, insect pests, and weeds in specific regions where organic acreage is increasing, and yet remain deficient in terms of numbers of certified and exempt organic farms, as compared to nationwide averages. For example, the southern region lags behind the northeastern and north central regions in organically certified acreage. Additional research and extension on pests, weeds, and diseases that may limit production in those regions should help overcome barriers to the growth of organic farming in these underrepresented regions. The southern region is often the first place that invasive plants, diseases, and pests are noticed. Controlling them in the region in which they first appear can help reduce the spread to other regions, as well as making additional management tools available as they are needed. Research in organic systems is particularly valuable, because organic farmers rely on a systems approach that includes rotation, cover crops, tillage, biological controls, and less toxic materials. Thus resistance is less likely to develop to a specific material.

Invasive pests, weeds, and diseases also can be a problem in animal agricultural systems. An additional priority in the 2011 OREI was to develop or improve systems-based animal production and pest management practices, especially in the areas of nutrition, grazing, pasture, and confinement requirements, to improve animal productivity, health, and welfare, while retaining economic viability. Thus two of the seven priorities in OREI pertained directly to pest, weed, and disease issues. In addition, plant breeding and animal selection for pest and disease resistance comprised two additional priorities of the seven. Therefore, more than one-half of the priorities for this program deal with some aspect of research and extension on management of pest, weeds, and diseases in organic farming systems. Compiling extension resources is another priority, and these resources could also address pest, weed, and disease management.

The Sustainable Agriculture Research and Education (SARE) program is another source of competitively awarded funding for improved pest management in organic production systems. Historically, approximately 20 percent of the SARE program awards have been for applied research in organic systems and pest control has been one of the predominant focus areas for the proposals that we receive. The SARE program had a funding line in 2010 of \$14.5 million for research and education and a funding line of \$4,705,000 for professional development and training. Together

these funds allow SARE to provide a seamless continuum that links research with outreach and implementation. The fiscal year 2012 budget proposes increases of \$10.8 million for SARE, including \$10 million for the creation of a new Federal-State matching-grant SARE program to assist in the establishment and enhancement of State-sustainable agriculture research, education, and extension programs. These increases will bring the total SARE funding to \$30 million in 2012.

In fiscal year 2012, total ARS and NIFA funding will provide more than \$38 million for direct organic research. ARS spends an additional \$32.5 million on research which indirectly contributes to organic production.

*Question.* What internal work is being done by ARS or other USDA entities that reduces the need for harsh chemical pesticides and improves the effectiveness of greener and organic alternatives?

*Answer.* ARS organic farming research is focused on understanding the scientific basis of biological and physical processes innate to plants, soils, invertebrates, and microbes that naturally regulate pest problems and soil fertility. ARS organic research emphasizes whole-system preventative solutions, rather than one-for-one substitution of conventional production materials and practices with organic ones. Results from ARS organic research can also benefit conventional agriculture by reducing the need for purchased synthetic agricultural chemicals. ARS organic research activities are coordinated with other agencies through the USDA Organic Working Group. In March 2011, three Research, Education, and Economics agencies (ARS; the Economic Research Service (ERS); and the National Institute of Food and Agriculture (NIFA)) together with the Office of the Chief Scientist and the Office of the Secretary hosted a very successful USDA Organic Research Conference in Washington, DC. Feedback from participants indicated that many were pleasantly surprised by the breadth, depth, and level of USDA support for organic agriculture research. Some specific examples of ARS internal research objectives and activities are:

- Identify genetic plant growth efficiency mechanisms and combine with soil fertility management strategies to increase crop productivity with improved cultivars suited to organic production conditions.
- Develop whole-system biological-based management strategies for weed, insect pest, and disease control using preventive approaches as first defense, and therapeutic controls as rescue practices.
- Develop whole-system biological-based management strategies for prevention of parasites in small ruminant grazing animals.

NIFA is engaged with a wide range of research, education, and extension programs that develop and help agricultural producers adopt IPM approaches on their farms and ranches. IPM provides a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks. These approaches encourage the use of the most environmentally friendly and sustainable methods for managing pests. NIFA programs support the development of IPM strategies and bio-based methods like biological control methods, microbial pesticides, mating disruption tactics, genetic manipulation of pests, and improving plant resistance to pests and diseases. The adoption and implementation of these science-based IPM methods helps reduce the need for pesticides on conventional and organic farms and ranches.

The National Organic Program (NOP) strictly regulates the pesticides that can be utilized in certified organic production. In most cases, these materials are less toxic and have reduced potential for an adverse environmental impact. In certified organic production, many of the allowed pesticides are restricted to use as a “last resort” in an overall approach that relies first and foremost on biologically based materials and cultural management practices. These practices include tillage, rotation, and cover cropping as a preferred alternative to herbicide usage. Very few herbicides are allowed in certified organic production. All these practices utilized by organic farmers reduce the potential for the development of resistance in pest and weed populations and the necessity for increasingly harsh and frequent application of pesticides.

*Question.* Organic products receive a substantial premium at market, and this has helped many farmers increase their income and improve their living conditions. But along with this premium comes the possibility that some farmers may seek to cheat the system and make false “organic” claims.

Please explain how \$10 million for NOP is sufficient to regulate and enforce a set of complex standards on more than 16,000 certified organic operations. What assurances can you give me, and all consumers of organic goods, that the USDA “Organic” label really means that the product was grown without pesticides or hormones?

Answer. NOP accomplishes its main mission by accrediting private and public entities as certifying agents to conduct organic certification of production and handling operations. There are currently 94 accredited certifying agents located around the world, certifying about 27,000 operations, about 17,400 of which are U.S. domestic operations. NOP authorizes the State of California to handle compliance and investigative activities for agents and operations located in the State. NOP also recognizes six foreign governments (United Kingdom, Denmark, Israel, New Zealand, India, and Japan) to exercise oversight for products certified to the NOP standards in their countries. The United States-Canada Organic Equivalency Arrangement allows products certified to each country's standards to go to the other country with minimal additional conditions.

NOP currently has a budget of \$7 million which supports 32 staff members. NOP staff members manage a comprehensive accreditation program, handle complaints and take enforcement actions on violations of the regulations, develop and revise standards and policy guidance, as well as coordinate the activities and implement the recommendations of the National Organic Standards Board.

NOP ensures organic integrity and consumer assurance through a rigorous accreditation and certification process. The accreditation applicants are first assessed through a comprehensive desk audit. Upon satisfactory completion, an onsite audit of personnel and system is then conducted. Subsequently, regular audits are conducted at every 2.5 years for all certifying agents, domestic and foreign. NOP certification is a process-based system that establishes proactive control measures through the development, approval and implementation of organic system plans (OSP). The OSPs describe detailed practices and procedures for production and handling, all inputs used and their source/composition/application, monitoring practices and procedures, record-keeping system, and management practices to prevent contamination and commingling. Implementation of the OSP is verified through annual onsite inspections.

NOP regulations require pre- or postharvest tests based on suspected use of prohibited materials or excluded methods. Such tests are often conducted in the process of complaint investigation and utilized as a tool to verify compliance. The program is presently considering additional measures to further deter the use of prohibited materials.

The program accomplishes these tasks by collaborating with other entities and leveraging resources to manage this complex global program within available resources. However, many areas could be enhanced to increase organic integrity of products shipped to the United States from around the world. To that end, a \$2.9 million increase has been proposed in the NOP budget for 2012 to conduct additional surveillance of foreign accredited certifying agents; increase the program's capacity to investigate complaints and violations (both domestic and foreign); educate certifying agents worldwide to ensure the organic regulations are consistently applied; and respond to requests for international equivalency agreements.

*Question.* Could you please provide me with a report on all enforcement actions taken by NOP in 2010, and with an enforcement strategy for the remainder of 2011 and beyond?

Answer. Responsibility for enforcement of the NOP regulations is shared by the certifying agents and NOP. Certifying agents ensure the correct implementation of NOP standards through annual inspections and require corrective actions by operations when noncompliances are identified. NOP takes enforcement action as part of its complaint investigation and accreditation audit processes.

NOP has increased its enforcement activities, not only in the United States but also in foreign countries, through monitoring recognition agreements and certification activity of foreign certifying agents. During fiscal year 2010, NOP conducted compliance assessments in Canada, Egypt, Israel, Denmark, Ghana, and China. AMS auditors also conducted organic audits in Argentina, Italy, Germany, Bolivia, and Mexico.

During fiscal year 2010, NOP closed 123 complaints. As a result of investigating these complaints, NOP issued 10 civil penalties, totaling \$64,000; and issued 52 cease-and-desist letters that stopped inappropriate use of the NOP logo or label.

Through the enforcement activity of NOP, three certifying agents have lost their accreditation status (Guaranteed Organic Certification Agency, California; California Organic Farmers Association, California; and Certified Organic, Incorporated, Iowa). Those certifying agents are no longer permitted to certify organic producers or handlers.

For the remainder of 2011 and beyond, NOP's No. 1 priority is to protect organic integrity through enforcement activities. NOP's plan is focused on the following 10 points:

- clear, enforceable standards;

- timely notification to certifiers, organic producers, and handlers concerning changes/clarifications to the standards;
- transparency of suspensions, revocations, adverse actions, and sanctions;
- quality certification program;
- effective and efficient complaint handling process;
- penalties for willful violations;
- market surveillance inspections;
- unannounced inspections;
- periodic pesticide residue testing; and
- continual improvement.

## SECTION 502 AND MUTUAL SELF-HELP HOUSING PROGRAM

*Question.* The administration's budget proposes to reduce funding for affordable housing for low-income families and improving housing conditions in smaller, poorer rural communities. The Department's Section 502 Single-Family Housing Direct Loan Program was funded at \$1.02 billion, but the administration has requested \$211 million for fiscal year 2012. This is a cut of nearly 79 percent to a program that small towns and rural communities rely on for affordable housing. In addition, the Mutual and Self-Help Housing Program, which was funded at \$43 million in fiscal year 2010, has been eliminated in the administration's request.

How will the Department continue to offer affordable housing to low-income families in rural areas despite the elimination of the Mutual and Self-Help Housing Program and a major budget cut in the section 502 program?

*Answer.* Housing is a vital economic pillar in rural America for creating wealth for communities and homeowners. USDA realizes that rural populations tend to be more economically challenged with lower incomes and fewer housing choices than their suburban and urban counterparts, and therefore we continue to offer a no-down payment homeownership program through both the Single-Family Housing Guaranteed and Direct Loan programs.

Providing credit in areas that lack private investment is a critical function of USDA Rural Development. To address the need for credit—particularly in the rural housing market—Rural Development has dramatically increased the Single-Family Housing Guaranteed Loan Program in recent years, doubling the Government's investment from \$12 billion in 2010 to \$24 billion in 2011. In these austere fiscal times, we are investing more than ever in rural housing at no cost to the taxpayer, because the Single-Family Housing Guaranteed Loan Program has a negative subsidy rate and does not require budget authority.

The need to address the state of the current housing stock, in particular for very low-income seniors, and in areas of persistent poverty like tribal lands and border communities, will be met through the Section 504 Home Repair Grant Program. There are fewer affordable housing options in smaller and more rurally remote communities and we continue to grow the Section 515 Multifamily Direct Program to address needs in these communities. Often the section 515 program is the critical element in making a low-income housing tax credit deal work in rural communities that are starved for private investment. We already serve hundreds of thousands of very-low and low-income tenants through our multifamily housing programs, and we intend to continue to invest in new properties and the revitalization of existing units.

USDA intends to continue a partnership in the immediate future with the Self-Help Housing Technical and Management Assistance (T&MA) contractors to provide guidance to Self-Help Housing grantees. As we transition out of a program that we recognize has made major contributions to rural housing, we will no longer have the ability to fund the administrative costs associated with Self-Help Housing due to budget constraints. Together with the grantees and T&MA contractors, USDA will identify other means for grantees to garner fees for their services and address regulations that will accommodate new ideas.

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 QUESTIONS SUBMITTED BY SENATOR MARK PRYOR

## FORMULA FUNDS

*Question.* Over the last three decades, formula funds (land grant institutions) as a percentage of the U.S. Department of Agriculture (USDA) extramural funding have declined in both absolute and relative amounts. To rectify that drop, the Congress filled in the gaps with special grants—earmarks—that are no longer available. With inherent limitations on the scope and effectiveness of competitive-funded re-

search and extension, do you believe it is wise to reduce our formula fund investment by 5 percent?

Answer. Although we are proposing modest cuts in formula funds, the National Institute of Food and Agriculture (NIFA) has proposed significant increases in the Agriculture and Food Research Initiative (AFRI) competitive grants program that includes increased investments in the integrated programs of AFRI. These integrated programs provide significant opportunities for support of multidisciplinary and multistate extension programs. Strong extension components within the integrated programs of AFRI will help ensure that research findings are accessible to agriculture producers and other key stakeholders. In addition, NIFA proposes to continue support for our electronically based initiative, eXtension, to ensure broad access to peer reviewed research-based information.

#### RESEARCH

*Question.* Why did the administration decide to cut funding to the Agricultural Research Service (ARS) at a time when we are depending on our leadership in science and technology to help our economy recover from the recession?

Answer. The President's fiscal year 2012 budget request for ARS proposes a net decrease of \$41.9 million. The budget proposes an increase of \$58.7 million, including \$55.7 million for new and expanded research initiatives in food safety, child and human nutrition; crop/animal breeding and protection; bioenergy/biomass; plant, animal, and microbial collections; production systems for sustainable agriculture; global climate change; and the National Agricultural Library. Investments in these high-priority programs will be critical to keeping the food and agriculture sector of the economy strong. These increases are offset by the proposed reduction or termination of ongoing ARS programs. The proposed net reduction in the fiscal year 2012 budget for ARS is achieved through the elimination of earmarked and other lower-priority projects.

#### HOUSING PROGRAMS

*Question.* Can you explain why the administration has sharply reduced funding for the Section 523 Mutual Self-Help Housing Program and the Section 502 Single-Family Housing Direct Loan Program which have been both successful and important in rural America?

Answer. The Department believes that the Section 502 Single-Family Housing Guaranteed Loan Program is the most cost-effective approach to providing a large number of housing loans. With a \$24 billion level, at a negative subsidy rate, the program provided more assistance and served more families in rural areas by far than any other housing program at the Department. For example, more than 30 percent of the loans made last year, were made to low-income families, the target population of the Section 502 Single-Family Housing Direct Loan Program (commonly known as the section 502 direct program). In fact the 30-percent figure represented 43,708 loans to low-income families, more than have ever been made in a single year by the section 502 direct program. While both the section 502 direct program and the Section 523 Mutual Self-Help Technical Assistance Grant programs have assisted low-income families, they are much more costly than the Section 502 Single-Family Housing Guaranteed Loan Program.

#### FOREST LEGACY PROJECTS

*Question.* I understand that the administration ranks Forest Legacy projects. Can you explain a little bit about that process? And can you explain to me how the projects will be funded? Will you go straight down the ranking list and fully fund project No. 1, No. 2, No. 3, and so on until you run out of funds?

Answer. Program priorities are developed in consultation with participating State-lead agencies. Each summer, the Forest Service sends a call letter to States asking them to provide a prioritized list of up to three projects. These projects always involve willing sellers who voluntarily seek to participate in the Forest Legacy Program. In many cases, there are other partners from the local community and forestry and conservation organizations who support the projects.

The call letter includes the scoring criteria that details how the projects will be ranked. In January, a panel convenes for 2 days to rank the projects and develop a prioritized list. The panel is composed of 10 members: 6 Forest Service employees and 4 representatives from State agencies responsible for implementing the Forest Legacy Program. Each member arrives at the panel having reviewed and scored the proposed projects based upon the scoring criteria. Once the prioritized list is developed, it is cleared through the Forest Service and the USDA and becomes part of the President's budget proposal to the Congress.

The intent is to follow the prioritized list as developed and fund as many projects as funding allows. The Forest Legacy prioritization process is well-developed and understood by our State partners and other conservation interests and we believe it is important to adhere to the competitively developed list.

#### CHINA FOOD SAFETY SYSTEM

*Question.* Can you please bring the subcommittee up to speed on how things are progressing with the implementation of section 743 of the fiscal year 2010 appropriations bill? Are the Chinese cooperating with efforts to establish the equivalency of their food safety laws with those of the United States?

Answer. From December 1–21, 2010, FSIS conducted two separate but simultaneous audits of China's poultry inspection system: one for poultry processing and one for poultry slaughter. FSIS continues to analyze materials provided by China during the on-site audits, and sought published information on China's food safety system from various domestic and international agencies, as part of its equivalence evaluation of China's poultry inspection system.

FSIS will submit two separate audit reports to China. China will then be responsible for working with FSIS to address any concerns that may be raised in the reports.

To date, FSIS has obtained from China's primary food safety authority all of the information necessary to conduct the equivalence audits.

#### GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION RULE

*Question.* Can you tell the subcommittee the status of the new analysis of the Grain Inspection, Packers and Stockyards Administration (GIPSA) rule, and explain how the administration is working to improve the rulemaking process at USDA?

Answer. GIPSA provided 150 days for the public to comment on the rule. The agency received 61,000 comments, and it is currently reviewing and analyzing the comments that were received. The Department will take the following steps in developing the final rule:

- Conduct a content analysis of comments and identify those requiring additional legal and policy analysis;
- Evaluate the proposed cost-benefit analysis in light of comments and revise as necessary;
- Draft a regulatory workplan and submit to the Office of Management and Budget (OMB);
- Revise the rule as necessary;
- Enter the rule into Departmental clearance;
- Submit the rule for OMB clearance; and
- Publish the rule.

The cost-benefit analysis that is being conducted will be guided by the comments that we received during the comment period. Further, officials within the Department and OMB will clear this rule before the rule is promulgated. USDA's Chief Economist, Joseph Glauber is taking the lead in coordinating a team of economists across the Department to provide rigorous review of the comments.

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#### QUESTIONS SUBMITTED BY SENATOR SUSAN COLLINS

##### RESOURCE CONSERVATION AND DEVELOPMENT FUNDING

*Question.* The U.S. Department of Agriculture's (USDA's) Resource Conservation and Development (RC&D) program provides important resources for many rural communities in Maine and around the country. RC&D-sponsored activities have led to more sustainable communities, better informed land use decisions, and sound natural resource management practices.

Maine's five RC&D councils have proven their effectiveness through a number of accomplishments. During fiscal year 2010, 79 RC&D projects were actively worked on and 35 projects were completed. Maine RC&D councils participate in a variety of successful projects that range from providing technical assistance for the development of community wind projects to helping build and sustain agricultural businesses.

One of the main benefits of the RC&D program is the promotion of local economies through the leveraging of Federal dollars. According to the National Association of RC&D Councils, the RC&D program returns \$5.60 for every \$1 the Federal Government invests to support economic development and resource protection in rural areas. For some RC&D councils the leverage is even greater.

In fact, the administration's budget document cites the program's history of success and ability to attract non-Federal dollars as a reason why Federal funding is no longer necessary. I appreciate that these are difficult budget times, and difficult decisions must be made as to where to allocate limited Federal dollars. I wonder, though, whether it makes sense to eliminate funding for successful programs. Shouldn't we be supporting programs that have a proven track record of being able to attract and leverage non-Federal funds?

Answer. President Barack Obama's budget proposal eliminates Federal technical assistance to the 375 RC&D councils, the majority of which have received Federal support for at least 10 years. Given the current budget situation, we have had to make some difficult funding decisions. As nonprofit organizations, RC&D councils will still exist and we believe that most have the capacity to identify, plan, and address their identified priorities without the need for continued Federal support. The RC&D program is not being targeted due to poor performance or lack of effectiveness. RC&D has been a remarkable program since 1964 and it is expected that many councils will continue to provide services to their communities.

#### INTEGRATED PEST MANAGEMENT

*Question.* Mr. Secretary, the science-based principles of Integrated Pest Management (IPM) have proven to be valuable tools for American agriculture. IPM has allowed American agriculture to address food safety issues by maintaining crop quality, avoiding crop losses, improving pest management strategies, and minimizing negative impacts to the environment. The four regional IPM centers have been invaluable in their effort towards increasing IPM programming breadth and depth throughout the United States. Many of these programs funded via USDA have demonstrated excellent cost-benefit ratios. For example, the University of Maine Cooperative Extension Potato IPM Program showed in 2009 that for every USDA \$1 invested, \$58 in benefits were returned. The UMaine's IPM program Web site is visited thousands of times per growing season, showing how integral it is to the potato industry. Farmers use the program to more appropriately treat their crops, to lessen the impact of chemicals to the environment, and to catch troubling diseases, like late blight and pests sooner.

Given the importance of these IPM programs, how does USDA plan to not only maintain but enhance these valuable IPM programs?

Answer. The National Institute of Food and Agriculture (NIFA) recognizes the importance of IPM in our science portfolio and will continue to provide national leadership for IPM research education, and extension programs. NIFA will continue to support IPM research, extension and education efforts through the Agriculture and Food Research Initiative (AFRI) and other NIFA programs. The consolidation of funding authorities into broader programs such as AFRI enhances NIFA's ability to address issues confronting U.S. agriculture in a more holistic way, and with a scale of investment that is large enough to make a real difference. Consolidation will also reduce transaction costs and improve the efficiency of program management in a climate of limited resources.

In fiscal year 2010, AFRI was restructured so that investments could be focused on five societal challenge areas: global food security, climate change, food safety, sustainable bioenergy, and childhood obesity prevention. The development of IPM methods for plant and animal production systems is a key element of efforts to ensure global food security, respond to climate change, and develop sustainable bioenergy production systems. AFRI supports the development and implementation of IPM approaches that help us address these challenge areas and contribute to the sustainability of U.S. agriculture.

For fiscal year 2012, NIFA will seek to expand the role and influence of science in agriculture through focused, problem-solving research, education, and extension activities related to IPM challenges in plant and animal production systems. The proposed budget consolidates funding for the Expert IPM Decision Support System, Pest Management Alternatives, and IPM and Biological Control into a single program to improve the efficiency of program implementation resulting in research investments with greater focus, more appropriate scale, and enhanced impact. The proposed budget maintains funding for the Smith-Lever 3(d) Pest Management Program, which addresses many challenges facing agriculture and the environment by delivering science-based IPM methods to producers and agricultural professionals. Supplemental programs like the IPM Potato Late Blight project with the University of Maine Cooperative Extension Potato IPM Program further address significant issues and are closely aligned with the Smith-Lever 3(d) program.

## FOREIGN MARKET DEVELOPMENT PROGRAMS

*Question.* Programs that increase market access for American agricultural products are important to increasing exports and market share for our farmers. In 2008, at the height of the economic downturn, Maine's wild blueberry industry was beginning market development work in China. Although it often can take 5 or 6 years to fully develop a new export market, Maine's wild blueberry industry was able to grow its market in China by 73 percent between 2009 and 2010.

Given the importance of such efforts and the President's National Export Initiative (NEI), why has the administration only provided a 1-percent increase for such programs?

*Answer.* The administration fully concurs that programs to increase market access for American agricultural products are important to increasing exports and market share for American farmers. To that end, the President's fiscal year 2012 budget includes full funding for the Market Access Program, Foreign Market Development Program, Emerging Markets Program, and Technical Assistance for Specialty Crops Programs consistent with the provisions of the 2008 farm bill; total funding for those programs is \$253.5 million. In addition, the fiscal year 2012 request includes an increase of \$20 million to provide additional funding for Foreign Agricultural Service market development efforts in support of NEI.

## FOREST LEGACY

*Question.* Maine has the largest private forest ownership in the country—some 18 million acres of diverse forest covering roughly 90 percent of its land area. These private landowners are the stewards of our forests and the caretakers of the natural resources that are vital to Maine's forest-products industry. In addition, they are the hosts for our increasingly important recreation economy.

One of the most important Federal programs to help forested landowners preserve working forest, protect natural resources, and promote outdoor recreation is the Forest Legacy Program. I appreciate your commitment to this program, and hope we can keep it going for the remainder of fiscal year 2011, as the House's decision to deeply cut Forest Legacy funding will directly affect Maine.

Maine's West Grand Lake Community Forest project, for example, was ranked the No. 1 Forest Legacy project in the Nation for 2011 through a competitive scoring process. This project will ensure sustainable forest management and public recreational access. It will also preserve and enhance Maine's timber economy and Grand Lake Stream's 180-year outdoor recreation heritage. It is a project led by the local community and accomplished in partnership with community, State, Federal, and nonprofit partners. West Grand Lake is a shining example of how the Forest Legacy Program works with local communities to prevent the conversion of forest land to nonforest uses while sustaining and improving both our local timber and recreational economies.

I understand that there is a great deal of uncertainty right now as to what the Department's budget will look like for the remainder of the fiscal year. And beyond fiscal year 2011, there are many worthy projects being proposed for fiscal year 2012. Recognizing that things are still very much in the air, has the Department considered how it might allocate funding within the Forest Legacy Program at a reduced funding level? It is my understanding that the fiscal year 2012 request assumes that the projects that were priorities for fiscal year 2011 are funded this year. How will Department allocate funding among the fiscal year 2011 and fiscal year 2012 priorities should full funding not be provided this year?

*Answer.* Currently, the intent is to adhere to the prioritized list. We are aware that the funded list may be a short one. The Forest Legacy Program prioritization process at the national level is undertaken without a known funding level. The intent is to identify the most important forestland for conservation funding. The relative importance of the projects does not change because of funding levels and we intend to adhere to the prioritized list.

It is true that there are projects on both the fiscal year 2011 and fiscal year 2012 priority lists. Due to the uncertainty of the fiscal year 2011 funding at the time of the fiscal year 2012 call for projects, some States chose to submit, as their priority, projects on the fiscal year 2011 list for consideration in fiscal year 2012. Each funding year represents a distinct national competition of projects. Fiscal year 2011 projects will not be prioritized in fiscal year 2012 as only projects submitted in response to the call for proposals for fiscal year 2012 will be on the fiscal year 2012 project priority list.



SUBCOMMITTEE RECESS

Senator KOHL. Thank you, Senator Pryor.  
And thank you very much, Secretary Vilsack.

We have about 5 minutes left in the vote.

But you've done a great job, been very complete. You've offered a lot of information, and we very much appreciate your coming here today. We're all looking forward to continuing to work with you.

Secretary VILSACK. Thank you.

Senator KOHL. Thank you so much.

The hearing is recessed.

[Whereupon, at 3:05 p.m., Thursday, March 10, the subcommittee was recessed, to reconvene subject to the call of the Chair.]



## **MATERIAL SUBMITTED SUBSEQUENT TO THE HEARING**

[CLERK'S NOTE.—The following testimony was received subsequent to the hearing for inclusion in the record.]

PREPARED STATEMENT OF HON. LELAND A. STROM, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, FARM CREDIT ADMINISTRATION

Mr. Chairman, members of the subcommittee, I am Leland A. Strom, chairman and chief executive officer of the Farm Credit Administration (FCA). On behalf of my colleagues on the FCA Board, Kenneth Spearman of Florida and Jill Long Thompson of Indiana, and all the dedicated men and women of FCA, I am pleased to provide this testimony.

Before I discuss FCA's role, responsibilities, and budget request, I would like to thank the subcommittee staff for its assistance during the budget process. Also, I would respectfully bring to the subcommittee's attention that the funds used by FCA to pay its administrative expenses are assessed and collected annually from the Farm Credit System (FCS) institutions we regulate and examine—the FCS banks, associations, and service corporations, and the Federal Agricultural Mortgage Corporation (Farmer Mac). FCA does not receive a Federal appropriation.

Earlier this fiscal year, FCA submitted a proposed total budget request of \$62,299,787 for fiscal year 2012. FCA's proposed budget for fiscal year 2012 includes funding from current and prior assessments of \$62,000,000 on FCS institutions, including Farmer Mac. Almost all this amount (approximately 82 percent) goes for salaries, benefits, and related costs.

The fiscal year 2012 proposed budget is driven largely by two factors:

- stress on FCS caused by conditions in the agricultural and the general economy; and

- the large number of retirements that FCA anticipates in the coming 5 years.

Although FCS remains safe and sound overall, risks have increased across FCS, and conditions in several institutions have deteriorated. As a result, we are hiring additional staff members to provide more intensive examination and oversight. We are also hiring employees to fill the positions of those who will be retiring soon. The funding we've requested for fiscal year 2012 will allow us to provide the additional supervision and oversight required in challenging economic times and to ensure that we maintain a staff with the skills necessary to properly examine, oversee, and regulate FCS.

### MISSION OF THE FARM CREDIT ADMINISTRATION

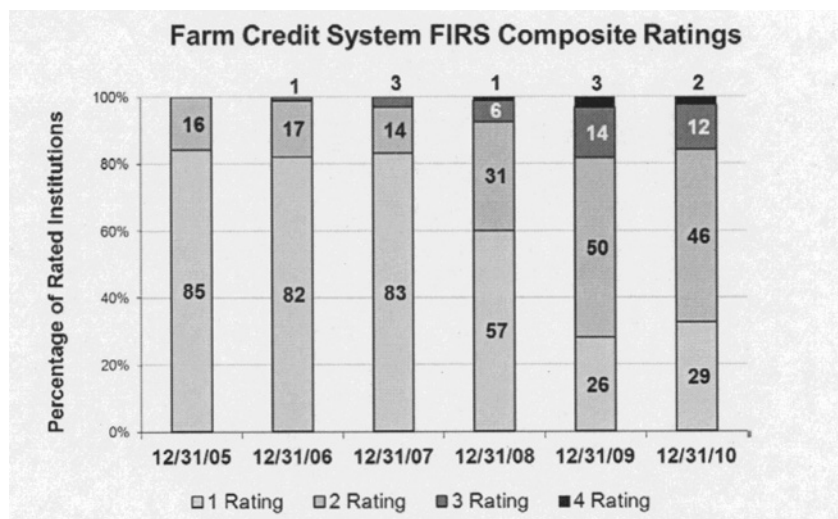
As directed by the Congress, FCA's mission is to ensure a safe, sound, and dependable source of credit and related services for agriculture and rural America. FCA accomplishes its mission in two important ways. First, FCA protects the safety and soundness of the FCS by examining and supervising all FCS institutions, including Farmer Mac, and ensures that the institutions comply with applicable laws and regulations. Our examinations and oversight strategies focus on an institution's financial condition and any material existing or potential risk, as well as on the ability of its board and management to direct its operations. We also evaluate each institution's compliance with laws and regulations to ensure that it serves all eligible borrowers, including young, beginning, and small farmers and ranchers. If an FCS institution violates a law or regulation or operates in an unsafe or unsound manner, we use our supervisory and enforcement authorities to take appropriate corrective action. Second, FCA develops policies and regulations that govern how FCS institutions conduct their business and interact with customers. FCA's policy and regulation development focuses on protecting FCS safety and soundness; implementing the Farm Credit Act; providing minimum requirements for lending, related services, investments, capital, and mission; and ensuring adequate financial disclosure and governance. The policy development program includes approval of cor-

porate charter changes, FCS debt issuance, and other financial and operational matters.

#### EXAMINATION PROGRAMS FOR FARM CREDIT SYSTEM BANKS AND ASSOCIATIONS

FCA's highest priority is to maintain appropriate risk-based oversight and examination programs to ensure the safety and soundness of FCS institutions. Given the increasing complexity and risk in FCS and human capital challenges at FCA, we have undertaken a number of initiatives to improve operations, increase examination effectiveness, and enhance staff expertise in key examination areas. FCA bases its examination and supervision strategies on institution size, existing and prospective risk exposure, and the scope and nature of each institution's business model. FCA also performs nationally focused examinations of specific issues and operational areas to monitor the condition and operations of FCS as a whole. On a national level, we actively monitor risks that may affect groups of FCS institutions or the entire FCS, including risks from the agricultural, financial, and economic environment.

The frequency and depth of examination activities vary based on risk, but each institution receives a summary of examination activities and a report on its overall condition at least every 18 months. FCS institutions are required to have effective loan underwriting and loan administration processes, to maintain adequate asset-liability management capabilities, and to establish high standards for governance and transparent disclosures for shareholder oversight. Because of the recent increased volatility in the agricultural and credit sectors, FCA has increased its on-site examination presence. Also, FCA is closely watching rapidly rising real estate values in certain sections of the country to ensure that FCS lending practices remain prudent.



In certain cases, FCA will use its enforcement powers to effect changes in the institution's policies and practices to correct unsafe or unsound conditions or violations of law or regulations. FCA uses FIRS as a key method to assess the safety and soundness of each FCS institution (see chart above<sup>1</sup>). The FIRS provides a general framework for evaluating significant financial, asset quality, and management factors to assign component and composite ratings. FIRS ratings range from 1 (for a sound institution) to 5 (for an institution that is likely to fail). Overall, FCS remains financially strong and adequately capitalized. The FCS does not pose material risk to investors in FCS debt, the Farm Credit System Insurance Corporation, or to FCS institution stockholders.

<sup>1</sup> SOURCE.—FCA's FIRS Ratings Database. The above chart includes only the five FCS banks and their affiliated direct-lender associations. The figures in the bars reflect the number of institutions by FIRS rating.

Although FCS's condition and performance remain satisfactory overall, a number of FCS institutions are experiencing stress and now require special supervision and enforcement actions. These actions reflect the weaknesses in the Nation's economy and credit markets, a rapidly changing risk environment in certain agricultural segments, and, in certain cases, management's ineffectiveness in responding to these risks. We have increased supervisory oversight at a number of institutions and dedicated additional resources in particular to those 14 institutions rated 3 or worse. Although these 14 institutions represent less than 4 percent of FCS assets and do not meaningfully impact FCS's consolidated performance, they require significantly greater FCA resources to oversee. As of December 31, 2010, five FCS institutions were under formal enforcement action, but no FCS institutions are in conservatorship or receivership.

#### REGULATORY AND CORPORATE ACTIVITIES

*Regulatory Activities.*—The Congress has given the FCA Board statutory authority to establish policy, prescribe regulations, and issue other guidance to ensure that FCS institutions comply with the law and operate in a safe and sound manner. FCA is committed to developing balanced, flexible, and legally sound regulations. Some of FCA's current regulatory and policy projects include the following:

- Revising regulations to implement the requirements of the Dodd-Frank Act;
- Revising regulations to ensure that FCS funding and liquidity requirements are appropriate and to ensure that the discounts applied to investments reflect their marketability;
- Revising regulations to require that each FCS institution's business plan includes strategies and actions to serve all creditworthy and eligible persons in the institution's territory and to achieve diversity and inclusion in its workforce and marketplace;
- Enhancing our risk-based capital adequacy framework to more closely align it with that of other Federal banking agencies and the Basel Accord;
- Revising lending- and leasing-limit regulations to ensure that FCS institutions maintain effective policies to measure and manage exposure to single counterparties, industries, and market segments, and to large complex loans;
- Revising regulations to allow FCS institutions to purchase eligible agricultural loans from the Federal Deposit Insurance Corporation;
- Revising regulations to enhance FCS disclosures of senior officer compensation and supplemental benefit programs; and
- Strengthening investment-management regulations to ensure that prudent practices are in place for the safe and sound management of FCS investment portfolios.

*Corporate Activities.*—While the number of FCS institutions has declined over the years as a result of mergers, their complexity has increased, which has placed greater demands on both examination staff resources and expertise. Generally, these mergers have resulted in larger, more cost-efficient, and better-capitalized institutions with a broad, diversified asset base, both by geography and commodity. Thus far in fiscal year 2011, two mergers of associations have become effective. In addition, two banks have submitted a plan of merger for FCA Board consideration. As of January 1, 2011, FCS had 84 direct-lender associations, five banks, five service corporations, and two special-purpose entities.

#### CONDITION OF THE FARM CREDIT SYSTEM

FCS remained fundamentally safe and sound in 2010 and is well positioned to withstand the continuing challenges affecting the general economy and agriculture. Total capital increased to \$33.3 billion at December 31, 2010, up from \$30.0 billion a year earlier. In addition, more than 81 percent of total capital is in the form of earned surplus, the most stable form of capital. The ratio of total capital to total assets increased to 14.5 percent at year-end 2010, compared with 13.9 percent the year before, as strong earnings allowed FCS to continue to grow its capital base.

Loan growth picked up in 2010, especially in the second half of the year when commodity prices increased sharply. In total, loans grew by 6.4 percent in 2010 compared with 2.1 percent in 2009. Nonperforming loans decreased modestly to \$3.4 billion as of December 31, 2010, and represented 10.2 percent of total capital at the end of 2010, down from 11.8 percent at the end of 2009. However, although credit quality is satisfactory overall, the volatility in commodity prices and weaknesses in the general economy have increased risks to some agricultural operators, creating the potential for future declines in asset quality.

FCS reported significantly higher earnings in 2010, with a combined net income of \$3.5 billion, up 22.6 percent from 2009. Return on assets remained favorable at

1.60 percent. FCS's liquidity position equaled 173 days at December 31, 2010, which was essentially unchanged from the 178 days a year earlier and well in excess of the 90-day regulatory minimum. The quality of FCS's liquidity reserves also improved in 2010. Further strengthening FCS's financial condition is the Farm Credit Insurance Fund, which holds more than \$3.2 billion. Administered by the Farm Credit System Insurance Corporation, this fund protects investors in FCS-wide consolidated debt obligations.

Farm income is expected to be very strong in 2011. The U.S. Department of Agriculture forecasts \$98.6 billion in farm net cash income—the highest since 1974, after adjusting for inflation. The high prices that grain, soybean, and cotton farmers will receive for their products will largely account for this increase. High feed costs, however, will present challenges for livestock producers. Already tight supplies of corn and soybeans in the United States could lead to significantly higher feed costs in 2011 and 2012 if growing conditions are unfavorable. High grain prices combined with extremely low interest rates are also propelling farmland values to record highs in parts of the Midwest. Although the current economy supports today's average land prices, some factors, such as higher interest rates, geopolitical developments that could undermine global demand for farm products, and an unexpected decline in grain prices because of a global supply response, could lead to a drop in the value of farm real estate. To address the issue of rising farmland values, FCA organized a meeting with the other Federal financial regulators to discuss concerns and observations regarding agricultural land values and associated risk to loan collateral. Our intent also was to foster a broad-based interchange on the appropriate regulator response to these risks and to develop a productive working relationship among banking regulators. We are considering additional meetings to continue our focus on topics important to agriculture.

FCS's access to capital markets returned to normal during 2010, which helped FCS further augment its solid overall financial strength, serve its mission, and maintain the Insurance Fund. FCS, as a Government-sponsored enterprise (GSE) with solid financial performance, benefited from monetary policy actions that helped to foster historically low domestic interest rate levels. Tepid investor demand for longer-term FCS-wide debt securities in 2009 improved appreciably in 2010, particularly for those with maturities of more than 5 years. Also, FCS continued to enhance its domestic marketing and internal liquidity reserve requirements. For 2011, FCS expects that the capital markets will continue to meet all of its financing needs.

#### FEDERAL AGRICULTURAL MORTGAGE CORPORATION

The Congress established Farmer Mac in 1988 to establish a secondary market for agricultural real estate and rural housing mortgage loans. Farmer Mac creates and guarantees securities and other secondary market products that are backed by agricultural real estate mortgages and rural home loans, USDA guaranteed farm and rural development loans, and rural utility loans made by cooperative lenders. Through a separate office required by statute (Office of Secondary Market Oversight), FCA regulates, examines, and supervises Farmer Mac's operations.

Farmer Mac is a GSE devoted to making funds available to agriculture and rural America through its secondary market activities. Under specific circumstances defined by statute, Farmer Mac may issue obligations to the Department of the Treasury, not to exceed \$1.5 billion, to fulfill the guarantee obligations on Farmer Mac Guaranteed Securities. Farmer Mac is not subject to any intra-FCS agreements and is not jointly and severally liable for FCS-wide debt obligations. Moreover, the Farm Credit Insurance Fund does not back Farmer Mac's securities.

Farmer Mac made continued financial progress during 2010. Although net income was down significantly from 2009, this decline was largely the result of unrealized gains and losses; however, core earnings, a measure based more on cash flow, was up by 56 percent. As of December 31, 2010, Farmer Mac's core capital totaled \$460.6 million, which exceeded its statutory requirement of \$301.0 million. The result is a capital surplus of \$159.6 million, up from \$120.2 million as of December 31, 2009. The total portfolio of loans, guarantees, and commitments grew 14 percent to \$12.2 billion.

In January 2010, Farmer Mac raised \$250 million in capital from a private offering of shares of noncumulative perpetual preferred stock of Farmer Mac II LLC, an operating subsidiary in which Farmer Mac owns all of the common equity. Farmer Mac used the proceeds to repurchase and retire \$150 million of Farmer Mac's outstanding series B preferred stock, with additional proceeds available for other corporate purposes. The new preferred stock has a lower net effective cost than the retired capital and has improved Farmer Mac's ability to generate new capital through earnings.

Farmer Mac's program-business portfolio shows stress in certain subsectors but remains manageable. Stress in the ethanol industry, as well as certain crop and permanent planting segments, contributed to an increase in the nonperforming loan rate. The nonperforming loan rate was 1.90 percent at December 31, 2010, compared with 1.41 percent at December 31, 2009. Loans more than 90 days delinquent increased from 1.13 percent at December 31, 2009, to 1.63 percent at December 31, 2010.

Regulatory activity in 2011 that will affect Farmer Mac includes an interagency joint Notice of Proposed Rulemaking to implement provisions of the Dodd-Frank Act relating to capital and margin requirements for over-the-counter derivatives that are not cleared through exchanges; a Notice of Proposed Rulemaking on nonprogram investments and liquidity at Farmer Mac that would, among other things, reduce reliance on credit ratings as required by section 939A of the Dodd-Frank Act; and an Advance Notice of Proposed Rulemaking that will request public input on how to reduce reliance on credit ratings in the methodology underlying the Risk-Based Capital Stress Test. In addition, FCA plans to finalize a rule to update the stress test to address Farmer Mac's new rural utility financing authority and make other technical changes.

#### CONCLUSION

We at FCA remain vigilant in our efforts to ensure that FCS and Farmer Mac remain financially sound and focused on serving agriculture and rural America. It is our intent to stay within the constraints of our fiscal year 2012 budget as presented, and we continue our efforts to be good stewards of the resources entrusted to us. While we are proud of our record and accomplishments, I assure you that FCA will continue its commitment to excellence, effectiveness, and cost efficiency and will remain focused on our mission of ensuring a safe, sound, and dependable source of credit for agriculture and rural America. This concludes my statement. On behalf of my colleagues on the FCA Board and at FCA, I thank you for the opportunity to share this information.





**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2012**

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**THURSDAY, MARCH 17, 2011**

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

The subcommittee met at 1:58 p.m., in room SD-124, Dirksen  
Senate Office Building, Hon. Herb Kohl (chairman) presiding.  
Present: Senators Kohl, Pryor, Brown, Blunt, and Moran.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**FOOD AND DRUG ADMINISTRATION**

**STATEMENT OF DR. MARGARET A. HAMBURG, COMMISSIONER**

**ACCOMPANIED BY:**

**PATRICK McGAREY, ASSISTANT COMMISSIONER FOR BUDGET,  
FOOD AND DRUG ADMINISTRATION  
NORRIS COCHRAN, DEPUTY ASSISTANT SECRETARY FOR BUDGET,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**OPENING STATEMENT OF SENATOR HERB KOHL**

Senator KOHL. We will come to order right now and start this hearing.

Today's hearing will focus on the fiscal year 2012 budget request of the Food and Drug Administration (FDA). We would like to welcome Commissioner Hamburg, as well as Mr. Patrick McGarey and Mr. Norris Cochran. It is very good to have you guys here with us.

The FDA budget request for this fiscal year includes an increase of \$385 million, or 14 percent, more than the funding level provided in fiscal year 2010. During a time when overall Government spending is declining, this budget request is an exception. Among other things, we are here to talk about why this increase is necessary.

Some people have questioned the role of the FDA and the growth of the agency's budget over the past several years. These are fair and important questions. I have been and continue to be a very strong supporter of the FDA. At the same time, I understand how difficult it is to talk about deficit reduction while at the same time defending such a large increase in the budget. Justifying that increase, Dr. Hamburg, is your task and it is not an easy one.

We have supported your work because we believe it is the job of the Federal Government to make sure that our food and drugs are

safe, and we need to make sure that you have the funding that you need to make that happen. This is not something we can relegate to States, local government, or private industry. The world and the way our food and drugs are produced are becoming more complex every day, and it is important for the FDA to have the ability to adapt to these changes.

Every \$1 that we spend in this bill must be questioned, of course, defended, of course, and well thought out. The administration has proposed to increase this budget while other areas of the Government are being cut. I believe the FDA's mission is critical to the safety of American families, but we must be able to justify the budget increase at this time.

So, we are looking forward to hearing from you, and first we will call on Senator Blunt.

#### STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. Thank you, Chairman Kohl, for holding this hearing on FDA and their budget request for fiscal year 2012. I know you have been a knowledgeable advocate for this work and look forward to your leadership on it.

I want to thank our witnesses for coming today as well.

The administration's request for FDA is an increase of 16 percent more than the current funding level, and if the budget request is approved, the agency will grow by an astonishing 60 percent since fiscal year 2008. This is one of the largest increases in the entire Department of Health and Human Services (HHS) and it is a higher percentage increase than in almost any agency in the U.S. Department of Agriculture (USDA).

As I mentioned at last week's hearing with Secretary Vilsack and earlier this week in a meeting I am pleased the Commissioner was able to have with me in anticipation of this hearing, I am concerned about the fragmentation among the food agency inspection services and hope we can look for ways to streamline wherever we can. I think it was Einstein who said everything should be as simple as possible but no simpler. So, we do not want to streamline it to the point that it does not work, but we do want to look for those efficiencies that we are able to find. According to the Government Accountability Office report released earlier this month, 15 Federal agencies are responsible for oversight of 30 food-related laws. It is important we look for ways to do what we can about duplication where it occurs.

The recent outbreak of salmonella in eggs showcased this fragmentation. Currently, the FDA has the responsibility of ensuring the safety of shell eggs, yet USDA oversees eggs that are processed into egg products. The Secretary himself used the example of a pepperoni pizza that is under the jurisdiction of one agency while cheese pizza is under the jurisdiction of another.

With significant investments, Dr. Hamburg, comes significant responsibility. I know you want your agency to be accountable and we do too. We cannot look at this budget without understanding that the Federal Government is borrowing \$4 billion every single day. Families all across America do not understand why their Government cannot operate with the same rules they face, and the

Government must start living within its means. So, I am looking forward to what we can do together to address these issues.

As we tackle funding decisions this year, we have to be mindful, of course, that the FDA touches the lives of every American every day, and amazingly around 20 cents out of every \$1 spent in America is used to purchase an FDA-regulated product. Americans expect these products to be safe and effective. Dr. Hamburg, I look forward to working with you and your team and certainly with Chairman Kohl as we move down the path to doing the things that make the most sense for the job you have to do.

And thank you, Chairman.

Senator KOHL. Thank you very much, Senator Blunt.

Commissioner Hamburg, we would love to hear from you.

#### SUMMARY STATEMENT OF DR. MARGARET A. HAMBURG

Dr. HAMBURG. Thank you very much, Chairman Kohl, Ranking Member Blunt, and distinguished members of this subcommittee. I appreciate the opportunity to present the President's fiscal year 2012 budget for FDA and our priorities for the coming year.

This hearing comes at a critical time for our Nation and for our agency. We must be prepared to meet and fully embrace the scientific challenges and global realities of our modern world, and the stakes for public health, for patients and consumers, and for our economic health have never been higher.

Our agency is charged with an extremely significant task, to promote and protect the health of the American people. This includes ensuring the safety, effectiveness, and wholesomeness of products that Americans rely on, as you noted, in fundamental, sometimes lifesaving, ways—drugs, vaccines, medical devices, our Nation's food supply, and more. But it also includes working proactively to foster the scientific innovation that will lead to tomorrow's new breakthrough products. Both roles are essential to delivering progress for the American people and both roles impact our economy by encouraging consumer confidence, growing key industries, and creating jobs.

Thanks to the support of the chairman and members of this subcommittee, FDA has been able to make forward progress on a wide range of vital priorities to improve the health, quality of life, safety, and security of all Americans. With the resources that you have appropriated, we have achieved tangible benefits for the people that we all serve.

During the past year, we have approved dozens of new drugs, vaccines for seasonal and pandemic flu, and medical devices for hearing and vision loss, severe asthma, and to perform 3-D mammography screening. We applied cutting-edge whole genome sequencing to trace foodborne illness outbreaks. We have launched a new system that identified 100 food safety problems in the first months of operation. We have collaborated with the National Oceanic and Atmospheric Administration to develop and to perform screening tests to assure seafood safety and reopen the gulf coast fisheries after the Deepwater Horizon oil spill. Those are just a few of the things that the agency has accomplished in the past year.

As you can see, FDA is charged with an enormous and unique set of tasks, and if we do not do our job and do it fully, there is

no other agency or entity to backstop behind us. That is why I am here to ask for your support of the fiscal year 2012 budget for the FDA.

The proposed budget includes \$4.4 billion overall and identifies four priority initiative areas: Transforming Food Safety and Nutrition; Advancing Medical Countermeasures; Protecting Patients; and Fostering FDA Regulatory Science and Facilities.

Compared to the fiscal year 2010 budget, the fiscal year 2012 budget represents an increase of almost \$1.1 billion, \$382 million in budget authority, and \$694 million in user fees. The amount of user fees includes \$60 million for three new user fees that FDA is proposing.

In addition, in an effort to contribute to deficit reduction, we will undertake nearly \$30 million in contract and administrative savings across the agency.

These four initiatives are critical to our mission of protecting and promoting the health of the public and they also represent important opportunities for our food and medical product industries to grow and to strengthen our economy. In other words, they will provide the significant return on investment that we all are looking for, for products, for people, and most importantly, for the public health. And let me just quickly explain how.

First, the Transforming Food Safety and Nutrition Initiative contains an increase of \$326 million to build a stronger, more reliable food safety system that will protect American consumers. We will use these resources to aggressively implement the Food Safety Modernization Act (FSMA) that the Congress passed in December. This landmark legislation provides FDA with the tools to establish a prevention-focused food safety system, placing the primary responsibility for prevention on the food producers and processors and leveraging the valuable work of FDA's State and local partners. FDA will also make sure that American families have the information that they need to make more healthful food choices through menu and vending machine labeling.

Second, for the Advancing Medical Countermeasures Initiative, FDA proposes \$70 million. Medical countermeasures include drugs, vaccines, diagnostic tests, and other medical equipment that are needed to detect and respond to deliberate chemical, biological, radiological, and nuclear threats, as well as emerging infectious diseases or other natural disasters, all of which threaten the lives and safety of the American people and I think weigh heavily on our minds right now given the tragic events in Japan. This investment will help accelerate the development of countermeasures to meet a set of critical national security and public health needs.

Third, the Protecting Patients Initiative, for which we are proposing an increase of \$123.6 million, will allow FDA to establish a pathway for approving lifesaving biosimilar products. This could offer substantial savings for the Federal Government and private-sector healthcare. This initiative also includes investments in scientific tools and partnerships to enhance the safety of increasingly complex drugs, medical devices, and biologics, and an increasingly complex foreign and domestic global supply chain.

Fourth, the FDA Regulatory Science and Facilities Initiative contains an increase of \$48.7 million to strengthen the core regulatory

scientific capacity that supports all of FDA's missions and will enable us to truly streamline and modernize our regulatory work by applying the best possible science, especially as we address more advanced therapies, complex devices, and emerging technologies. It will also allow FDA to outfit and to occupy the Center for Biologics and Center for Drugs Life Sciences–Biodefense Laboratory complex which will play a critical role in shaping strategies in response to pandemics, emerging infectious diseases, and deliberate biological threats.

So, even in these difficult times, the FDA's fiscal year 2012 budget is essential to our ability to take meaningful, science-based action on behalf of the American people. With these investments and your support, I am confident that we can build on our past successes and better ensure our Nation's health.

Thank you for the opportunity to testify and I am happy to answer your questions.

[The statement follows:]

#### PREPARED STATEMENT OF DR. MARGARET A. HAMBURG

##### INTRODUCTION

Chairman Kohl, Ranking Member Blunt, and members of the subcommittee, I am Dr. Margaret A. Hamburg, Commissioner of the Food and Drug Administration (FDA). I am pleased to present the President's fiscal year 2012 budget request for FDA.

For today's hearing, I am joined by Patrick McGarey, FDA's Assistant Commissioner for Budget and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services (HHS).

In my testimony today, I will outline the important initiatives in FDA's fiscal year 2012 budget request to the Congress. My testimony also highlights FDA's unique role in protecting public health and the value that FDA delivers for American taxpayers.

##### UNIQUE ROLE OF FDA

FDA is charged with ensuring the safety, effectiveness, and wholesomeness of products that Americans rely on in fundamental, sometimes lifesaving, ways—drugs, vaccines, medical devices, our Nation's food supply, and more. These are products that people need; products they care about; and products that are critical to their health, safety, and well-being. Our role is unique and if we don't do our job completely and responsibly, there is simply no other agency or entity to backstop us.

Fulfilling our mission—to promote and protect the public health—is a difficult task under any circumstances. But these are especially challenging times. Today, the powerful forces of globalization are reshaping our world. We face complex threats—both accidental and deliberate—that pose new risks to FDA-regulated products and the Americans who rely on them. And we have been forced to rethink the way we do our job.

But we also live in a time of great advances in science and technology. Breakthroughs in the life sciences have provided industry with new opportunities to invest, innovate, create new markets, strengthen our economy, and most important, deliver new products and benefits for the American people.

##### FDA INNOVATION, ACCOUNTABILITY, AND RESULTS

My dedicated colleagues at the FDA are deeply committed to the health of American patients and consumers—and they recognize that innovation is essential to progress in public health.

Innovation is the foundation of the successful industries we regulate, and innovation is responsible for remarkable advances across all of the product areas within FDA's jurisdiction—which is why we must work proactively to foster the scientific innovation that will lead to tomorrow's breakthrough products.

Innovation is also critical to maintaining U.S. global leadership in many areas, including medical product development. Currently, most new drugs are approved in

the United States before they are approved in Europe. And according to a recent industry study, we either are ahead of or tied with Europe for approval of medical devices that fall into the lower-risk category, which represents 90 percent of medical devices.

In my testimony, I highlight some recent FDA actions that allow the food, drug, biologic, and device industries—all engines of innovation—to bring new products and technologies to market.

We also recognize that just as FDA supports the ability of industry to innovate, FDA itself must innovate and become more efficient. In FDA's fiscal year 2012 budget, we highlight more than 100 examples in which FDA centers and offices are improving the efficiency of our programs, and in many of these examples, we are also supporting industry efforts to develop new products. Examples of FDA innovation include the recent launch of the Innovation Pathway, a program to stimulate new, breakthrough technology and advances for medical device manufacturers, as well as a scientific collaboration with industry to develop novel technologies to detect new and traditional foodborne contaminants and to develop safe food packaging. These efforts reduce the risk and expense of recalling products that fail to meet safety standards.

FDA is also committed to accountability. During the past year, we developed and implemented FDA-TRACK, an agency-wide system to monitor key performance measures for more than 90 FDA programs. Through FDA-TRACK, we are systematically monitoring FDA's progress as we work to achieve our performance measures and allowing stakeholders and the public to witness our progress through quarterly reports that we post on [www.FDA.gov](http://www.FDA.gov).

But the best measure of the value that FDA delivers is the opportunity to reduce costs and achieve measurable savings in areas that are important to America's health. One example is FDA support for the generic drug industry, which markets drugs that save American patients and taxpayers \$140 billion per year.

A second example is FDA's food safety program, which is making significant progress to reduce foodborne illness that costs the U.S. healthcare system \$88 billion annually. A third example is the fiscal year 2012 Generic Biologics Initiative, which will generate significant savings for the Federal Government and for private-sector health plans.

#### FDA ACCOMPLISHMENTS

Thanks to the support of this subcommittee, FDA continues to achieve important public health milestones. Since early 2010, FDA has supported industry efforts to bring new products and technologies to market—and to think creatively about how to promote and protect the health of the American people in meaningful and sustainable ways.

During the past year, FDA:

- approved new drugs to treat diabetes, hypertension, osteoporosis, bacterial infections, chronic pain, rheumatoid arthritis, preterm birth, gout, immune deficiencies, schizophrenia, major depressive disorder, and pulmonary disease;
- approved five new therapies to treat rare diseases;
- conducted four workshops to stimulate new orphan drug development;
- tentatively approved the 126th anti-retroviral drug under the President's Emergency Plan for AIDS Relief;
- approved vaccines for seasonal and pandemic influenza;
- approved new donor screening tests for HIV and Chagas disease;
- cleared a new test to support kidney transplant patients;
- approved new medical devices to treat hearing loss, severe asthma, and vision loss, and to perform 3-D mammography screening;
- cleared technology for physicians to view diagnostic images on iPhones and iPads;
- identified measures to prevent radiation overdoses during computed tomography scanning;
- permitted the marketing of the first test to identify norovirus, a common foodborne illness;
- applied genome sequencing to trace foodborne illness outbreaks;
- collaborated with the National Oceanic and Atmospheric Administration to develop tests to re-open gulf coast fisheries;
- formed public-private partnerships to improve produce safety; and
- launched a new system that identified 100 food safety problems in first 7 months of operation.

## FISCAL YEAR 2012 BUDGET SUMMARY

Although the President emphasized in his fiscal year 2012 budget message that the fiscal realities we face require “hard choices,” the 5-year freeze on Federal spending announced in the fiscal year 2012 budget is not an across-the-board cut. Although the overall budget represents a freeze in the aggregate, it also contains investments in areas critical to sustain and grow the American economy.

FDA is one such area of critical investment. As you can see from FDA’s fiscal year 2012 priorities—food safety and nutrition, medical countermeasures (MCMs), patient safety, and FDA regulatory science—an investment in FDA is an investment in the economic health of two of the largest segments of America’s economy: our food and medical products industries.

Our fiscal year 2012 budget is also an investment in health—in the health of individuals and the public health of our Nation. As a result, the budget includes \$4.4 billion in budget authority and user fees to protect and promote the health of the American public every day, and through every stage of life.

## CONTRACT AND ADMINISTRATIVE SAVINGS

Although FDA’s fiscal year 2012 budget is an overall increase for FDA, it also contains savings that contribute to the administration’s deficit reduction goals. FDA is proposing \$29.7 million in contract and administrative savings designed to achieve reductions and cut costs across all FDA program areas.

To achieve these savings, FDA will reduce administrative staff by 46 full-time equivalents, lower contract costs by increasing competition, and expand the use of blanket purchase agreements and other agency-wide approaches to reduce contract costs. Where possible, we will also save by using technology to improve how we manage our contracts and the contracting process. Finally, in some program areas, FDA will reduce the cost of employee training by replacing the traditional classroom model with online training.

## TRANSFORMING FOOD SAFETY AND NUTRITION

For fiscal year 2012, FDA proposes an increase of \$326 million for the Transforming Food Safety and Nutrition Initiative to build a stronger, more reliable food safety system that will protect American consumers. This increase includes \$225.8 million in budget authority and \$100.2 million for user fees, including the four new user fees enacted in the FDA Food Safety Modernization Act (FSMA).

With this increase, FDA will begin to implement the landmark food safety legislation, which the Congress enacted last December. Under this initiative, FDA will also ensure—through menu and vending machine labeling—that American families have the information they need to make more healthful food choices.

*FDA Food Safety Investment.*—The passage of FDA FSMA, the first major overhaul of our food safety law in more than 70 years, will transform FDA’s food safety program. Through FFSMA, the Congress enacted new safeguards and enhanced tools to protect America’s food supply by preventing food safety problems rather than reacting to problems after they occur.

Regrettably, foodborne illness is pervasive across America. Each year, nearly one of every six Americans gets sick due to foodborne illness. Some cases are severe—128,000 require hospitalization, and 3,000 Americans die from foodborne illness.

FFSMA closes significant and longstanding gaps in FDA’s food safety authority. For example, FFSMA gives FDA important new tools to ensure that imported foods are as safe as domestic foods and directs FDA to build an integrated national food safety system in partnership with State, local, and tribal authorities.

FDA will use these resources to establish a prevention-focused food safety system that leverages the valuable work of FDA’s State and local food safety partners. In addition to yielding profound public health benefits, the FFSMA focus on prevention offers the opportunity for a dramatic return on the resources that this subcommittee invests in food safety. According to recent studies and the latest estimates of foodborne illness, the healthcare cost of foodborne illness—not including costs to the food industry—exceeds \$88 billion each year.

The combined result of these actions will be a stronger, more reliable food safety system that protects the American people.

In its fiscal year 2012 budget, FDA is organizing its food and animal feed safety programs and investments to implement FFSMA. Our detailed budget documents display the specific dollar amounts that FDA will allocate to implement the 22 separate sections of the law.

*Nutrition.*—As part of the Transforming Food Safety and Nutrition Initiative, FDA will also begin an \$8.8 million program to improve nutrition labeling on res-

restaurant menus and vending machines so that consumers can adopt healthier diets. This small but significant initiative offers powerful return on investment. A fiscal year 2009 analysis estimated the medical costs of obesity at \$147 billion per year (Finkelstein, et al., Health Affairs), which means that controlling obesity goes hand-in-hand with controlling healthcare costs and reducing a significant burden on our economy.

The investments in this initiative will empower consumers to make better nutritional choices and will motivate food producers to develop healthier foods.

#### ADVANCING MEDICAL COUNTERMEASURES

For fiscal year 2012, FDA proposes \$70 million for the Advancing MCMs Initiative. MCMs include drugs, vaccines, diagnostic tests, and medical equipment and supplies to respond to deliberate chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious diseases, such as pandemic influenza.

The Advancing MCM Initiative will strengthen FDA's ability to respond to these national security threats by supporting the development of MCMs as well as enhancing review by allowing FDA to work interactively with product developers and Government partners from early in the development process. With this investment, FDA will be better able to anticipate and resolve bottlenecks in MCM development and accelerate development of MCM products for pressing public health and national security needs.

*MCM Gap.*—Today, our Nation lacks the range of MCMs required for emergency response. For example, there are no countermeasures to treat acute radiation syndrome, which would afflict millions in the aftermath of a nuclear event.

Moreover, no FDA-cleared, rapid, point-of-care diagnostics exist for any of the bi-threat agents of greatest concern. Such diagnostic tests are essential to guiding the public health response; ensuring that patients receive the most appropriate treatment; and promoting appropriate use of the limited supplies of MCMs available during a public health emergency.

*Analysis of the Need for MCMs.*—In December 2009, on the heels of the influenza pandemic, HHS Secretary Sebelius called for a comprehensive review of the Nation's readiness to defend against CBRN threats. The HHS review was prompted by recognition that influenza vaccine became available only after pandemic influenza was already widespread across the United States. The HHS review called on the expertise of the scientific leadership of all Federal agencies that work with MCMs, as well as State and local health departments, the National Biodefense Science Board, and the Institute of Medicine.

The review, released on August 19, 2010, identified the barriers to MCM development as well as significant opportunities to improve the path for successful MCM development. The review identified FDA as critical to the success of the MCM Enterprise, primarily because FDA evaluation of product safety and efficacy can significantly affect the course of product development.

The report further recognized that robust FDA engagement from the earliest stages of product development can substantially increase the odds of successful approval. In other words, increased support for FDA's MCM activities is one of the most critical steps the Federal Government could take to transform the larger MCM Enterprise.

*Threat Assessment.*—Dozens of reports since September 2001 and the October 2001 anthrax attack have affirmed the risk of terrorist groups wielding biological weapons and the suffering, death, and social and economic disruption that would result in the case of an attack. Therefore, the fiscal year 2012 investment in FDA medical countermeasure development and review offers the potential for a strong return on investment.

The analysis of the National Security Strategy warns that the effective dissemination of a lethal biological agent within a U.S. population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, social, and political consequences. The National Security Council warned in 2009 that the economic cost of a well-executed bioterrorist attack on American soil could exceed \$1 trillion.

Clearly, such an attack would have profound consequences on our social and political order, and more broadly, our way of life. Without this investment, America's public health and national security will continue to be at risk.

#### PROTECTING PATIENTS

For fiscal year 2012, FDA proposes an increase of \$123.6 million for the Protecting Patients Initiative. This increase includes \$64.8 million in budget authority and \$58.8 million from three new user fees. FDA is proposing new fees for reviewing



generic drug applications, paying the cost of medical product reinspections, and inspecting imports that arrive by international courier.

*Generic Biologics.*—With the fiscal year 2012 increase in budget authority, FDA will establish a pathway for approving generic biologics. Generic biologics are biological drugs shown to be highly similar to an FDA-approved biological product. In some cases, generic biologics may also be interchangeable with the FDA-approved biological product.

Biological products include therapies to treat certain cancers, rheumatoid arthritis, age-related macular degeneration, and HIV. These therapies cost \$15,000 to \$150,000 or more per patient per year—and represent a significant share of Federal Government and private-sector pharmaceutical costs.

Approving biosimilar versions of these products offers the potential for substantial savings for the Federal Government and private-sector health plans. However, these savings will not materialize unless FDA has the resources to implement a clear regulatory pathway for approving generic biologics. FDA is requesting these funds for fiscal year 2012 because the sooner we make this investment the sooner we will see savings from generic biologics.

*Other Medical Products.*—In addition to investing in generic biologics, the Protecting Patients Initiative also invests in new scientific tools and partnerships to enhance the safety of increasingly complex drugs, medical devices, vaccines, and other biological products. For example, the Protecting Patients Initiative will strengthen FDA efforts to modernize and improve safety throughout the supply chain of medical products at a time when the number of medical products manufactured abroad is increasing dramatically, which presents real challenges for medical product and manufacturing safety.

Safer medical products not only benefit patients, but also benefit the manufacturers of drugs, biologics, and medical devices. Safer products reduce healthcare costs and allow manufacturers to avoid the expense of product recalls.

With the resources in this initiative, FDA will modernize its approach to ensure safety across the supply chain for medical products. The initiative will also expand FDA's capacity to conduct medical product safety assessments and strengthen the safety of vaccines and the blood supply.

The proposals in this initiative offer a high rate of return for the investment of Federal dollars. They can reduce the cost of care and promote safe, high-quality, and accessible healthcare that Americans deserve. In addition, the administration is proposing additional measures for fiscal year 2012 designed to reduce costs and increase the availability of generic drugs and biologics.

#### FDA REGULATORY SCIENCE AND FACILITIES

For fiscal year 2012, FDA proposes an increase of \$48.7 million for the FDA Regulatory Science and Facilities Initiative.

The FDA Regulatory Science and Facilities Initiative will strengthen the core regulatory scientific capacity that supports all elements of the FDA mission. Regulatory science focuses on developing the knowledge and tools to properly assess the safety, effectiveness and quality of products that are being developed or are already on the market. Specifically, this initiative will help modernize and streamline the regulatory pathways that industry relies on to bring new, innovative products to market.

It will also modernize the FDA review and approval process for products that rely on new and emerging technologies. The result will be promising new opportunities to diagnose, treat, cure, and prevent disease.

Finally, the resources in this initiative will also allow FDA to outfit the Center for Biologics Evaluation and Research—Center for Drug Evaluation and Research Life Sciences-Biodefense Laboratory complex. On August 18, 2010, the General Services Administration awarded the construction contract for the new laboratory complex at White Oak, and construction work is currently underway. Without this investment, FDA must pay double the rent: the first for a new lab we cannot occupy and second for the old lab we cannot vacate.

The new laboratory complex will help FDA fulfill our scientific responsibilities to promote drug and biologic safety and MCM development and prevent threats, including annual influenza. FDA must make this investment in fiscal year 2012 to ensure that the laboratory is operational and ready for occupancy in fiscal year 2014.

#### FDA CURRENT LAW USER FEES

For fiscal year 2012, FDA proposes an increase of \$634.5 million for 12 current law user fee programs.

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, medical devices, and other FDA-regulated prod-

ucts. Fees also allow FDA programs to achieve timely and enhanced premarket review performance. Finally, fees support the programs and operations of the FDA Center for Tobacco Products.

Existing user fee laws authorize fee increases for many FDA user fee programs. The increases expand the available options for treating and curing diseases and addressing other important public health needs.

#### CONCLUSION

The FDA budget for fiscal year 2012 contains important investments for critical public health priorities. With these resources, FDA will transform food safety; support the development of urgently needed MCMs; protect patients by assuring that the drugs and other medical products they rely on are safe; and advance regulatory science, which serves as the foundation for all science-based decisions at FDA.

Thank you for the opportunity to testify. I am happy to answer your questions.

Senator KOHL. Thank you very much, Dr. Hamburg. We will now embark on a round of questions from the panel.

#### FOOD AND DRUG SUPPLY

Your statement highlights what FDA can do with additional funding, but what happens if you do not get the full amount you are asking for like, for example, can you still tell us that you will be able to ensure a safe food and drug supply with your present budget?

Dr. HAMBURG. Well, as you know, FSMA, which just went into law, gives us a historic opportunity to really transform the food safety system in our country into one based on prevention and one that will really make a difference in preventing costs in terms of illness and death of people, consumers, and preventable costs to our healthcare system and to the food industry.

If we cannot get additional resources to support the implementation of this bill, we will, of course, continue to pursue important aspects of what is contained in that legislation, but we will only really be able to put forward regs. We will be able to put ideas and programs on paper, but we will not be able to fully implement all that needs to be done. We will not be able to pursue the ambitious inspection program domestically and internationally that enables us to have a hands-on look at how food production and processing is being done to ensure safety.

Importantly, we will not be able to work with manufacturers and producers to really put in place the prevention-based strategies, the risk-based approaches that are really so vital to what we need to be doing so that we are not scrambling after outbreaks occur but actually preventing them in the first place. That will save lives. That will save money.

And we will not be able to address the increasing challenge of import safety. More and more of the food we eat in this country is actually grown, produced, manufactured, distributed overseas in an increasingly complex supply chain, and we really have a responsibility to enhance our efforts to ensure the safety of that global food supply as well.

And at the end of the day, it is very, very important to industry that we have and maintain the reputation of a strong food supply. We do, at the present time, have one of the strongest food safety systems in the world. That is very, very important. It matters to people and it matters to the health of the industry, their ability to have markets that people have confidence here at home, and export

markets depend on the confidence of the public at large in the work of the FDA working with industry.

#### MEDICAL COUNTERMEASURES

Senator KOHL. The budget for fiscal year 2012, Commissioner Hamburg, proposes an increase of \$70 million to help develop new therapies that could be quickly used in the event of a chemical or biological attack or a natural disaster of another sort. The tragedy in Japan where they are confronting so many challenges right now including, of course, radiation exposure, does focus our attention on the importance of preparedness.

Can you tell us a little bit about this initiative of yours? What will we be getting with this investment? What can we tell the American people about our present state of preparedness with respect to something comparable to what happened in Japan?

Dr. HAMBURG. This is a very important initiative, and as you say, it is underscored by recent events. As a Nation, we must be prepared and we must be resilient in the face of a range of potential threats, both naturally occurring and deliberately caused. And at the present time, we have more work to do, and this Medical Countermeasures Initiative at FDA is part of a broader administration-wide initiative to ensure that we as a Nation are prepared for the kinds of potential threats to our Nation's security that can occur.

If we cannot move forward with this Medical Countermeasures Initiative, we will not be able to ensure that we have the drugs, the vaccines, the diagnostics, the medical equipment that is necessary to respond to an event. We need to be developing, for example, with respect to radiation safety, state-of-the-art therapies that will enable us to treat both acute radiation syndrome, such as, sadly, workers in the nuclear plant in Japan are potentially being exposed to, and other forms of radiologic exposures, both the threat of a dirty bomb or an intentional nuclear event, or a catastrophic, unexpected event, such as what has occurred in Japan.

#### RADIATION PREPAREDNESS

Senator KOHL. Are we prepared at this time to deal with the fallout of a nuclear meltdown such as they have had in Japan? Are we prepared?

Dr. HAMBURG. There are many aspects of preparedness, and actually FDA is involved in a number of them. There is the issue of ensuring that any imported products from Japan are screened and safe for consumption, and we are actively involved in addressing that. At the moment, there are not imports from that region coming in.

Senator KOHL. I was referring to something akin to what happened in Japan. Are we prepared today to deal with it here in the United States?

Dr. HAMBURG. Oh, an event in—you know, we have many systems of preparedness in place, but we are lacking some critical elements of preparedness, including these important medical countermeasures. We need to make sure that we have the medical treatments necessary. We do not have treatments for acute radiation sickness. We need to develop those treatments and we need to

make sure that they are available for the American people and potentially available for people around the world.

Senator KOHL. Before I turn this over to Senator Blunt, I believe I hear you saying that we could not assure the American people here today that in the event of something similar to what happened in Japan, we would be in a position to take care of the needs of the people in the areas where the nuclear disaster occurred. We are not prepared to take care of them.

Dr. HAMBURG. We have systems for response and we have some acute measures that we could provide, but we do not have, for example, as I said, the treatment of acute radiation sickness that we would need to be able to benefit people exposed to very high levels of radiation exposure. We do not have the treatments to address a range of potential nuclear exposures. We would be able, in the case of a nuclear reactor event, to provide potassium iodide for limited protection of the thyroid organ. There are other potential exposures, and we are working to develop, as a Government, interventions that will make a difference.

But we need to make targeted investments today to be prepared for tomorrow. That is what this Medical Countermeasures Initiative is about. In the field of radiation exposure absolutely, yes, we have other gaps in preparedness that we need to address whether it is naturally occurring infectious disease threats or the potential for biological, chemical, nuclear terrorism. We really have a responsibility to make sure that we make these investments today, and I think it is something that we all, for our Nation's security, need to work on together.

Senator KOHL. Senator Blunt.

#### RADIATION TREATMENTS

Senator BLUNT. Thank you, Chairman.

Commissioner, are you saying on this area of radiation problems, that we do not have a stockpile of the treatments or that the treatments do not exist?

Dr. HAMBURG. The treatments do not exist for many aspects of radiation exposure.

Senator BLUNT. And are you saying that under this program you are talking about, one of the FDA's goals would be to develop those treatments?

Dr. HAMBURG. Would be to work with industry and Government scientists to, yes, develop and also to get them reviewed and approved for safety and effectiveness so that they could be available to the American people.

#### RESPONSIBILITY DUPLICATION

Senator BLUNT. Well, I am going to get to review and approval here in 1 minute. Let me go through things with some quickness, if I can.

On the duplication issues that I talked about earlier and that we talked about the other day, is there any ongoing effort in the food and drug safety agencies to try to figure out how we can do that in a more focused way?

Dr. HAMBURG. It is an important area of focus. Soon after the President was inaugurated, he initiated the Food Safety Working

Group to bring together the different agencies of the Federal Government that have responsibilities for food to really look at how they could coordinate better and to develop key cross-cutting strategic priorities as well.

It is the case that FDA and USDA have the major responsibilities for food safety in this country, and we, of course, do work closely together and we are examining ways to work more closely going forward. Certainly, in FSMA implementation, we are working closely with USDA in order to take advantage of their expertise and experience working in farming communities, to take advantage of the resources that they already have on the ground. We are also talking with them about how to more effectively share information around inspections and other food safety-related activities.

The partnership is also very important, and the integration working with State and local authorities as well, and that is an important component of FSMA, and it is a very important component of how we do business and need to do business more efficiently going forward.

Within the FDA itself, we have looked hard at how to make our work more efficient and integrated as well because we had components of the FDA working on food safety issues and we have now created an Office of Foods with a Deputy for Foods in charge of all of those activities and are integrating our food safety activities across both the human and the animal food safety arenas to make our program more robust, more integrated, and more efficient. And there is lots more work to be done.

#### FOOD SAFETY MODERNIZATION ACT

Senator BLUNT. Well, I encourage you to pursue all of that work as vigorously as we can. We need to be able to defend the things we do and to argue with justification that we are trying to do those things better and not duplicate our effort.

On the duplication of effort, one of my big concerns about FSMA was yet another on-farm presence of another Government regulator. What are you doing there, as you look at those new responsibilities, and are you working with agencies like USDA that are already there to see how you can work with the information and structure they have?

Dr. HAMBURG. Yes. No, very much so. We have been working hard to really make sure that we understand the challenges and the concerns of the farming community as we move towards implementing FSMA. We, of course, have been on farms in the past when there are food-borne outbreaks around BSE issues and tissue residue issues. So, it is not completely new territory to us. But we recognize that we are now undertaking a new set of roles and it is very important that we work constructively with the farming community and with other partners that interact with the farming community.

I have been out to visit quite a number of farms and my Deputy for Foods even more, have learned a lot about the full range of different types of farms and their different issues and have listened hard and will continue to try to work with the farming community. And USDA has been very helpful to us and the Extension Service

is a critical component of our ability to do outreach to farmers and to consumers.

We recognize that nobody wants more people in their farming communities telling them what to do. We view this as a collaboration. We view this as an opportunity for us to pursue a common goal of ensuring that the food supply is safe, doing what I think every farmer and food producer wants to be able to do, which is to make sure that the food they produce is safe and wholesome and that consumers can count on it and trust it.

#### FOOD TRACEABILITY

Senator BLUNT. And do you have new responsibilities for food traceability in this law?

Dr. HAMBURG. It is an important component of what we need to do as part of FSMA, and it will certainly prove to be of value if we can put that kind of a program in place because it will enable much more rapid identification of a problem and its source when it should occur so that we can identify and respond rapidly, control the problem, and mitigate the effects, and get those companies back up and running, producing the food with a robust market for the food that they produce.

Senator BLUNT. Would that be across the board? This is a question I do not know the answer to. Is that across the board for your agency? Does that include livestock as well?

Dr. HAMBURG. No. We regulate about 80 percent of the food supply, but we are not responsible for meat, poultry, processed eggs, and catfish.

Senator BLUNT. And particularly catfish.

Dr. HAMBURG. Right.

Senator BLUNT. Mr. Cochran will be glad to know that you are not going to get involved in catfish. Probably Mr. Pryor as well.

But you will have new traceability requirements or obligations on the things you do regulate on the farm.

Dr. HAMBURG. We are going to be starting to have those discussions about what such a system should look like. Industry has an important voice and a lot of experience in these issues because it is so important in terms of being able to rapidly identify problems and address them.

#### REVIEW PROCESS

Senator BLUNT. Let me ask just a couple of quick questions on review processes, particularly since you mentioned you might have some other ways to try to get these products that Chairman Kohl was talking about to the market quicker.

#### USER FEE REVIEWS

Two of your largest fee programs, prescription drugs and medical device review, are up for reauthorization in this fiscal year. How do you intend to approach those fee negotiations with industry?

Dr. HAMBURG. Well, these are very important activities, and the user fee programs that were introduced in the 1990s have demonstrated their value on the drug side and on the device side in terms of helping to give us the resources that we need to be able

to ensure the best possible review in the most timely way possible. The negotiations are underway. We have actually just begun negotiations with the generic industry as well, which currently does not have user fees. We are optimistic that we are going to be able to achieve a good proposal for the next user fee legislation that will come before you. And I think both the industries we regulate that provide user fees and certainly our agency feel that these are critical programs that help to enable us to be able to do our job. And I think that overall we have been performing well in response to the introduction of the user fees and meeting the targeted goals both on the drug side and the device side.

Senator BLUNT. I do not know what the fiscal year 2010 numbers were. I think the fiscal year 2009 numbers—and clearly, this is the first 9 months of this administration, so numbers that may be even less than fiscal year 2009. But I think in fiscal year 2009, the agency failed to meet one-third of its drug review goals and approximately 20 percent of its device review goals.

Dr. HAMBURG. Well, those are different numbers than I have seen. On the drug side, it is the case that in recent years we have not met all of the goals, although in the first 15 years of the program, we met and surpassed the goals. In 2007, the FDA Amendments Act (FDAAA), gave FDA quite a comprehensive set of additional new responsibilities mainly focused on drug safety, and it is the case because our resources are fairly limited, we had to target resources that might have gone into drug review into responding and implementing the requirements of this new and important Amendments Act. So, we saw some drop-off in our review times as we began to implement those components of FDAAA. We are getting right back up to the performance levels prior to that though. But we have had a lag. That is true.

On the device side, most of the device program is focused on the premarket notification program, what is called the 510(k) process. About 95 percent, I think, of the devices that we review are part of that program. And we have been meeting the targets agreed to with industry in that program.

Senator BLUNT. And they should expect you to do that.

Dr. HAMBURG. And they should expect us to do that.

In the premarket approval area, which is a more rigorous approval mechanism and has more requirements, we can and will do better. We have put forward, under the leadership of our new center director, Dr. Jeffrey Shuren—he has led a very serious review of our regulatory pathways, how we can make them more effective and efficient, how we can bring the best possible science to bear. He put forward in January of this year 25 recommendations that reflected a lot of public comment, discussions with industry, stakeholders, patient advocates, and others. He put forward these 25 recommendations for how we can do better.

We have also asked the Institute of Medicine of the National Academies of Sciences to take a look at some of the regulatory issues in the device area to make broader recommendations about how we can modernize and improve our regulatory pathways.

Senator BLUNT. Good.

Dr. HAMBURG. So, we want to keep working on it.

Senator BLUNT. If my figures are wrong here, would you please get back to me and let me know? But my notes here indicate that FDA failed to meet one-third of the drug review goals and approximately one-fifth of the device review goals. And if that is not right, just tell me at some future time.

Dr. HAMBURG. We will get back to you.  
[The information follows:]

#### DRUG AND DEVICE REVIEW GOALS

In fiscal year 2008, we met or exceeded the 90-percent performance levels for 33 percent—or 4 of 12 goals—of the drug review performance goals. In fiscal year 2009, we demonstrated significant improvement in regaining stability in meeting our performance goals and met or exceeded the 90-percent performance levels for almost 60 percent—or 7 of 12 goals—of the drug review performance goals.

The Food and Drug Administration (FDA) agreed to more stringent device performance goals as part of the Medical Device User Fee Amendments of 2007, also known as MDUFA II. For fiscal year 2009, FDA is on track to meet or exceed 7 out of 10 device performance goals for which we have reportable results, including the goals relating to 510(k) devices, which represent more than 90 percent of the devices FDA clears or approves for marketing. The goals not met by FDA in fiscal year 2009 represent less than 3 percent of the submission volume FDA reviews, and performance has been steadily improving for these goals. The Center for Devices and Radiological Health has undertaken a number of steps to continue making improvements towards meeting these goals, including drafting clinical trial guidance, identifying, and recruiting needed staff expertise, strengthening its external experts program, and improving its premarket information management systems.

Senator BLUNT. I would also be pleased to see the numbers for fiscal year 2010, if they are available now, the data that ended September 30.

[The information follows:]

#### FISCAL YEAR 2010 DRUG AND DEVICE REVIEWS

It is too early to determine the overall performance for fiscal year 2010, given the current number of pending applications. While drug review performance numbers for fiscal year 2010 are still preliminary, it appears that the Food and Drug Administration (FDA) is on track to meet or exceed 11 of the 12 drug review performance goals called for under the Prescription Drug User Fee Act. Preliminary data as of the fiscal year 2010 Medical Device User Fee Amendments of 2007 performance report indicates that FDA is meeting or exceeding 5 of the goals for which there are sufficient results to reliably estimate current performance, and has the potential to meet or exceed all 12 performance goals.

Senator BLUNT. I have got a couple other questions, but I think I will try to do those a little later, chairman, and let others ask questions. Thank you.

Senator KOHL. Thank you.  
Senator Brown for 5 minutes.

#### MAKENA

Senator BROWN. Thank you, Mr. Chairman. I will take less time. My Governor from Ohio is coming in and I have a meeting with him in a few minutes.

But just one brief line of questioning, Dr. Hamburg. And thank you for joining us.

As you know, after the FDA-approved Makena, which was the version of a longstanding medicine that had been produced by compounding pharmacies for years given to women who were at high-risk of low birth weight, early birth babies, K-V Pharmaceutical announced that the price for the product would jump from



about \$10 to \$20 per injection and typically a woman would take 20 doses of it, I guess, over 20 weeks. It would jump from \$10 to \$20 per injection to \$1,500 per injection, which by my calculations is from \$10 to \$1,500 is a 14,900-percent increase.

Since the drug plays such a critical role in reducing the incidence of premature birth and the associated deaths and disabilities and costs, this price increase marks a dramatic setback for public health, to insurance carriers, to businesses, to taxpayers, to anyone and to the individuals trying to pay them going from \$10 times 20 injections to \$1,500 times 20 injections.

What can the FDA do to stop manufacturers from exploiting this existing approval process? Even though K-V has admitted that the price increase does not derive from R&D or from production costs, all they did was—my understanding—they say, pay \$200 million for the clinical trials, but they did not do the R&D. In fact, taxpayers did most of the R&D here. So, taxpayers, in the end, get a good drug, but it looks a lot like blackmail to me. Seat belts serve an important purpose too, but they are not priced in the stratosphere to reflect the fact they save lives. But they are pricing it in a way that they will make huge profits and it will compromise the public health.

What can you do? Administrative, legislative strategies? What do we do about a drug that has been used for decades and prevented an awful lot of low birth weight baby births and instead will become so, so, so prohibitively expensive?

Dr. HAMBURG. Well, it is such an important concern, and like you, I was very surprised when I learned about the price increase. I think it is important and an advance that we have an FDA-approved drug to prevent preterm pregnancy and all of its consequent serious medical concerns for both mother and infant. And while the drug had been available through compounding, compounding as a practice has been associated with serious health risks, contamination—

Senator BROWN. I am not in any way questioning that FDA did the right thing here. But my understanding is under Bayh-Dole enacted decades—three decades—25, however many years ago, I think in the 1980s. Under Bayh-Dole, you in fact do have the power to do something about this price and do something about K-V Pharmaceutical's actions. And if you do not, it is so important that we figure out something to do here.

This price increase in my understanding started this week, and it is only going to get worse. And if K-V is not willing to back down, I would hope the embarrassment of doing this to America's families would cause them to want to back down, at least try to price it a little more reasonably. But if you cannot use Bayh-Dole, you need to figure out a strategy what to do here.

Dr. HAMBURG. I am not as expert on these issues as I perhaps should be. I am told that Bayh-Dole does not fall under FDA's jurisdiction.

Senator BROWN. It is HHS with Bayh-Dole. You are suggesting that to them. You are writing a letter. You are weighing in with them, as we are doing and some other Senators are starting to now, as we worked on this.

Dr. HAMBURG. This is an issue that, as you know, has arisen recently. It did come as a surprise to us, very surprising, especially in that the National Institutes of Health, as you indicated, did the original clinical trials on which this approval was based. I think it is a very important issue to raise. FDA does not make its approval decisions with pricing considerations.

Senator BROWN. Nor should you.

Dr. HAMBURG. So, I think our role is a different one, but I think that the issue that you are raising about the accessibility to this important drug is a critical one.

Senator BROWN. I made clear I am not blaming FDA. FDA did the right thing. This company acted I guess you cannot say criminally, but immorally and any other string of adverbs you might want to choose. I am just looking for FDA to take leadership with HHS in finding a way, a strategy, or a path quickly to get this company to price its drug more reasonably for American women. Fair enough. Thank you.

Dr. HAMBURG. Thank you.

Senator KOHL. Thank you very much, Senator Brown.

Senator Moran.

#### FOOD FROM THE FARM

Senator MORAN. Chairman Kohl, thank you very much.

Thank you, Dr. Hamburg, for joining us.

In a broad sense, I was pleased to hear you indicate that you are working to understand the challenges of the farm community. In a broad sense, a broad question that I would ask you is what does that mean within FDA. Have you hired people as a result of the passage of the legislation who have farm experience—agronomists, actual farmers, or ranchers who produce food for our country?

#### LIVESTOCK ANTIBIOTICS

And then in a very narrower, more specific way, I want to raise concerns that I have raised previously in regard to your draft guidance No. 209 issued June 28, 2010, “The Judicious Use of Medically Important Antimicrobial Drug in Food-Processing Animals.” We are very much a livestock-producing State, and I generally would tend to avoid commenting on what I would hope would be scientific-based decisions by FDA, but I continue to raise significant concerns about FDA’s proposal in that draft guidance document.

It appears, from reading that draft, that FDA did not engage in rigorous review of current research in regard to antimicrobial resistance and is attempting to ban the use of those antibiotics for growth promotion, feed efficiency, and in some instances preventive treatment based upon uncertain evidence. In fact, if you read the report, the analysis uses the phrases like—when you cite reports in that draft, they fail to establish a direct link between antibiotic use and the risk to human health, not adequate epidemiological evidence, a very limited amount of that research unable to find a substantial body of evidence. And so there is, in my view, great uncertainty about the specific risk posed by antibiotics shown in your draft. And it also appears that the most recent scientific evidence was completed 10 years ago.

And so I am asking what has changed, other than personnel at the FDA, that now causes the FDA to have a significant interest in regulating antibiotics.

Also in that draft you state, in fact, that before withdrawing a drug that is for—a labeled use of an approved drug, Federal law requires the FDA to demonstrate that new evidence shows that a drug is not shown to be safe under approved conditions. And I am interested in knowing what that new evidence is and how you are proceeding with this draft, what time frame, have you read the comments, and the direction that you are going.

Dr. HAMBURG. As you well know, antibiotics are an essential and vital tool for the health of animals and the health of people. It is a limited resource. There is a serious and growing problem with antibiotic resistance, and that is well documented in human populations and in animal populations. And that is the concern that we are trying to address. We do not want to go back to an era of pre-antibiotics because the antibiotics that we have no longer work. And in some areas of serious medical disease, we have begun to see that kind of a circumstance occurring.

We are a science-based agency. It is our mission, our orienting purpose to make data-driven science-based decisions. So, it is very, very important to us that we do that rigorous review of the scientific literature and really look at what the data tells us about these important questions. There is broad scientific literature in this area. There is a lot of data to support the concerns about the use of antibiotics in food-producing animals for growth promoting or feed enhancement purposes. Many, many of the public health, medical, and scientific societies have reviewed the science and have made recommendations that such use should not be considered judicious, therapeutic use. We, of course, are doing our own internal reviews.

But this guidance is voluntary guidance. We are working on it with industry and other stakeholders. When we proposed our framework, which was to limit medically important antimicrobial agents in food-producing animals to the circumstances that are necessary for assuring health and to also have those antibiotics used under the supervision or oversight of a veterinarian, that was done as guidance. It was put forward over the summer. We have received a lot of comments from a range of stakeholders, all with very different and very hard-held perspectives. We are analyzing those comments and continuing to look at the data. We will be coming forward with a revised guidance and we will continue to have that open for comment from the public. We want to move towards something that benefits the health of animals and humans.

Senator MORAN. Mr. Chairman, I have follow-up, but I notice they have just called the vote and I would not want to prevent Mr. Pryor from having his opportunity to question.

But I would say that the draft proposal that you have put forth does not demonstrate the things that you said about the broad scientific evidence. It lacks the connection. And I also still continue to believe that the scientific research that you announced or indicated in your draft proposal is still 10 years old. And so if there is more to come or you have additional scientific-based evidence, I would welcome that.

Thank you, Mr. Chairman.  
 Senator KOHL. Thank you, Senator Moran.  
 Senator Pryor.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Senator PRYOR. Thank you.

Thank you for joining us today, Commissioner. It is always good to see you.

Let me start with something that you know is near and dear to my heart. It happens to be located in my State. It is the National Center for Toxicological Research (NCTR). NCTR focuses on technological research so that the FDA can make science-based decisions, and this includes an emphasis on regulatory science. The decisions that the FDA makes based on this research range from food safety to safety devices used in the medical community to safety of basic cosmetics.

The House has proposed a very significant cut—I believe it is 43 percent—in their continuing resolution, and my understanding is that might even lead to the closure of NCTR. I guess the first question is, do you have any idea why the House targeted NCTR?

Dr. HAMBURG. No, I really do not, but it is a grave concern to me what that will mean.

Senator PRYOR. If you do not mind, tell the subcommittee what NCTR is and what it does and what its unique role is at the FDA.

Dr. HAMBURG. Well, it is a unique resource for FDA and for the Nation. It is a center for toxicological research really focused on strengthening our understanding of a set of safety concerns that cut across drugs and cosmetics and food, dietary supplements, a range of issues that FDA regulates. It is helping us to really understand emerging new technologies in terms of the scientific promise that they hold, things like nanotechnology. They have been a leader in nanotechnology research which offers applications in so many areas. But also, we need to understand what are the implications in terms of near-term and long-term safety issues, and they are a leader in research in that area.

They undertake important research in areas that are very much on the minds of Americans these days, issues like bisphenol-A (BPA), a chemical in plastic and the lining of food containers, really trying to sort out what are the risks and benefits of a substance like that and really understand and trying to modernize the underlying science of toxicology so that we can get important answers for consumers and to support industry in key areas and to make sure that we have the innovative products that Americans are counting on.

Senator PRYOR. Is there another facility that does all this type of research?

Dr. HAMBURG. It is really quite a unique resource, a whole center really focused on toxicology research and doing this research in the service of product evaluation for safety and efficacy.

NANOTECHNOLOGY

Senator PRYOR. You mentioned a few moments ago about nanotechnology and research in that area at NCTR. There are more and

more products that are coming onto the market that claim to be nanotechnology products. I am sure a lot of them are.

What steps is FDA taking to ensure the American public that nano products are safe?

Dr. HAMBURG. Well, there is a broad research agenda that needs to be undertaken to really understand the effects that these very, very small nano-sized materials have when they are introduced into the human body, often with chronic exposures, and they can be used to deliver drugs in exciting ways to get targeted therapies to people. They can be used in food products, in cosmetics. They are used in non-FDA-regulated products as well, including fabric and clothing.

But NCTR is really helping to develop and undertake important areas of research to examine how these nano particles work under different circumstances, how the human body responds, and to look at it under different conditions, different models, different products, and of course, working in partnership with others, but it is a unique resource.

Senator PRYOR. And my last question on nanotechnology—maybe my last question because I am out of time—is should the FDA have a regulatory science program on nano-toxicology.

Dr. HAMBURG. I think that we are undertaking important experiments in that arena. I think it probably needs to be developed as a full-fledged area of focus, and FDA clearly should be at the center of those activities in that as we see more and more products using this technology, we need to be able to fully assess the risks and the benefits and we need to have a strong, sound science base to enable us to make the most informed decisions possible.

Senator PRYOR. Thank you.

Thank you, Mr. Chairman.

#### GENERIC DRUGS

Senator KOHL. Thank you very much, Senator Pryor.

Dr. Hamburg and I talked about this issue before. Over the years, we have provided funding to speed approval of generic drugs because, as everybody knows, they save the consumer tons of money. Unfortunately, the backlog of applications awaiting approval continues to grow and at this point, we have no indication that it will slow down. The budget proposes a very slight increase for generic drugs, not enough to keep up with the increased workload and again proposes to create a user fee for generic drugs in order to offset the costs, which would speed up our ability to get these generic drugs approved.

Research shows that it is the first and second generic drugs coming to the market that save consumers the real money, and of those at FDA awaiting approval, how many of the pending applications, if approved, would be the first or second generic of their kind on the market?

Dr. HAMBURG. Of the pending applications, I believe that about 365 or so are first generics. I would be delighted to give you more specifics on the numbers of second generics. I do not have that information at hand. But it is the case that with the additional dollars that you have helped us get in recent years and what we hope to get going forward through a combination of budget authority and

user fees, that we will be able to make a significant dent in the pending applications and be able to continue to get these important products to people as quickly as possible.

You correctly note that they have had a huge impact. I was told that over the last decade, it has been about \$284 billion saved, and of course, people getting access to these drugs. So, it is a hugely important area.

[The information follows:]

#### FIRST AND SECOND GENERIC DRUGS

It is not possible to immediately determine which pending generic applications would be the first or second generics on the market. Whether a generic is first or second is based on the order in which it is approved and marketed. A number of factors can affect which drug is marketed first, making it difficult to identify which pending applications will ultimately become first or second generics. However, FDA makes every effort to ensure that generics are available to consumers as soon as possible. In most cases, a first generic is approved shortly after all relevant exclusivities have expired, and all relevant patents have expired or are successfully challenged.

#### GENERIC DRUG USER FEES

Senator KOHL. Yes, as you point out, it has been a tremendous savings, if we can just get these drugs to market. And the reason I say first and second, if a standard drug from a brand name company is priced at \$10, maybe the first generic comes out at \$8, but then the second generic might come out at \$4 or \$2 in order to get their share of markets. So, oftentimes it is the second generic that comes to market that really impacts the price of that product to consumers.

Do you support user fees?

Dr. HAMBURG. I do support user fees. I think that the user fees will enable our generic program to be much stronger and I think that it is increasingly important that we have a robust generic review program both because of the importance of these drugs to the American people, as we have been discussing, but also because our ability to review them is getting harder and harder. In a way, we are a victim of our own success. Number one, because the industry has really taken off, we are getting more and more applications. Believe it or not, we actually approve about two generic drugs per working business day at the FDA. So, it is a huge volume that comes before us.

And many of the generic drugs are part of this more globalized supply and manufacturing chain that we have touched on briefly. So, increasingly, in order to do the approvals, we have to go overseas to do inspections of the manufacturing plants, and that takes more time and money as well.

So, as we are seeing the generic industry really expanding and the challenge of the review process increasing because of this globalization—and in some cases, because of the complexity of the drugs that are coming before us, but mainly we are facing growing challenges and we need to meet them. I think that both industry and the public benefit. So, I think it is appropriate to have the program funded by budget authority and user fees.

Senator KOHL. Thank you.

Senator Blunt, go ahead.

Senator BLUNT. Well, we do have votes, and I may have some written questions. I would be interested in how big these user fees are for generics compared to the original certification of drugs.

Dr. HAMBURG. Well, we are just—

Senator BLUNT. If you had them, what are we talking about here?

Dr. HAMBURG. We are beginning to sit down at the table for the negotiations. The President's budget proposes, sort of targets a \$40 million user fee for generic drugs in fiscal year 2012.

[The information follows:]

#### GENERIC DRUG USER FEE

The fiscal year 2012 budget proposal calls for a generic drug user fee program of about \$40 million. In relation to the market for generic drugs, estimated at \$58 billion, according to the Generic Pharmaceutical Association, this represents a modest expense.

The economics of the generic drug market make it difficult to determine precisely what impact this \$40 million would have on the price of generic drugs. We note that this \$40 million is significantly less than the \$250 million user fee program which members of the generic drug industry have outlined in public meetings; any impact from the \$40 million user fee would therefore be significantly less than any impact resulting from the \$250 million user fee proposed by industry.

Senator BLUNT. If you have any studies on what impact that has on the prices of these drugs, and maybe it is over such a large number of drugs it is varied, but I would like to see that if you have that information. You know what I am asking? What impact do you think \$40 million of user fees would have on the price of drugs, and is there a way to differentiate that out?

Dr. HAMBURG. Okay. Well, we will take our best stab at doing that.

[The information follows:]

#### GENERIC DRUG PRICE IMPACTS

The Federal Drug Administration and the generic drug industry have only recently begun negotiations to discuss generic drug user fees. At this time, FDA does not know what type of fee structure will be established, let alone the amount of each fee. FDA's goal is to work with the industry trade associations to establish a program that promotes the timely review and inspection of the growing number of generic drug applications. Members of the generic drug industry outlined proposals at a public stakeholders meeting that would equate to about \$250 million in annual user fees. Given that sales of generic drugs are about \$58 billion, from the GPHA, such a user fee would represent less than 1 percent of sales.

By contrast, the prescription drug industry paid approximately \$459 million in fiscal year 2008, on 2008 sales of \$234 billion, according to a report by the Kaiser Family Foundation in 2010, also less than 1 percent of sales.

#### ADDITIONAL COMMITTEE QUESTIONS

Senator BLUNT. I would think that would be something we would want to know as part of the whole evaluation of what impact this has on the generic marketplace.

And I may have some other written questions, Mr. Chairman.

Dr. HAMBURG. Okay, delighted to take them.

Senator BLUNT. Commissioner, thank you for your knowledgeable answers today.

Dr. HAMBURG. Thank you very much.

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

## QUESTIONS SUBMITTED BY SENATOR HERB KOHL

## OVERALL BUDGET

*Question.* Please provide a priority list of the increased funding items you are requesting in the budget.

*Answer.* The Food and Drug Administration (FDA) is responsible for protecting Americans many times each day and through every stage of their lives. Our role in protecting public health is unique, and there is no one to backstop us.

With these principles in mind, the FDA fiscal year 2012 budget supports many urgent public health priorities. It contains the resources to achieve fundamental public health responsibilities entrusted to FDA. The budget recommends new resources for FDA to transform America's food safety and nutrition, speed the development of medical countermeasures to meet critical national security priorities, protect American patients, and advance the regulatory science that serves as the foundation for FDA public health decisions.

The initiatives and resources that FDA recommends for fiscal year 2012 will allow us to act more quickly and strategically to protect consumers from food safety threats and help deliver safer, more effective medical therapies to the American people. Fulfilling our responsibilities to the American public requires additional resources, as recommend in the fiscal year 2012 budget, across all of these priorities.

Like many Government executives, I am carefully watching the progress of the ongoing bicameral, bipartisan discussions between the administration and congressional leadership on the Nation's long-term fiscal picture. These discussions will likely affect the overall funding for Federal programs, the scope of many programs and the size of individual budgets. We look forward to working with you and others in the Congress as this process moves forward.

The administration is committed to making the difficult decisions necessary to reduce the deficit. However, we must do so in a way that safeguards the public health of Americans now and in the future. That is what FDA and its employees strive to do every day.

## MEDICAL COUNTERMEASURES

*Question.* The budget for fiscal year 2012 proposes an increase of \$70 million for advancing medical countermeasures (MCMs). This is on top of a fiscal year 2011 request to use \$170 million in unspent pandemic flu money for these activities.

Can you talk a little bit about this initiative—it's a lot of money. What, specifically, will we be getting with this investment? Is the initiative scalable, and to what degree?

*Answer.* FDA plays a key role in facilitating development and availability of the Nation's MCMs. To successfully contribute and keep pace with the multibillion-dollar investments being made in MCM development by the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA) of the Office of the Assistant Secretary for Preparedness and Response, and the private sector, FDA needs funding to support its MCM Initiative. The fiscal year 2012 investment of \$70 million in the MCM is critical to successfully developing innovative, safe, and effective MCMs to counter identified chemical, biological, radiological, and nuclear (CBRN) threats and emerging infectious disease threats. The \$70 million investment is also essential to develop the capacity to rapidly develop MCMs in the face of new threats.

The fiscal year 2012 investment in the MCM will help to accelerate the pace and increase the probability of successfully developing MCMs for these threats. FDA will use the fiscal year 2012 funds in a number of ways. FDA will create and maintain a highly qualified workforce with the appropriate technical training, scientific skill, and subject-matter expertise to fully support FDA's MCM responsibilities. FDA will also improve the MCM infrastructure at FDA, such as laboratory equipment and information technology, so that our researchers and reviewers have the tools they need. FDA will establish multidisciplinary Action Teams that will work to establish clear, science-based pathways for evaluating and approving MCMs. FDA will expand FDA's regulatory science program to help overcome existing hurdles in MCM development and to facilitate the translation of scientific discoveries into MCMs. And, FDA will modernize agency regulations and policies to make the FDA evaluation and review process more efficient and to ensure that MCMs can be made readily available to the public when needed.

Regarding the question about whether the MCM is scalable, we recognize the budget challenges that the Congress and the Federal Government face. The FDA investment has been carefully designed and balanced to fulfill the resource needs for the activities that FDA must conduct and the performance that FDA must de-



liver. It has also been designed to sustain the MCM infrastructure and programs already under way and to continue and build on this critical work. If the Congress must scale its investment in MCM, FDA will determine how to make adjustments.

*Question.* Are there specific threats that you are working on that are greater than others?

*Answer.* Yes, FDA is fully engaged with its MCM Enterprise partners throughout the Federal Government to establish and maintain MCM programs and activities based on MCM Enterprise partner priorities based on anticipated.

The Department of Health and Human Services (HHS) prioritizes both the threats and the MCM programs to counter those threats. The highest priority threats include CBRN threats for which a Material Threat Determination has been issued by the Department of Homeland Security. Examples include anthrax, smallpox, botulinum toxins, and radiological nuclear threats. These have been determined to present a material threat against the United States population sufficient to affect national security. Pandemic influenza is also a high-priority threat.

The HHS review, “The Public Health Emergency Medical Countermeasures Enterprise Review”, released in August 2010, envisioned the Nation’s MCM Enterprise evolving from its current threat-specific approach to a flexible capability that can produce MCMs rapidly in the face of any attack or threat, known or unknown. As a result, FDA is also focusing on supporting the development of broad-based platform technologies in support of MCM Enterprise priorities that can offer scalable and flexible advantages over agent-specific MCM programs for high-priority threats.

*Question.* I know you’ve started working on some of this in earnest—what happens if you don’t get the money you are requesting in fiscal year 2011 or fiscal year 2012?

*Answer.* HHS provided FDA with the funding to launch and begin implementing the MCM by allocating \$170 million from previously appropriated funds for pandemic influenza activities. The \$70 million budget request for fiscal year 2012 is designed to provide base funding for the MCM.

As already noted, the \$70 million fiscal year 2012 budget request for the MCM is designed to sustain the MCM and to enable it to keep pace with the multibillion-dollar investments ongoing at NIH and BARDA. If FDA receives less than the amount requested, the agency must limit its investment in the MCM, regulatory science program, and the full-time equivalents (FTEs) necessary to support the enhanced review process for MCMs. The risks of receiving a reduced amount include an inability to adequately implement FDA’s MCM, which will ultimately degrade the ability of the MCM Enterprise to achieve its mission to protect the Nation from these threats.

The HHS review, “The Public Health Emergency Medical Countermeasures Enterprise Review”, stressed that improving the regulatory environment for MCMs is critical to the success of the MCM Enterprise and is among the challenges the U.S. Government must address if it is to successfully develop MCMs. Moreover, investments in the MCM have implications for improving the health and security of the U.S. population beyond countering CBRN threats and emerging infectious disease threats. Investments to advance regulatory science to support development of MCMs will contribute directly and indirectly to development of products to treat other diseases and conditions and help improve the safety and efficacy of and access to FDA-regulated products.

#### PREGNANCY RULE

*Question.* An estimated 75 percent of all pregnant women use 4–6 prescriptions or over-the-counter drugs at some time during their pregnancy. It’s widely acknowledged that information provided to pregnant women on drug labels is confusing at best. I know FDA has been working on this issue and even proposed a rule in 2008.

I understand that 73 comments were received on this proposed rule. Even if they are extremely complex, I can’t see why I would take several years to go through 73 comments. Can you tell me the reason for the delay?

*Answer.* FDA staff have been reviewing the comments, identifying and considering the issues raised by the comments, determining whether any revisions should be made to the proposed regulation and preparing the final rule. FDA staff are continuing to work on the final rule. Because of the importance of this public health issue, FDA wants to proceed with the appropriate care and judgment.

*Question.* Is it a priority for FDA, and when do you think it will be finalized?

*Answer.* Publication of the final rule regarding prescription drug labeling for pregnant and lactating women remains a strong priority within FDA. FDA staff are actively working on the rule. Please be assured that FDA is committed to finalizing this rule as promptly as feasible and practical.

## GENERIC DRUGS

*Question.* Dr. Hamburg, I ask about this every year. Over the years we have provided funding to speed approval of generic drugs. We do it because they save consumers and the Government significant money. Unfortunately, the backlog of applications awaiting approval continues to grow. And at this point, we have no indication that it will slow down. The budget proposes a slight increase for generic drugs—not enough to keep up with the increased workload, and again proposes to create a user fee for generic drugs in order to offset the costs. These user fees would allow you to collect more than \$40 million in fiscal year 2011.

To put the question in context, how many generic drug applications are pending at FDA right now?

*Answer.* There are approximately 2,400 generic drug applications pending. These pending applications include applications that are awaiting FDA's original assessment or review, applications that FDA found were not ready for approval and the company is preparing a resolution or response to address the FDA concerns, and applications awaiting re-review where companies submitted responses to deficiencies previously identified by FDA. This last category of applications is known as amendments.

*Question.* Research shows that it's the first and second generic drugs that save consumers the most money. Of those in the backlog, how many, if approved, would be the first or second generic of their kind on the market?

*Answer.* Our current tracking system does not allow us to identify pending generic applications as first or second generics. Whether a generic is first or second is based on the order in which it is approved and marketed. A number of factors can impact this order and factors can cause the order to shift with the passage of time. In addition, a first generic might be only one of the dosage strengths that the brand manufacturer makes, so the actual definition of first generic is not always clear. The Food and Drug Administration makes every effort to ensure that generics are available to consumers as soon as possible. In most cases, a first generic is, as with multiple generic drugs, approved shortly after all relevant patents and exclusivities have expired or the relevant patent is successfully challenged.

*Question.* And within those, how many could go on the market tomorrow, as opposed to those being delayed due to lawsuits, etc.?

*Answer.* As explained earlier, we cannot specify the number of pending first and second generic applications, and therefore, we cannot specify how many of those applications are not blocked by patents or exclusivities.

However, of the approximately 2,400 abbreviated new drug applications currently under review, about two-thirds are currently blocked from approval by patents or other exclusivities. Please note that applications waiting for expiration of patents or exclusivity to expire may be tentatively approved. A tentatively approved application has been found to meet FDA's rigorous approval requirements, and is ready to be marketed as soon as the innovator patent expires, the patent is successfully challenged, or all exclusivities expire. As a general matter, all patent or exclusivity issues related to the brand product or reference listed drug must be resolved before the generic product can be approved. Currently, there are 309 tentatively approved applications.

## FOOD SAFETY MODERNIZATION ACT

*Question.* The Food Safety Modernization Act (FSMA), passed last year, was the largest expansion of FDA's authorities in 70 years. Obviously, the way food is produced, transported, stored, and consumed has changed since then, so this updated law was long overdue.

The Congressional Budget Office has estimated that it will cost \$1.4 billion over 5 years to fully implement this law. Your budget proposes an increase of around \$225 million for your Transforming Food Safety and Nutrition Initiative, which includes \$183 million for you to begin implementation. Will this amount fully fund FDA's first year costs for the new food safety law, and how much additional funding do you think you'll need over the next few years?

*Answer.* With the requested increase of \$183 million to implement FSMA, FDA expects to make substantial progress in building the science-based, prevention-oriented, and efficient food safety system mandated by the Congress. FDA plans to issue the key regulations required by FSMA, including produce safety standards, preventive controls in food facilities, and standards for preventing intentional adulteration. In addition, we would strengthen the scientific basis for the Foods Program, including the ability to make the design and implementation of our prevention standards more risk-based and effective in preventing food safety problems.

FDA plans to train FDA investigators in the latest inspection techniques that take advantage of the preventive controls regulatory framework. FDA will also build State capacity and create a national inspection work plan so that State inspections can be leveraged to meet FDA's domestic inspection frequency requirements.

FDA plans to design and implement a new import safety framework for carrying out the FSMA mandates. The new framework will include stronger importer accountability through the foreign supplier verification program, an accredited third-party certification program, comparability assessments to determine if foreign governments have food safety systems comparable to that of the United States, a voluntary qualified importer program to expedite review and importation of food by qualified importers, and expansion of the foreign inspection program. Finally, FDA will need to rely on better information technology to support more efficient domestic inspection and effective oversight of imports.

In future years, FDA will need to continue to invest in implementing these programs, including increasing FDA science capacity, strengthening the integrated food safety system, and implementing the import safety framework. We hope to work with the Congress to ensure that FDA has adequate resources to achieve our shared food safety goals.

*Question.* There have been statements made that this law isn't really necessary. Some people point to the recent decreases in the Centers for Disease Control and Prevention (CDC) estimates of the numbers of deaths and illness from food-borne illnesses. Particularly at a time when Federal spending is declining, how would you respond to those criticisms? Why do we need to spend this additional money right now, when we continue to have one of the safest food supplies in the world?

*Answer.* The revised CDC estimates still demonstrate a significant public health burden due to foodborne diseases with an estimated 48 million illnesses, affecting one in six Americans each year and resulting in 128,000 hospitalizations, and 3,000 deaths each year. It is true that the United States has one of the safest food supplies. For the most part, the food industry does a good job of providing abundant, safe food to American consumers. However, there has been a continuing series of food safety problems—major recalls, outbreaks, and illnesses—most of which are preventable. FDA FSMA, which gives FDA new tools to prevent foodborne illness, received the support of industry and consumer groups, as well as the Congress, and represents a consensus that improvements in the current system are necessary.

*Question.* How will these efforts help our economy? What is our return on investment?

*Answer.* Efforts to improve food safety through the prevention-focused framework envisioned in FSMA will result in fewer outbreaks of foodborne illness and more rapid response when they do occur. Outbreaks are costly to all involved—to consumers, to the food and feed industries, and to the healthcare industry. A 2007 study estimated the average hospital stay at 5.8 days for each case of foodborne illness requiring hospitalization. The same study estimated the average cost per case of foodborne illness at between \$16,100—for an adult—and \$26,700—for a child. In the case of the 2006 spinach recall, the Institute of Food Technologists estimated the cost of recalled spinach, lost sales, lost productivity, and other costs at \$129 million. Likewise, in the case of the 2008 Peanut Corporation of America (PCA) peanut product recall, one major manufacturer—Kellogg—estimated its costs to recall peanut-containing products at \$65 million to \$70 million. FDA expended more than 100 staff years—full-time equivalents—to protect consumers and conduct PCA-related inspection and recall activities. In the aggregate, the costs of foodborne illnesses and outbreaks are in the billions of dollars.

*Question.* How can you ensure that the produce safety regulations you are drafting will not follow a one-size-fits-all approach, which would harm small and organic growers?

*Answer.* FDA is aware of the tremendous diversity in farming operations and that a one-size-fits-all approach to produce food safety will not be practicable. Over the past year, FDA and U.S. Department of Agriculture (USDA) technical experts, scientists, and other staff participated in listening sessions and meetings in 13 States. In some of those States, we were able to tour large and small farms and speak with people who have the on-the-ground knowledge that FDA realizes must be reflected in the proposed rule. FDA is committed to providing operators with flexibility and innovation in their approaches to on-farm food safety for their operations.

#### FOOD SAFETY DUPLICATION EFFORTS

*Question.* The Government Accountability Office (GAO) recently issued a report on duplicative Government programs. Duplication in food safety across Federal agencies was a major theme in the report. Of the 15 agencies with oversight over

food safety activities, the FDA is in charge of 80 percent of domestically produced and imported food.

Since your agency has responsibility for the vast majority of the food we eat and in light of the fact that we just passed a massive food safety overhaul bill, can you please respond to the findings of the report regarding overlap in food safety activities?

Answer. The GAO report, “Federal Food Safety Oversight—Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation,” highlighted the positive steps taken by the Federal food safety agencies under the auspices of the Food Safety Working Group (FSWG) to coordinate and collaborate on cross-cutting food safety issues, such as produce safety, salmonella contamination, and food safety performance measures. The report contained one recommendation for the Office of Management and Budget (OMB) to develop a Governmentwide performance plan for food safety. FDA continues to work through FSWG with its food safety partners to address a coordinated agenda of food safety issues as appropriate within our statutory frameworks.

*Question.* How often and how well do you work with the Food Safety and Inspection Service and other Federal, State, and local food safety agencies during an outbreak that would affect both agencies, and how can you improve?

Answer. FDA works with its State and local food safety partners during every outbreak of foodborne illness. FDA and its State and local counterparts are striving to improve how they work together on outbreaks. Efforts include cooperative agreements with States to form rapid response teams (RRTs). The RRT agreements allow the selected recipient to build State program infrastructure and rapid response capabilities for food and feed emergencies and implementation of the Manufactured Foods Regulatory Program Standards. This project engages partners to develop innovative programs and tools, both within each individual program and jointly among the nine pilot teams.

During the past 2 years, there have been three specific investigations in which FDA and USDA have had close, very positive collaborations—salmonella enteritidis in shell eggs, salmonella montevideo in spices used in deli meat, and salmonella enteritidis in liquid-/pasteurized eggs. In these investigations, FDA and USDA senior level and field level staff have planned the investigation, worked side by side in the field, shared laboratory resources, and coordinated closely on messages to consumers. Also, senior outbreak staff from FDA, CDC, and USDA now participate in 1- to 2-week orientation visits within each agency to better understand policies and procedures, and allow networking outside of emergency events. In addition, through FSWG, the Federal food safety agencies recently formed a group to improve how they work together during outbreaks. The agencies have formed a standing Multi-Agency Coordination Group for Foodborne Illness Outbreaks (MAC-FIO). MAC-FIO is comprised of a designated representative from each of the Federal agencies with food safety responsibilities, which allows for rapid coordination and communication during an outbreak that involves multiple Federal food safety agencies.

#### ADVANCING REGULATORY SCIENCE

*Question.* The budget includes an increase of \$49 million for your regulatory science initiative. Of this, nearly \$24 million is to pay for FDA staff to occupy a new lab.

What specifically will these funds be used for? Please provide a breakout of spending. Is this a top priority?

Answer. The Advancing Regulatory Science funding relating to White Oak are required to ensure that the new Life Sciences-Biodefense Laboratories and supporting facilities on the White Oak Campus are outfitted and operational to support critical FDA biologic and human drug research programs. Since these laboratories use select agents, they must undergo a highly specialized certification process before we can conduct research in these facilities to advance FDA’s mission. These funds will allow the testing and commissioning of state-of-the art laboratory equipment required for FDA science operations to support the following programs: annual and pandemic influenza, nonpandemic MCMs, blood and other biological products, biosimilars, and regulatory science. System testing and commissioning includes building automation system operation and monitoring, air flow tests, HEPA air filter tests, primary bio-containment device effectiveness, room pressurization control, and power tests. Funding will also allow FDA to provide for cabling and telecommunications equipment to support lab operations.

This is a top priority as the funding will allow FDA to demonstrate that all systems and standard operating procedures will provide environmental and biological

safety. We will be severely hampered in our ability to protect national security and world-wide public health if funding is not received as our existing laboratories are outdated and filled to capacity. In addition, FDA lab facilities would not be able to move to White Oak from National Institutes of Health and other locations and FDA would continue to pay approximately \$20 million in annual rent for existing facilities.

#### DRUG SAFETY

*Question.* Drug recalls have increased significantly since 2009, and there have been several high-profile cases of tainted drugs reaching the market. There have been many potential causes discussed for these increases. Some point to the high cost of manufacturing drugs, and cost-saving measures taken by manufacturers that lead to problems. Others point to manufacturers rushing too quickly to be the first company to submit an application, especially in the case of generic drugs. Another obvious concern is that 40 percent of drugs consumed in the United States are imported, while 80 percent of the ingredients used in U.S. drugs come from other countries, and these numbers continue to rise. Both you and your senior staff have said very recently that we continue to be at risk, and another drug safety problem is all but unavoidable. The budget includes an increase of \$56 million for the Protecting Patients Initiative, of which \$12 million is for import safety.

Can you talk specifically about this increase, and more generally about how you intend to address problems like this when increased funding is not a certainty?

*Answer.* The increased funding will be used to strengthen our multifaceted approach for leveraging different opportunities for additional knowledge of imported products and foreign manufacturers. As resources allow, we will continue to pursue our efforts to conduct additional foreign inspections, enhance our working relationships with international regulatory counterparts, and strengthen our foreign presence. FDA conducts inspections of foreign facilities that offer FDA-regulated products for import into the United States, and in some cases supplements information gathered during inspections with knowledge gained from foreign regulatory counterparts. In this regard, we continue to enhance working relationships and information-sharing with our international regulatory partners which, in turn, help FDA identify problem products before they are offered for import and enter U.S. commerce. Another important opportunity is FDA's acceptance into the Pharmaceutical Inspection Cooperation Scheme, whose primary goals are to foster the international development, implementation, and maintenance of harmonized Good Manufacturing Practice standards, and further the development of a quality system of inspectorates in medicinal products.

FDA is also participating in a pilot program with the European Medicines Agency on the coordination and performance of joint inspections. The overall objective is to see whether greater international collaboration can better distribute inspection capacity, allowing more sites to be monitored and reducing duplication. In addition, FDA's Office of International Programs has opened several foreign offices to further enhance FDA's ability to protect U.S. consumers from unsafe foreign-sourced products. Establishing a foreign presence reflects the evolution of FDA's regulatory strategy and its responsiveness to U.S. consumers in meeting its mission of public health protection.

An additional example of international collaboration includes the FDA's memorandum of understanding with the Health Products and Food Branch of Health Canada. This allows FDA and Canada to develop specific procedures for sharing of regulatory, emergency management, and public health information related to drug products. This can include information on quality defects or product recalls of therapeutic products manufactured or distributed in Canada, inspection reports, product samples, enforcement activities, product investigations, as well as information on facilities registered or authorized to market products.

#### PATIENT MEDICATION INFORMATION

*Question.* I understand that FDA has been working on a new process for producing consumer and patient medication information (PMI) that is included with patient prescription medication. This is due to a general belief that the current format can be confusing, and too much information can be included, which makes it less useful to consumers. This information is currently produced by private publishing companies. My understanding is that the current proposal would require each manufacturer to provide a consumer/PMI insert with each drug they produce, and the information would be limited to one page.

Concerns have been brought to my attention that requiring every drug manufacturer to independently produce this information could lead to inconsistent informa-

tion being provided to patients, and limiting the documents to one page could lead to the omission of important information. I have further been informed that FDA has stated they will not be able to provide oversight of these documents.

What is the current plan for modernizing the consumer and PMI? What was the thought process behind requiring each manufacturer to publish this information independently?

Answer. FDA's ongoing analysis of and plans for modernizing consumer and PMI are intended to achieve the goals of Public Law 104-180, enacted in 1996, which included specific targets regarding the distribution and usefulness of PMI. FDA-commissioned studies subsequent to the enactment of Public Law 104-180 have indicated that those statutory goals are not being met by current private sector efforts, and we are considering next steps.

Currently, documents are developed by drug manufacturers, other private organizations, or individuals and patients may receive several different types of information, developed by different sources. PMI may be duplicative, incomplete, inconsistent, or difficult to read and understand, and distribution is voluntary for certain types of PMI. The distribution of Medication Guides, in accordance with 21 CFR part 208 and some patient package inserts in accordance with 21 CFR 310.501 and 310.515 is mandatory as described in the regulations.

FDA has determined that the current system is not adequate to ensure patients receive essential medication information needed to safely use drugs. Based on recommendations from FDA's Risk Communication Advisory Committee and other stakeholder input, FDA sees merit in adopting the use of a single document with standardized content and format. FDA is working with all relevant parties, such as patients, healthcare providers, drug manufacturers, interested professional organizations, and PMI developers and publishers, to determine the appropriate regulatory path forward. For example, the Engelberg Center for Health Care Reform at the Brookings Institution is working with key stakeholders, including FDA, to conduct initial demonstration pilots, designed to evaluate feasibility of various PMI distribution channels and assess patient and provider PMI preferences.

FDA does not intend to limit production of PMI solely to drug manufacturers. Our goal is to establish standards regarding the content and format of PMI in order to increase the overall quality of the documents patients receive and hopefully enhance patient care through proper medication use. FDA is still considering how best to accomplish this goal, and has not finalized requirements for the procedural aspects surrounding the creation of PMI or the single page limitation. When making any determinations, FDA will consider all stakeholder input, including the comments received in your statement.

*Question.* Can you please address the concerns that have been brought to my attention?

Answer. We understand that concerns have been voiced that requiring every drug manufacturer to independently produce PMI could lead to inconsistent information being provided to patients, and limiting PMI documents to one page could lead to the omission of important information. To address those concerns, FDA is seeking public input and taking a scientific approach, including conducting research, as part of our decisionmaking process. FDA has developed three draft PMI prototypes to be used in consumer testing. The results of the consumer testing will inform FDA of the usefulness and various format options for PMI documents. FDA recognizes that FDA review and approval of all PMI documents prior to distribution may not be feasible given our resource constraints and the potential volume of products that may require PMI, perhaps as many as 22,000 products. FDA is considering developing standardized content and format requirements, which should enhance quality and accessibility of information in PMI, similar to the standardized labels on over-the-counter drugs and many food products, and should lead to improvements in patient care due to safer use of medications.

*Question.* Will there be rules regarding updating and streamlining information to make it easily understandable for consumers, which providing an appropriate amount of information? Will FDA provide oversight on these publications?

Answer. Yes, FDA intends to develop rules or guidance based in part on the outcomes of our testing and pilot projects. FDA has developed three draft PMI prototypes to be used in consumer testing. Based on public comment and expert panel input, FDA is also finalizing the design of the consumer testing study of the prototypes. Consumer testing will begin when the final study design is approved by OMB. The results of this study will inform FDA of the usefulness and various format options for PMI documents.

FDA intends to provide oversight of PMI documents, and is considering the best approach for doing so. Although one approach to oversight could involve FDA review and approval of all PMI prior to distribution, we recognize that this may not be fea-

sible given FDA's resource constraints and the potential volume of products that may require PMI—perhaps as many as 22,000 products when including all innovator and generic products.

*Question.* What is the timeline for this change?

*Answer.* Before implementing changes to PMI, the plan is for FDA to first study and test the utility of PMI prototypes. Approval by the White House OMB for this research is expected by July 2011 and results of the study are expected in 2012.

One option for implementing changes to PMI might be to develop a new rule. The timeframe for developing and finalizing a new rule at FDA varies, but the process can take a 5 years. Thus, implementation of a PMI rule would likely not occur prior to 2015/2016. During FDA's decisionmaking process, FDA plans to continue to study prototypes, research potential processes, and discuss and evaluate the impact of those potential procedures. FDA intends to continue to involve all interested stakeholders in these activities.

#### GENERIC FOR LIPITOR

*Question.* I understand that later this year, a generic for the blood pressure drug Lipitor will be eligible to enter the market due to patent expirations. The entry of generic competition to Lipitor has the potential to save consumers as much as \$6.7 billion.

Are you working to try to reach a decision as to whether to approve a generic drug application for Lipitor in a timely fashion?

*Answer.* Lipitor, which has the chemical name atorvastatin, is a drug used to treat high cholesterol. The FDA recognizes the benefits and value of making safe, effective, high-quality generic drugs, such as Atorvastatin, available to the American public. FDA is fully dedicated to doing so as quickly as possible within the framework of the law and applicable regulations.

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#### QUESTIONS SUBMITTED BY SENATOR DIANNE FEINSTEIN

##### PROGRESS ON RESEARCH INTO BISPHENOL-A

*Question.* I remain particularly concerned about the use of bisphenol-A (BPA) in food containers, particularly those used to provide food and beverages to infants and children. Mounting scientific evidence demonstrates a link between BPA exposure, even at low doses, and a host of harmful health effects such as cancer, diabetes, behavioral disorders, and heart disease. This is why I have introduced legislation in the 112th Congress that would ban the use of BPA in baby bottles, sippy cups, infant formula, and baby food.

In January 2010, the Food and Drug Administration (FDA) released an "Update on Bisphenol A for Use in Food Contact Applications" (update) to explain your current perspective on BPA, including support for additional research and interim recommendations for public health.

In this update, you agreed with the National Toxicology Program (NTP) at the National Institutes of Health (NIH) and expressed "some concern about the potential effects of BPA on the brain, behavior and prostate gland in fetuses, infants, and young children." You also cited additional research being pursued by the FDA's National Center for Toxicological Research (NCTR), and the interim steps you would take to reduce exposure.

What progress have you made in your consideration of the low-dose toxicity studies and peer-reviewed studies of BPA?

*Answer.* FDA announced the availability of updated review documents on low-dose studies in a Federal Register Notice published on April 5, 2010. Since that notice published, FDA has continued to incorporate new published information and information from studies conducted at FDA's NCTR into our review of the safety of BPA in FDA-regulated products.

*Question.* What is the status of the research being conducted by the FDA's NCTR, including those studies being conducted in collaboration with NTP?

*Answer.* FDA's NCTR is conducting studies characterizing the toxicities of BPA in several animal models in partnership with NTP. Study designs are using both oral and intravenous routes of exposure. The results with oral studies are used to model dietary exposure while intravenous studies are used to model neonatal and infant exposure in a medical setting.

To date, the results of several studies have been published in the peer-reviewed scientific literature. Four studies were published that characterize systemic distribution and excretion patterns following oral and intravenous administration of BPA using rat and nonhuman primate models. Human biomonitoring data are also being

collected in conjunction with research partners, including FDA's Center for Devices and Radiological Health; the Centers for Disease Control and Prevention (CDC); and the Pacific Northwest National Laboratory. The animal study data and the human biomonitoring data will be combined into mathematical models to minimize uncertainties in estimates of human tissue exposures.

Several additional, longer-term exposure studies with BPA evaluating effects of in utero and neonatal exposures are in progress in rats, which include the effects on the brain structure and behavior. Additional long-term exposure studies are scheduled to begin in fiscal year 2012. These studies include a lifetime cancer bioassay, and an evaluation of factors related to diabetes and heart disease. All the studies have been designed to fill data uncertainties identified by FDA and NTP in order to assess potential impact of BPA on human health.

*Question.* What is the status of your consultations with other expert agencies including the NIH, the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), and CDC?

*Answer.* FDA included scientists from several other agencies including NIH, EPA, and CPSC in an external review of our most recent memorandum on low-dose studies of BPA. We continue to interact with Government scientists from all these agencies to better inform our safety assessment process. For example, FDA's on-going studies at the NCTR are being performed in collaboration with the National Institute for Environmental Health Sciences (NIEHS), as mentioned previously and FDA scientists have attended NIEHS BPA grantee meetings. In addition, in November 2010, FDA scientists participated with other U.S. Government scientists as well as international experts in a Food and Agriculture Organization (FAO)/World Health Organization (WHO)-sponsored consultation regarding the safety of BPA in food contact applications. One conclusion of the FAO/WHO consultation was that it would be premature to initiate public health measures based on current data.

*Question.* You cite support for the industry's actions to stop producing BPA-containing bottles and infant feeding cups in the U.S. market. What specific actions, if any, have you taken to express this support?

*Answer.* FDA announced its support for these actions in a January 10, 2010, announcement posted on FDA's Internet site. At that time, FDA announced that major manufacturers had stopped selling new BPA-containing baby bottles and infant feeding cups for the U.S. market since early 2009. FDA's contact with these industry members over the past year continues to confirm that BPA is not being used for the manufacture of infant feeding articles.

*Question.* You also cite the FDA is facilitating the development of alternatives to BPA for the linings of infant formula cans by working with manufacturers, giving technical advice on the approval of alternatives, and expeditiously reviewing new applications for alternatives. Please provide details of the efforts you have taken in this area.

*Answer.* FDA has worked with industry to increase our understanding of the different packaging materials currently used for infant formula and the types and quantities of infant formula packaged in these materials. At the present time nearly 90 percent of infant formula—primarily those that are powdered—sold in the United States is packaged in materials that are not manufactured using BPA. Over the past year, FDA has actively worked with industry on a wide range of alternative materials for liquid infant formula packaging. Because of the complexities in this market and the higher potential exposures to infants to these materials, FDA has provided substantial individualized guidance regarding the development of appropriate safety data to ensure safe use of replacement products. These efforts have been the subject of over a dozen presubmission applications, a tool FDA uses to communicate with industry prior to the formal submission process. Once an applicant submits a complete premarket submission is made to FDA, the review time is 120 days. We continue to work with the infant formula and packaging industries to bring safe alternative materials to the market.

#### NUCLEAR RADIATION AND ITS EFFECT ON OUR FOOD SUPPLY

*Question.* The tragic events that continue to unfold in Japan are having extraordinary consequences even within our own society. In addition to the earthquake's much publicized effect on gas prices and the price of consumer electronic goods, there is substantial concern about the safety of food produced in regions affected by the nuclear radiation emitting from the damaged power plants.

What extra precautions is the FDA taking to ensure that all food that has been exposed to high levels of radiation is either destroyed or decontaminated before it enters the U.S. market?



Answer. From the earliest days of the situation in Japan, FDA has been actively protecting United States consumers from potentially contaminated products; instituting import controls to ensure such products do not enter the United States marketplace, and adjusting those controls as circumstances warranted. These controls include the detention of specific products from prefectures reported by the Japanese Government as being found to contain radionuclides; and increased examinations and FDA analysis of other FDA-regulated products. These controls provide a blanket of coverage for FDA-regulated products from Japan. As this situation evolves, our targeted coverage is evolving.

As of today, March 17, 2011, FDA-activated electronic screening criteria to hold all lines of products manufactured or shipped by Japanese firms. This screening provides instructions to FDA's field offices when encountering shipments from Japan. The instructions include documenting review and disposition of all shipments from Japan based upon when the shipment left Japan. For those shipments that left Japan prior to March 11, no further action is required. Admissibility is determined as per normal procedures. For all lines shipped on or after March 11, if the shipment originated from an area outside of our areas of concern, admissibility is determined as per normal procedures. If the shipment originated from within the affected area, FDA investigators are instructed to check with local Customs and Border Protection (CBP) to determine if the shipment went through CBP's radiation screening. CBP will contact FDA if CBP has not screened the line or if CBP screening indicates adverse readings for the presence of radionuclide contamination.

If the importer of contaminated product does not voluntarily destroy or decontaminate the product, we will rely on CBP's seizure authority to take control of the product and ensure it is properly disposed.

*Question.* What steps is FDA taking to ensure that the elevated levels of radiation in the United States does not impact food production in California and across the rest of the country?

Answer. EPA is monitoring atmospheric radiation levels and collects environmental samples, such as rainwater, to monitor radiation and any increases that may occur due to the tragedy in Japan. Monitoring allows FDA to react swiftly in the unlikely event of significant amounts of radionuclides reaching our shores. So far, EPA's monitoring has detected only very low traces of radionuclides characteristic of a power plant accident. These levels do not present a public health concern. FDA has had a sampling program in place domestically for many years collecting samples of food products from areas around nuclear facilities to monitor any potential problems, including California and other States across the country. There have been no sample results from this program indicating harmful levels of radionuclides. We continue to keep abreast of EPA's monitoring to ensure that there is no threat to our domestic crops.

#### FOOD SAFETY BILL IMPLEMENTATION

*Question.* I strongly supported the passage of FDA FSMA last Congress because I believe that the FDA needs to move towards preventative model when it comes to protecting the safety of our food supply. I believe that all processors should have in place a Hazard Analysis and Critical Control Point (HACCP) plan, and I believe that we must fully enforce the requirement that these plans are in operation any time food is being produced.

However, produce farmers in my State that are concerned that FDA will take a one-size-fits-all approach when it comes to the implementation and approval of these food safety plans. I do not think that this would be in the best interest of safety, and it certainly would not be in the best interest of the food production industry.

What are you doing to ensure that HACCP plans will be product specific? What assurances can I give farmers in California that the FDA will not treat spinach HACCP plans, like almond or dairy HACCP plans?

Answer. We understand your question to relate to the produce safety standards required by section 105 of the FDA Food Safety Modernization Act. FDA is aware of the tremendous diversity in farming operations and that a one-size-fits-all approach to produce food safety will not be practicable. FDA is committed to providing operators with flexibility and innovation in their approaches to on-farm food safety for their operations. FDA intends to propose a rule containing requirements that will be commensurate to the hazards and risks associated with any particular operation.

#### ANTIBIOTICS IN FOOD PRODUCTION

*Question.* I remain concerned about the overuse of antibiotics in food animal production and FDA's slow response to address this critical public health matter. While

I was encouraged to see the FDA proposal in guidance for industry (GFI) No. 209 in June of last year, I have not seen or heard of any definitive progress since. I cannot underscore the importance of swift action in addressing this concern—in the last 10 years antibiotic resistant *E. coli* infections have risen by 16.5 percent, antibiotic resistant *P. mirabilis* infections have risen by 19 percent, and MRSA infections rose by 22.4 percent.

When will FDA offer a definitive plan of action on how to reduce the over- and misuse of antibiotics in food animal production?

Answer. FDA's action plan for promoting more judicious use of medically important antimicrobial drugs in food-producing animals began in 2010 with the publication of draft GFI No. 209. GFI No. 209, which, for the first time, lays out FDA's policy on the use of these drugs in animal agriculture provides two definitive guiding principles. The first principle is that medically important antimicrobial drugs should be used in food-producing animals only when necessary for assuring animal health. The second, that such use should include veterinary oversight or consultation. We believe that by communicating these key principles we have identified a clear pathway forward as we work with the animal health and animal agriculture industries to reduce the overuse and misuse of antibiotics in food animal production. FDA is close to completing review of comments received regarding draft GFI No. 209 and plans to finalize the guidance later this year.

However, while this was an important first step, the goal now is to put these principles into action. Since publication of GFI No. 209, we are very encouraged by the interactions we have had to date with key stakeholders, including the animal health industry, on plans for implementation. Sponsors of some of our most important antimicrobial drugs have already initiated discussions with FDA about updating their animal drug products in a manner consistent with the principles of GFI No. 209.

To further support implementation of GFI No. 209 principles, FDA intends to issue additional guidance which will provide more specific information for animal drug sponsors. In addition, FDA has initiated the rulemaking process to streamline the Veterinary Feed Directive System to facilitate the transition to veterinary oversight of the use of medically important antimicrobial drugs in feed. Work has already begun on both of these tasks and related publications can be expected sometime within the next year.

*Question.* If you intend to follow the general principals laid out in GFI No. 209, how will you define the term "nontherapeutic use of antibiotics"? Will the definition include prophylactic use of these drugs?

Answer. The intent of GFI No. 209 was to make a distinction between those uses of medically important antimicrobial drugs in food-producing animals that FDA considers judicious and those we consider injudicious. In this context, FDA believes those uses that are considered necessary for assuring animal health are judicious uses and those uses for production purposes in healthy animals, such as to promote growth or improve feed efficiency, represent injudicious use. As noted in the GFI, FDA considers uses that are associated with the treatment, control, or prevention of specific diseases to be uses that are necessary for assuring the health of food-producing animals. However, while FDA does believe that some prevention uses are necessary and judicious, we also believe it is imperative that such uses include veterinary oversight or consultation. Veterinary involvement in the decisionmaking process associated with the use of medically important antimicrobial drugs is an important aspect of assuring appropriate use, including judicious preventive use.

*Question.* It is also my understanding that the FDA intends on revisiting the Veterinary Feed Directive (VFD) program and the approval of new animal drugs under FDA GFI No. 152. What revisions to these documents are you considering and by when do you plan on making these recommendations public?

Answer. In March 2010, FDA published an Advance Notice of Proposed Rulemaking (ANPRM) regarding the VFD program. This action was taken in response to informal comments received by FDA that characterize the current VFD process as being overly burdensome. FDA is concerned that the VFD process in its current form may be difficult to administer in the future as the number of approved VFD animal drugs increases. Therefore, the goal will be to streamline the regulatory requirements where possible while still protecting public and animal health. The target date for publishing of specific proposals based on the comments we received on the ANPRM is planned for sometime during 2012. Of course, FDA's publication date can be affected by issues that emerge during the review and clearance process.

FDA believes that GFI No. 152 has provided an effective mechanism for evaluating antimicrobial resistance concerns as part of the new animal drug approval process. This GFI includes a table that ranks antimicrobial drugs with respect to their importance to human medicine. FDA has acknowledged that this listing may need to be periodically updated so that it reflects current conditions regarding anti-

microbial use in humans. FDA intends to seek public comments on any updates to the GFI prior to implementation.

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QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

USE OF VETERINARY DRUGS IN FOOD-PRODUCING ANIMALS

*Question.* The international body that establishes standards for food safety, known as Codex Alimentarius, is playing an increasing role in the facilitation of market access for U.S. agricultural products to a growing number of countries and customers around the globe. Standards set by Codex should be established based on scientific merit and be used to improve trade, not hinder it.

Specifically, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) has had a maximum residue standard for a Food and Drug Administration (FDA)-approved veterinary product, ractopamine, pending for the past 3 years. The adoption of this standard should move forward.

FDA chairs this particular Codex committee, what are your thoughts on the current process as it relates to this particular situation?

*Answer.* An FDA employee chairs the CCRVDF and another FDA employee serves as the U.S. delegate to this committee. Proposed ractopamine maximum residue levels (MRLs) for cattle and swine have been advanced from this committee to the Codex Alimentarius Commission (CAC) for adoption. Adopting MRLs is pending at the CAC level. The U.S. Government is part of a small group of countries that have been meeting at the CAC level to resolve the ractopamine issue before the next CAC meeting. The U.S. delegation remains hopeful the deliberations will be successful and the recommended ractopamine MRLs will be finalized and adopted by the CAC as a Codex standard.

The U.S. delegation is committed to moving forward to adopt MRLs for ractopamine on the merits of the scientific evidence presented to Codex, without exemptions that would undermine the international Codex standard. The ractopamine MRLs have been recommended as safe after extensive review by the Joint Expert Committee on Food Additives (JECFA), an independent Food and Agricultural Organization/World Health Organization scientific body of recognized world experts. Adopting Codex MRLs for ractopamine is especially important for countries that do not have the resources to carry out their own risk assessments and rely on Codex MRLs. Other countries that do not have an MRL, but want to import from countries that enforce Codex MRLs can do so with confidence in the safety of the product.

Some countries are trying to block adoption of the ractopamine MRLs using arguments that include national interests, national laws, or preferences regarding product use. Blocking the ractopamine MRLs after they have been evaluated and deemed safe by JECFA undermines the ability of Codex to establish international food safety standards, and may set a precedent for discounting the advice of its scientific experts.

*Question.* How is FDA engaging within with our trading partners to ensure a science-based outcome of Codex meetings?

*Answer.* The FDA works very closely with the U.S. Codex Office in the U.S. Department of Agriculture (USDA) on all matters related to Codex. The U.S. Chair of CCRVDF, and the U.S. Delegate to CCRVDF are FDA employees and have been actively engaged with the U.S. Codex Office, the Foreign Agriculture Service, and the U.S. Trade Representative to reach out to other countries on this issue.

FOOD MARKETING GUIDELINES

*Question.* In December 2009, the Federal Trade Commission (FTC), FDA, USDA, and the Centers for Disease Control and Prevention (CDC) released a proposal for voluntary guidelines for food advertising to children and teens. These guidelines applied certain nutrition criteria to advertising during television programs that are viewed by children and teens. Some have complained that the proposal would prohibit the marketing of products that clearly fit within USDA and FDA's dietary guidelines.

To what extent was FDA involved in the development of these guidelines?

*Answer.* The committee reports that accompanied the 2009 Omnibus Appropriations Act included a provision calling for the establishment of an Interagency Working Group on Food Marketed to Children, made up of members from FDA, CDC, USDA, and FTC. The FDA representative to this working group was the Director of the Office of Nutrition, Labeling, and Dietary Supplements, at the Center for Food Safety and Applied Nutrition.

In 2009, the working group met and held conference calls. The FDA representative worked to ensure that the working group understood the FDA nutrition labeling requirements and policies, and the FDA representative drew upon the technical expertise of FDA staff as necessary.

The working group's discussions in 2009 on nutrition principles led to the development of the guidelines that your question refers to. Developing the tentative guidelines was the first phase of preparing a report to the Congress containing the working group's final findings and recommendations, as required by the committee reports that accompanied the 2009 Omnibus Appropriations Act. These guidelines were a tentative set of recommendations for voluntary nutrition principles. The voluntary principles were designed to guide industry self-regulatory efforts to improve the nutritional profile of foods that are most heavily marketed to children.

These tentative guidelines were made public at a forum hosted by the FTC in December 2009, entitled "Sizing Up Food Marketing and Childhood Obesity." At the forum, the FDA representative joined representatives from the other participating agencies to discuss the standards that the working group had tentatively agreed to. Throughout 2010, the working group met to refine the voluntary nutrition principles based on comments provided at the public forum and based on newly issued nutrition reports. Once again, the FDA representative and staff worked to ensure consistency with existing nutrition labeling requirements and current Federal nutrition policy. The continuing discussion of the working group has led to the development of a report on a set of proposed nutrition principles published for comment on the FTC Web site on April 28, 2011.

*Question.* Are you aware of any scientific study that directly links television advertising to obesity?

*Answer.* The Interagency Working Group evaluated research related to associations between television viewing, including advertisements, and childhood obesity. At the forum hosted by FTC in December 2009, the CDC representative to the working group, from CDC's Division of Nutrition and Physical Activity, provided data in his presentation from research on television viewing and links to childhood obesity. The CDC representative noted that although there is some evidence to suggest an association between television viewing and childhood obesity, the Institute of Medicine, part of the National Academies of Science, has concluded in a report entitled "Food Marketing to Children and Youth" that there is insufficient evidence of a causal relationship between TV advertising to obesity. The primary objective of the Working Group has been the promotion of children's health through better diet, with particular, but not sole, emphasis on reducing the incidence of childhood obesity. The proposed recommendations are therefore designed to encourage children, through advertising and marketing, to choose foods that make a meaningful contribution to a healthful diet and minimize consumption of foods with significant amounts of nutrients that could have a negative impact on health or weight.

*Question.* Would these guidelines prohibit the marketing of foods that you would define as healthy?

*Answer.* Neither the tentative guidelines on the recommendations for voluntary nutrition principles issued in December 2009 nor the report on the proposed nutrition principles that issued in April 2011 prohibit the marketing of any foods. The nutrition principles in each document contain recommendations related to advertising practices to guide industry efforts to improve the nutritional profile of foods marketed directly to children and to tap into the power of advertising and marketing to support healthful food choices. Such recommended principles should not be interpreted as a substitute or a replacement for any of FDA's food labeling regulations or a change in Federal dietary guidance for industry (GFI).

The final product of the working group will be a report to the Congress containing recommendations for voluntary nutrition principles for industry to consider in advertising practices and not regulations promulgated by the agencies. Therefore, any guidelines from the working group would not prohibit the marketing of any foods.

#### GENERIC DRUG REVIEW

*Question.* Since the fiscal year 2008 appropriation, funding for the Office of Generic Drugs (OGD) has increased by 23 percent. However, during this same time period, the median approval time for generic drugs has gone from 18.89 months to more than 26 months.

How do you explain this decline in performance?

*Answer.* FDA used the increased resources to hire more reviewers. However, it takes several months to train new reviewers and even longer before new reviewers become fully productive.

In addition, the new and experienced reviewers are dealing with more complex new drugs that are becoming eligible for generic competition. Therefore, more time is required to review and approve the generic drug versions. Also, more resources are required to develop recommendations and GFI to address complex products.

The number of new generic drug applications submitted to FDA remains at a high rate of more than 800 per year, compared to just more than 300 per year a decade ago. Complicating the review is an increase in the number of new companies, often relying on overseas manufacturing and bioequivalence testing sites. Approval of applications from new companies often takes longer as the new companies are less familiar with FDA requirements.

This review effort makes up only part of the median approval time. The other part is time that the applications are with the firm to address deficiencies raised during review. More than 90 percent of the original generic drug submissions are found deficient. The companies must address these deficiencies before they can gain approval. The responses from companies are not always timely due to the companies' own priorities. Furthermore, there may be multiple review cycles before approval.

Finally, other postapproval activities compete with FDA's efforts to review generic drug applications. There are many more marketed generic drugs products now than ever before. These products must be monitored to assure the safety of American patients. For example, any change to an already-approved generic drug must be reported to FDA's OGD. The growing workload to evaluate these changes competes with the workload of new generic drug application review.

*Question.* Specifically, what have we been getting for our investment in generic drug review?

*Answer.* The following is a brief summary of just a few of the benefits of the generic drug review program. For the decade 2000 through 2009, according to a publication from the Generic Pharmaceutical Association, the use of generic prescription drugs in place of their brand-name counterparts saved the Nation's healthcare system more than \$824 billion. In fiscal year 2009 alone, the use of FDA-approved generics saved \$139.6 billion.

It is estimated that more than 20 percent of all the drugs products on the market are only available in generic form. Therefore, generic drugs play a role in augmenting the supply and sources of drug products for national emergencies.

In fiscal year 2010, 565 generic drugs were approved or tentatively approved. In fiscal year 2010, the OGD took 2079 actions on original/new generic drug applications. These exceeded estimates for the program.

As of March 2011, OGD has posted more than 800 product-specific bioequivalence draft GFI documents, including more than 150 that have been finalized after considering public comments. Approximately 15–30 new GFI documents are posted every quarter. The information that FDA posts has been responsible for an approximately 75-percent reduction in the number of bioequivalence inquiries during the past 3 years. This timely and transparent provision of bioequivalence recommendations allows all interested parties equal access to information, and OGD believes the overall quality of submissions has improved.

#### MEDICAL DEVICE REVIEW

*Question.* Recently, medical device manufacturers have complained that FDA's review process is expensive and unpredictable which leads to costly delays in approval. Many United States-based device companies have indicated that it makes far more financial sense to apply for approval and market new medical devices in Europe than in the United States. This has led some to worry that this sector would relocate to other countries and focus more intently on developing new products for marketing in other countries.

Given that FDA missed 30 percent of its device review goals for fiscal year 2009, I wonder if there is any credence to this concern.

What is your response to this industry complaint?

*Answer.* Overall, FDA is meeting or exceeding the Medical Device User Fee Act (MDUFA) performance goals for more than 95 percent of the more than 4,000 annual device applications subject to these goals. For example, under the 510(k) program—the pathway used by 90 percent of the devices we examine each year—FDA completed 90 percent of our reviews in 90 days or less, which met the applicable goal. FDA also completed 98 percent of our reviews in 150 days or less, just as we committed to under MDUFA. For most of the goals FDA is not yet meeting, our performance has been steadily improving. FDA published more detailed performance information in FDA's fiscal year 2010 MDUFA Performance Report to Congress.

The model of the European Union (EU) has important limitations. Unlike the United States, the EU does not require that a device be shown to be effective. More-

over, decisions to approve a device in the EU are made by private companies, called Notified Bodies. There are more than 70 from which a manufacturer can select and to whom it pays a fee. Notified Bodies are subject to variable amounts of oversight. The information on which Notified Bodies make an approval decision is not made available to the public. In addition, it is difficult to compare the United States and EU systems because, unlike in the United States, the EU does not have a centralized, publicly available database of review performance, summaries of approval decisions, or important measures of safety, such as adverse event reports.

The European Commission has recognized that the EU model does not always offer a uniform level of protection of public health. As a result, it has sought comment on proposals to change the EU model. FDA believes that the best approach is not to replace the U.S. model, which has served the American public well, but rather to make the U.S. model more robust. With this goal in mind, in January 2011 FDA announced 25 actions we will take this year to make our premarket review programs more predictable, consistent, and transparent. As a further effort to make the U.S. model more robust, in February we announced our Innovation Initiative to help bring breakthrough technologies to patients more quickly.

*Question.* Could you be doing more outreach with device manufacturers during the review process to increase review certainty?

*Answer.* FDA currently conducts interactive reviews on many submissions. As part of the Medical Device User Fee Amendments of 2007 (MDUFA II) negotiations, FDA agreed to continue to incorporate an interactive review process. The commitment letter for MDUFA II states:

“The agency will continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and sponsors to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and sponsors.”

In response to this commitment, FDA has developed GFI titled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements.”<sup>1,2</sup> We also added an interactive review log in the Center Tracking System database and trained Center for Devices and Radiological Health and Center for Biologics Evaluation and Research staff on interactive review with sponsors.

In addition, as reflected in the public meeting minutes, FDA has proposed to industry during the Medical Device User Fee Amendments of 2012 (MDUFA III) negotiations to further enhance interactive review by making mandatory the tracking of interactive review and by establishing interaction goals for premarket notification, or 510(k), submissions and for premarket approval submissions. The proposal also included identifying best practices and incorporating them into a Good Review Management Practices GFI.

#### COUNTERFEIT DRUGS

*Question.* This week, you were on 60 Minutes discussing the \$75 billion counterfeit drug industry. During this interview, you stated that the agency does not know the extent to which counterfeit drugs have entered the domestic drug supply, but that you are aware that 30–50 percent of important drugs for public health in certain countries are counterfeit.

What would it take to get a handle on counterfeit products in the domestic drug supply?

*Answer.* Addressing the challenge of counterfeit drugs is an important challenge and FDA uses a multifaceted approach to address this challenge. Counterfeiters take steps to avoid detection so it is very challenging to determine the prevalence of counterfeit drugs in the domestic drug supply. FDA can only quantify those events that we discover. FDA believes the U.S. drug supply is one of the safest in the world due to the closed distribution system and we rely on global estimates and reports to gauge the relative risk to U.S. consumers.

FDA uses a multilayered approach to minimize the risk of counterfeit drugs entering the United States and to protect the U.S. drug supply. FDA works closely with supply chain stakeholders to secure the product, the supply chain, and distribution of the product by engaging in public outreach and education, coordinating regulatory actions with State and other Federal agencies, cooperating internationally, conducting criminal investigations, and enhancing enforcement.

A robust track and trace system could help decrease the opportunities for diversion and counterfeiting by allowing distributors and pharmacies to authenticate

<sup>1</sup> PMA refers to premarket approval.

<sup>2</sup> BLA refers to biologics license application.

product origin and supply chain by ensuring that a drug was handled only by legitimate entities. FDA is working to develop such a system, but implementation by the drug supply chain is essential to its success.

FDA collaborates with many State and Federal agencies, in addition to international law enforcement and regulatory bodies to combat counterfeit drugs. FDA's Office of Criminal Investigations (OCI) works to identify counterfeit drug manufacturing locations, and prosecutes those responsible for the manufacturing and distributing of counterfeit drugs.

Drug counterfeiting is a global problem so FDA is tackling this issue internationally by actively working with the World Health Organization and other private and public sector partners to develop tools, implement strategies, and take action to prevent and detect counterfeits that threaten the global marketplace and U.S. consumers.

*Question.* Do you work with industry to find these products?

*Answer.* FDA collaborates with industry to identify counterfeit drug products and warn the public once the products are identified. FDA's OCI collaborates with industry on a regular basis regarding illegal drug products, including counterfeit drugs. An example of this collaboration occurred last year when GlaxoSmithKline (GSK) received several reports of suspected counterfeit over-the-counter weight-loss product from consumers and GSK notified OCI. GSK worked with FDA to quickly identify the counterfeit product, warn the public about the danger of the counterfeit since it contained the wrong active ingredient, and educate consumers on how to distinguish counterfeit products from the authentic products. FDA issued two press releases with important information for consumers which assisted them in protecting themselves from buying or taking a counterfeit product. Additionally, OCI successfully identified and prosecuted those responsible for manufacturing and distributing the counterfeit product.

FDA also has a Counterfeit Alert Network (CAN) a coalition of health professional and consumer groups. This network also includes associations that represent distributors and pharmacies. Participants in the network agree to develop educational information and to rapidly disseminate important information about confirmed counterfeit products to their members. The CAN is another way for FDA to engage other parts of the drug supply chain and share information with healthcare professionals and consumers so they can identify counterfeit products.

*Question.* Would you agree that before we move forward with any proposal to allow Americans to buy drugs from other countries, we should demonstrate that we can do so safely and do so without increasing the chances that Americans may get a contaminated or potentially dangerous or counterfeit medication?

*Answer.* FDA's main concern with the importation of prescription drugs is patient safety. Many of the drugs currently being illegally imported are not FDA-approved and come from unknown sources and foreign locations that may not be manufacturing the products in accordance with FDA regulations. In addition, these products may be counterfeit or may contain potentially harmful ingredients. FDA does not have the same information for drugs produced and approved for foreign markets or that are manufactured in foreign facilities not inspected by FDA as we do for products approved and manufactured for the U.S. market.

Expanding the purchase of drugs from other countries would provide additional opportunities for counterfeits and other substandard or contaminated products to enter into the U.S. supply chain. FDA continues to identify appropriate compliance, enforcement, and information technology tools to monitor and address unapproved or otherwise illegally imported drugs. FDA is also developing a risk-model associated with importation to identify and minimize the risks to consumers, drug quality, and the supply chain. In addition, FDA is analyzing and assessing potential policies and operations that could reduce the risks from allowing foreign-approved drugs into the United States. This assessment includes exploring policy options that strike a balance between providing adequate safety measures and reducing costs to patients.

#### FDA MODERNIZATION

*Question.* In February, The Financial Times reported that, "Barack Obama has warned that the U.S. Food and Drug Administration is a candidate for a sweeping revamp amid complaints that it is ill-equipped to handle biotechnology and advances in medicine. I've gotten a lot of commentary about the fact that . . . essentially their model was designed for the kind of medical devices you see in museums," the president said in remarks before a new panel on jobs and competitiveness. While he was short on details, Mr. Obama singled out the FDA as an agency that ought to be modernized".

What changes has the President specifically asked you to initiate?

Answer. The President has directed agencies to review regulations and other procedures to see if they can withdraw or modify regulations, or otherwise improve procedures, to reduce regulatory burden and improve competitiveness, innovation, economic growth, and jobs, while assuring safety. FDA has identified improvements to regulatory science as well as other initiatives—such as its Medical Device Innovation Initiative, the 510(k) Plan of Action, and the voluntary pilot program by FDA and the Centers for Medicare & Medicaid Services—also referred to as Parallel Review of Medical Devices—that will help it and the industries it regulates innovate and remain competitive.

FDA has also identified regulations for revision and is continuing its review of its rules and procedures to identify additional opportunities. For example, FDA recently revised its biologics regulations to permit approval of exceptions or alternative to the regulation of constituent materials. This action recognizes advances in the development and manufacture of safe, pure, and potent biological products that, in some instances, render the existing constituent materials regulation too prescriptive and unnecessarily restrictive. FDA will maintain its ongoing review of device classifications to determine whether devices can be classified to a lower level, which reduces burdens on industry while maintaining product safety and efficacy. FDA is also revising its device adverse event reporting requirements to convert to a more efficient paperless, electronic system. In addition, FDA is pursuing initiatives to permit electronic submission of clinical trial data and other information related to drugs and medical devices, which will create efficiencies for both industry and FDA.

#### ADVISORY PANELS

*Question.* At advisory panel meetings, FDA reviewers often instruct the panel on the standards that apply for assessing the safety and effectiveness of the product at hand. It appears that in the context of certain advisory panel presentations, FDA reviewers have put forward standards that differ from regulations and applicable binding agreements.

What procedures are in place to ensure that FDA review teams' presentations to panels comply in every respect with the regulations and applicable binding protocol agreements?

Answer. FDA presentations at panel meetings undergo multiple levels of review by scientific and supervisory staff to ensure that statements made by FDA are factually correct. FDA provides information that will be presented at the meeting to the sponsor of the product under review. Sponsors may suggest corrections, clarifications, or edits to these materials in advance of the meeting.

*Question.* Does a product sponsor have any recourse if the review staff's presentation to an advisory panel provides incorrect information to the panel regarding the standards of safety, effectiveness, or the terms and obligations under a binding protocol agreement?

Answer. In advance of a panel meeting, the product sponsor has the opportunity to comment on the review staff's presentation if they have any concerns. During the meeting, the sponsor may make a request to address the panel with any concerns it may have related to the material presented by FDA.

#### BLOOD TESTING

*Question.* I understand FDA is considering whether to require all blood donations for human transfusion be screened for hepatitis B virus (HBV) using nucleic acid testing (NAT). The last public discussion on this issue took place at the April 2009 meeting of FDA's Blood Products Advisory Committee (BPAC).

What is the agency's current thinking is regarding an HBV NAT mandate?

Answer. FDA is evaluating and considering the required testing of blood for transfusion using HBV NATs. FDA currently requires that blood for transfusion be tested for HBV surface antigen and antibody to HBV core antigen. FDA brought the issue of testing of human blood for transfusion by HBV NAT to BPAC on April 1, 2009. The committee discussed scientific issues related to the risk of HBV transmission by blood for transfusion. The committee supported routine HBV NAT for blood donations, and establishment of a minimum sensitivity standard for the test. Currently, multiplex nucleic acid assay systems that simultaneously detect human immunodeficiency virus (HIV), hepatitis C virus (HCV), and HBV are in widespread use for testing blood donations. Therefore, because HIV and HCV NAT are required by FDA for testing blood donations, HBV NAT is also already widely performed to test blood for transfusion.

*Question.* Is FDA preparing to issue GFI regarding this topic?



Answer. FDA is considering issuing draft GFI for public comment on the use of HBV NAT to test both blood for transfusion and Source Plasma for further manufacture into derivatives.

#### DIABETES AND OBESITY DRUGS

*Question.* I understand FDA is now requiring additional clinical trials, including cardiovascular (CV) studies, for new diabetes and obesity drugs.

What is the agency doing to ensure that changing product requirements do not get in the way of making better therapies available to patients?

Answer. For diabetes drugs, new concerns have recently been raised regarding the CV safety of drugs to treat diabetes. In May 2007, a meta-analysis of clinical trials of the diabetes drug, Avandia, also referred to as rosiglitazone, was published that suggested an increased risk of heart attacks in patients taking this widely used drug. The controversy surrounding the meta-analysis and other data on the CV safety of diabetes drugs were discussed at several public advisory committee meetings. In July 2008, FDA held a 2-day advisory committee meeting to seek advice from a panel of experts in the field of endocrinology, cardiology, statistics, and drug safety on the extent of assessment of CV safety that should be required of new therapies to treat type-2 diabetes mellitus (T2DM). The panel, by a majority of 14-to-2, voted in favor of requiring a prospective assessment of CV safety prior to approval. Subsequently, in September 2010, FDA announced that it would restrict the use of Avandia in response to data suggesting an elevated risk of cardiovascular events by requiring a restricted access program under a risk evaluation and mitigation strategy. In December 2008, FDA issued GFI titled, "Diabetes Mellitus—Evaluating CV Risk in New Anti-diabetic Therapies to Treat T2DM." This GFI articulates FDA expectations for CV safety assessment of new drugs to treat T2DM. Under this GFI, collection of controlled data of new anti-diabetic therapies for at least 2 years is anticipated.

Regarding obesity drugs, in February 2007, FDA issued a draft GFI entitled, "Developing Products for Weight Management." The recommendations provided in the 2007 draft GFI document continue to guide the development of novel obesity drugs. Significant safety issues with three recently reviewed obesity drugs—Qnexa, Lorcress, and Contrave—led FDA to request that the drug sponsors conduct additional studies. In one case, FDA requested that a cardiovascular safety study to provide for a more complete benefit-risk assessment.

*Question.* What has FDA's performance, in terms of months to review and number of review cycles, been for diabetes and obesity drugs?

Answer. Since the diabetes GFI was issued in December 2008, FDA has approved three new molecular entity new drug applications (NDAs), submitted for the treatment of T2DM. Of these three NDAs, two were approved within their Prescription Drug User Fee Act goal dates for FDA to complete its review and take an action. All three NDAs were approved during their first review cycle.

Since 1999, four NDAs for prescription obesity drugs have been submitted to FDA. Qnexa, Lorcress, and Contrave were all reviewed within one review cycle and were acted upon within 10 months of submission. In addition, the drug Rimonabant was reviewed within 10 months of initial submission in 2005 and was undergoing a second review cycle when the sponsor withdrew the application.

The prescription obesity drug, orlistat, was approved in 2007 for use without a prescription. The nonprescription application was approved following an initial 10-month review cycle and a subsequent 6-month review cycle.

#### QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

##### ANTIBIOTICS IN FOOD PRODUCTION

*Question.* As discussed by the Food and Drug Administration (FDA) in draft guidance for industry (GFI) No. 209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Processing Animals," antibiotic drugs, and the drugs' labeled uses, are approved on an individual basis, utilizing a drug-specific risk assessment. In the draft GFI, the FDA states that before withdrawing a previously approved use of an approved drug, Federal law requires the FDA to demonstrate that "new evidence . . . shows that a drug is not shown to be safe under the approved conditions of use." Then, once the FDA meets this initial burden, under Federal law, the drug sponsor is entitled to demonstrate the drug is still safe for its intended use. Despite this Federal mandate, it appears that FDA is trying to generally ban the use of antibiotics for growth promotion, feed efficiency, and certain types of preventive treatment through the draft GFI. However, the draft GFI makes no finding

in regard to a specific animal drug. Furthermore, the studies cited by the draft GFI are dated and generally confirm no direct link between antibiotics used for growth promotion, feed efficiency, and certain types of preventive treatment and risk to human health. Has FDA made any specific findings on individual, previously approved drug applications that demonstrate that animal “production uses” of a specific drug should be withdrawn based on new evidence that the drug is no longer safe under the approved conditions for use? If so, how many and for which drugs has it made such a finding?

Answer. No, FDA has not yet made such a finding regarding any individual, previously approved new animal drug application.

*Question.* In draft GFI No. 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Processing Animals,” the FDA states that rather than follow statutory procedures to withdraw an approved drug use, the FDA will sometimes address issues through an informal process where it convinces a drug sponsor to voluntarily withdraw an approved use.

Which drug sponsors of animal antibiotic drugs is the FDA, through an informal process, currently trying to persuade to withdraw approved uses of antibiotics for animal growth promotion, feed efficiency, and preventive treatment? Of these drug sponsors, which approved animal antibiotic drugs are implicated in the informal withdrawal process?

Answer. As discussed in draft GFI No. 209, the focus of FDA’s concerns are on the use of medically important antimicrobial drugs in food-producing animals for production purposes, such as to promote growth or improve feed efficiency. FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed and water, to be uses that are necessary for assuring the health of food-producing animals.

Currently, FDA is conducting outreach to the animal health industry on this issue. Since publication of draft GFI No. 209, we have been very encouraged by the interactions we have had to date with key stakeholders, including the animal health industry, on plans for implementation. Sponsors of some of our most important antimicrobial drugs have already initiated discussions with FDA about updating their animal drug products in a manner consistent with the principles of draft GFI No. 209. Regarding which specific animal drug products are in most need of updating, FDA intends to issue additional GFI, which will provide more specific information on this topic and allow stakeholders the opportunity to comment on it.

*Question.* Once draft GFI No. 209 is finalized, which drug sponsors is the FDA, through an informal process, planning to persuade to withdraw approved uses of antibiotics for animal growth promotion, feed efficiency, and preventive treatment? Of these drug sponsors, which approved animal antibiotic drugs are implicated in the informal withdrawal process?

Answer. As previously noted, the focus of FDA’s concerns are on the use of medically important antimicrobial drugs in food-producing animals for production purposes, for example, to promote growth or improve feed efficiency. FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed and water, to be uses that are necessary for assuring the health of food-producing animals. Also as noted previously, FDA intends to issue additional GFI, which will provide more specific information on this topic including identifying which specific drugs or drug classes are subject to the recommendations outlined in draft GFI No. 209.

*Question.* What is the FDA’s timeline for publication of the final GFI for draft GFI No. 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Processing Animals”?

Answer. Once review of the comments received on draft GFI No. 209 is complete, FDA plans to issue final GFI implementing draft GFI No. 209. FDA is still developing a timeline for issuance of the final GFI No. 209. In addition, FDA continues to work collaboratively with other agencies and FDA stakeholders to develop sound strategies for implementing the recommendations outlined in the draft GFI.

*Question.* Has the FDA reviewed and responded to all of the submitted comments to draft GFI No. 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Processing Animals”?

Answer. FDA is nearly finished reviewing the comments received regarding draft GFI No. 209. FDA is using the comments to assist in development of the final draft GFI No. 209.

The FDA has requested an increase of nearly \$326 million to fund its Food Safety and Nutrition activities associated with implementation of the FDA Food Safety Modernization Act (FSMA). I am concerned about how FDA plans to use these funds to create on-farm production standards and traceability rules.

*Question.* First, I would like to know whether the FDA will abide by the law's exemption from on-farm production standards and traceability rules for grain commodities and livestock and not interfere with on-farm decisions made by producers of these agricultural products.

*Answer.* FDA FSMA contains numerous provisions requiring FDA to develop more than 50 new regulations, GFI documents, and reports to the Congress. As FDA is in the process of developing the required regulations, it is too soon to be able to provide specificity about the new requirements. However, I can assure you that, as we move forward, we will certainly be mindful of any exemptions contained in the statute. We also are committed to continuing to engage all our stakeholders to gain the information needed to inform our rulemaking activities and to help the affected industry implement the new food safety requirements.

*Question.* Second, I would like the FDA to explain how it plans to set on-farm production standards for fruits and vegetables. Is FDA planning on promulgating broad, flexible standards that defer to the expertise of the individual producer or is FDA planning to promulgate specific production standards that restrict producer flexibility and ultimately hamper on-farm innovation?

*Answer.* FDA is aware of the tremendous diversity in farming operations and that a one-size-fits-all approach to produce food safety will not be practicable. FDA is committed to providing operators with flexibility and innovation in their approaches to on-farm food safety for their operations. FDA intends to propose a rule containing requirements that will be commensurate to the hazards and risks associated with any particular operation.

*Question.* During the hearing on March 17, 2011, Commissioner Hamburg noted that she recently appointed a new director for the FDA Office of Foods and plans to hire additional personnel to assist in implementation of on-farm production standards and traceability under the new authorities granted by FDA FSMA. Does FDA plan to hire individuals with production agriculture experience and education? For instance, does FDA plan to consider hiring personnel with a degree in agronomy or other applied agricultural science degrees?

*Answer.* The authorities granted to FDA under FSMA cover many disciplines in the area of food safety, including production agriculture. FDA currently has staff whose expertise is production agriculture and with degrees in agronomy. FDA is committed to hiring subject matter experts from any field relevant to its needs, which would include consideration of individuals with degrees in applied agricultural sciences.

#### CONCLUSION OF HEARINGS

Senator KOHL. Thank you very much, Senator Blunt.

And Commissioner Hamburg, you have been great. You have been very informative. We have had a good discussion on many issues. I am sure you are looking forward to following it up with us.

Dr. HAMBURG. Yes. Thank you so much.

Senator KOHL. Thank you very much.

The hearing is recessed.

[Whereupon, at 2:58 p.m., Thursday, March 17, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]



**AGRICULTURE, RURAL DEVELOPMENT, FOOD  
AND DRUG ADMINISTRATION, AND RE-  
LATED AGENCIES APPROPRIATIONS FOR  
FISCAL YEAR 2012**

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

NONDEPARTMENTAL WITNESSES

[The following testimonies were received by the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for inclusion in the record. The submitted materials relate to the fiscal year 2012 budget request for programs within the subcommittee's jurisdiction.]

PREPARED STATEMENT OF THE AMERICAN COMMODITY DISTRIBUTION ASSOCIATION

On behalf of the American Commodity Distribution Association (ACDA), I respectfully submit this statement regarding the budget request of the Food and Nutrition Service for inclusion in the subcommittee's official record. ACDA members appreciate the subcommittee's support for these vital programs.

We urge the subcommittee to maintain administrative expense funding for the Emergency Food Assistance Program (TEFAP) at \$74.5 million; to make TEFAP food purchase dollars available for 2 fiscal years; to approve the administration's budget request for the Commodity Supplemental Food Program (CSFP) and provide an increase of \$5 million to begin operations in six additional States approved by the U.S. Department of Agriculture (USDA); and to evaluate alternative approaches for the Department of Defense (DOD) Fresh Program.

ACDA is a nonprofit professional trade association, dedicated to the growth and improvement of USDA Commodity Food Distribution Program. ACDA members include:

- State agencies that distribute USDA-purchased commodity foods;
  - agricultural organizations;
  - industry;
  - associate members;
  - recipient agencies, such as schools and soup kitchens; and
  - allied organizations, such as anti-hunger groups.
- ACDA members are responsible for distributing more than 1.5 billion pounds of USDA-purchased commodity foods annually through programs such as the National School Lunch Program, TEFAP, Summer Food Service Program (SFSP), CSFP, Charitable Institution Program, and Food Distribution Program on Indian Reservations (FDPIR).

THE EMERGENCY FOOD ASSISTANCE PROGRAM ADMINISTRATIVE FUNDS AT \$74.5  
MILLION, AS PROVIDED FOR FISCAL YEAR 2009 AND FISCAL YEAR 2010

We urge the subcommittee to maintain TEFAP administrative funds at \$74.5 million, as provided for fiscal year 2009 and fiscal year 2010 when American Recovery and Reinvestment Act (ARRA) funds were added to the regular appropriation.

Food banks around the Nation are in great need. The number of Americans who are turning to food banks for assistance continues to increase. The Congress appropriated \$49.5 million for TEFAP administrative funds in both fiscal year 2009 and

2010, and through ARRA, supplemented these amounts with an additional \$25 million. These resources have been used responsibly, and are sincerely appreciated.

Donations to food banks are declining as many individuals and businesses no longer have the ability to be as supportive as they had been in the past. ACDA members tell us that unless TEFAP expense funds are restored to the fiscal year 2009–2010 level, they will have to accept less food to reduce shipping/warehousing expenses, and will likely have to cut reimbursement to local distributors. These reimbursements are key to maintaining distribution sites, especially in rural distribution sites.

The lower funding level available in fiscal year 2011 has already had a negative impact. In Wisconsin, this year's lack of administrative funding to compensate for the increased quantities of bonus commodities required a mid-year cut in support to Wisconsin's 16 Emergency Feeding Organizations administrative budgets.

We recognize that States have had the ability to convert a portion of their food funds to administrative funds, and have done so. We appreciate this flexibility, but must respectfully point out that even if this flexibility is continued, TEFAP operators will experience a significant reduction in available administrative expense funds that jeopardizes their ability to provide essential food assistance to needy Americans.

Section 4201 of the Food, Conservation, and Energy Act of 2008 (Public Law 110–246) increased the authorization for TEFAP administrative expense funds from \$60 million to \$100 million, recognizing the need for increased expense funds to responsibly manage increased TEFAP food supplies. Our request for \$74.5 million, is well within the amounts authorized.

MAKE THE EMERGENCY FOOD ASSISTANCE PROGRAM FOOD DOLLARS AVAILABLE FOR 2  
FISCAL YEARS

We urge the subcommittee to make TEFAP food dollars available for 2 fiscal years, as was done under ARRA.

While the agencies of USDA work closely with food banks to provide as much food for distribution as possible, there are occasions when food dollars are at jeopardy through no fault of recipient agencies. If food orders are canceled by either USDA or vendors for any reason near the end of the Federal fiscal year, State agencies must either purchase whatever items might be available through USDA, or lose these end-of-year balances.

At the end of fiscal year 2009 Florida had an ARRA TEFAP balance of \$1.6 million on September 28, 2009, due to the cancellation of cheese orders that day. Florida's regular TEFAP balance was \$218,023. On September 8, 2009, the TEFAP entitlement balance in New York was just more than \$12,000. On September 28, it was \$415,000 due to the significant cancellations and deletions of truckloads of commodity foods. On July 28, 2009, New York's ARRA balance was \$11,000. On September 28, it was \$481,000. Other ACDA members have told us of similar experiences in their States.

Food banks are working diligently to use every \$1 responsibly because every \$1 is needed. When ARRA was passed, TEFAP food dollars were allowed to be carried over from fiscal year 2009 to fiscal year 2010. This procedure helped food bank operators to make responsible decisions and to take maximum advantage of available resources.

We urge the subcommittee to make TEFAP food dollars available for 2 years, and urge the Secretary of Agriculture to allow those States who made responsible efforts to use their TEFAP food dollars to roll over to the next fiscal year balances unexpended through no fault of the TEFAP operator.

FUNDING FOR THE COMMODITY SUPPLEMENTAL FOOD PROGRAM

ACDA supports the fiscal year 2012 budget request of \$176,788,000 for CSFP, but urges the subcommittee provide an additional \$5 million to begin CSFP operations in six States that now have USDA-approved State plans—Connecticut, Hawaii, Idaho, Maryland, Massachusetts, and Rhode Island. This additional funding would make CSFP available in 45 States. CSFP now serves primarily elderly individuals, many of whom are homebound. States currently operating CSFP requested 137,276 additional caseload slots for the current program year, clearly showing the need for this program.

AMERICAN COMMODITY DISTRIBUTION ASSOCIATION REQUESTS THE EVALUATION OF  
ALTERNATIVE APPROACHES FOR DOD FRESH

There is broad consensus that improving the nutritional well-being of Americans, particularly children, includes increasing fruit and vegetable consumption, including

fresh items. USDA's commodity program is constrained in its ability to distribute fresh foods.

However, in the 1990s, the Department developed a partner relationship with DOD to utilize some of the Federal commodity entitlement for school meal programs to allow school districts to purchase through the DOD distribution system. This program, DOD Fresh, was very successful.

Changes in the DOD procurement and distribution program which have outsourced these procurement activities have had a deleterious effect on the school program. This change has also created a situation where each school that participates must pay a fee to access the DOD secure ordering system.

The Secretary has worked to ameliorate these fees, approximately \$3 million per year, in the short term, but this is a temporary fix. We believe that there may be an alternate approach that will restore the many benefits of the original DOD Fresh Program.

We once again ask the subcommittee to direct the Secretary to evaluate alternative approaches for replacing DOD Fresh including, but not limited to, developing an analog program through the Agricultural Marketing Service, and report back to the subcommittee on these options.

We look forward to continuing to partner with you and USDA in the delivery of these needed services.

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#### PREPARED STATEMENT OF THE AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation (AFBF) has identified three priorities for emphasis and funding for U.S. Department of Agriculture (USDA) programs in the fiscal year 2012 agriculture spending bill. They are:

- programs that expand export markets for agriculture;
- programs that promote broadband expansion; and
- programs that further develop renewable energy.

AFBF strongly opposes any cuts to funding for the farm safety net. Such cuts would break a 5-year commitment made to America's farmers and ranchers in the 2008 farm bill. Producers have made business decisions based on this contract with the Government, and to break these commitments would severely impact the rural economy. The farm bill discussion should occur when the House and Senate Agriculture Committees begin hearings and draft legislation for the next farm bill.

#### PROGRAMS THAT EXPAND INTERNATIONAL MARKETS FOR AGRICULTURE

In order to take full advantage of the market opportunities offered through trade agreements, AFBF supports funding at authorized levels for:

- The Foreign Agricultural Service (FAS) to maintain services that expand agricultural export markets. We urge continued support for the Office of the Secretary for trade negotiations and biotechnology resources.
- The Market Access Program, the Foreign Market Development Program, the Emerging Markets Program, and the Technical Assistance for Specialty Crops Program that are effective export development and expansion programs. These programs have resulted in increased demand for U.S. agriculture and food products abroad and should be fully funded.
- Public Law 480 programs which serve as the primary means by which the United States provides needed foreign food assistance through the purchase of U.S. commodities. In addition to providing short-term humanitarian assistance, the program helps to develop long-term commercial export markets.

We support full funding for the following Animal Plant Health Inspection Service (APHIS) programs:

- The APHIS Plant Protection and Quarantine personnel and facilities, especially the plant inspection stations, which are necessary to protect U.S. agriculture from costly pest problems that enter the United States from foreign lands.
- APHIS trade issues resolution and management activities that are essential for an effective response when other countries raise pest and disease concerns (i.e., sanitary and phytosanitary measures) to prohibit the entry of American products.
- APHIS—Biotechnology Regulatory Services (BRS) that play an important role in overseeing the permit, notification, and deregulation process for products of biotechnology. BRS personnel and activities are essential to ensure public confidence and international acceptance of biotechnology products.

Funding for the U.S. Codex Office is essential to developing harmonized international standards for food and food products. Codex standards provide uniformity

in food rules and regulations by allowing countries to adopt similar levels of safety protection for consumers while concurrently facilitating transparency in food trade.

#### PROGRAMS THAT PROMOTE BROADBAND EXPANSION

The lack of high-speed, modern Internet service in rural America prevents rural Americans' access to educational, medical, and business opportunities, and hampers the economic growth of rural America. We support funding for loans and grants administered by the Rural Utilities Service to increase rural broadband capacity and telecommunications services and to fund the Distance Learning and Telemedicine Program.

#### PROGRAMS THAT FURTHER DEVELOP RENEWABLE ENERGY

AFBF supports funding for the following programs, which help farmers and ranchers contribute to our Nation's goal of energy independence and a cleaner environment.

We support funding the Biomass Crop Assistance Program (BCAP) at levels authorized by the 2008 farm bill. BCAP provides vital financial assistance to farmers who produce and transport eligible biomass feedstocks and helps growers meet the capital-intensive costs of transitioning to producing new crops and delivering them to market.

Additionally, we support increasing funding for the Renewable Energy for America Program (REAP). REAP offers grants, guaranteed loans, and combination grant/guaranteed loans for agricultural producers to purchase renewable energy systems and energy efficiency improvements, as well as offers funding for energy audits and feasibility studies.

AFBF has identified five other areas of importance for USDA programs in the fiscal year 2012 agriculture spending bill. They are:

- programs that promote conservation;
- programs that strengthen rural communities;
- programs that enhance and improve food safety and protection;
- programs that promote animal health; and
- research priorities.

#### PROGRAMS THAT PROMOTE CONSERVATION

AFBF supports full funding for working lands programs. In this time of fiscal constraint, it is imperative to invest in programs that contribute to the world's production of food and fiber. Farmers and ranchers have made great strides in conserving our natural resources and believe that these gains can continue through working lands programs.

#### PROGRAMS THAT STRENGTHEN RURAL COMMUNITIES

Rural entrepreneurs often lack access to the capital and technical assistance necessary to start new businesses. These new ventures are needed for rural communities to sustain themselves and contribute to our national economy. AFBF supports funding for USDA Rural Development (RD) programs that foster new business development in rural communities. These programs include the Value-Added Agricultural Producer Grants, Rural Innovation Initiative, Rural Microentrepreneur Assistance Program, and Business and Industry Direct and Guaranteed Loans.

Many rural communities lack access to the tax base necessary to provide modern community facilities like nursing homes, fire stations, and food distribution centers. AFBF supports funding for the construction, enlargement, or improvement of essential community facilities in rural areas and small towns through RD's Community Facility Direct and Guaranteed Loans. The use of Community Facility Guaranteed Loans encourages synergy between USDA, private lenders, and local communities.

The Revolving Fund Program grant helps communities acquire safe drinking water and sanitary, environmentally sound waste disposal facilities. With dependable water facilities, rural communities can attract families and businesses that will invest in the community and improve the quality of life for all residents. We support funding for this important program.

AFBF supports funding for the Resource Conservation and Development Program. This vital program supports economic development and resource protection. This program, in cooperation with rural development councils, helps local volunteers create new businesses, form cooperatives, develop marketing and agri-tourism activities, improve water quality and flood control, improve leadership and other business skills, and implement renewable energy projects.



AFBF supports continued funding for the Beginning Farmer and Rancher Development Program, which provides farmers information, skills, and tools needed to make informed decisions for their operations, with the goal of enhancing the success of beginning farmers and ranchers.

AFBF supports full funding for Agriculture in the Classroom, a national grassroots program coordinated by the USDA. This worthy program helps students gain a greater awareness of the role of agriculture in the economy and society, so that they may become citizens who support wise agricultural policies.

#### PROGRAMS THAT ENHANCE AND IMPROVE FOOD SAFETY AND PROTECTION

The continued safety of food is crucial to consumers, as well as production agriculture and the rest of the food industry. Sufficient, reliable Federal funding for the Government's food and feed safety and protection functions is vital to this effort. Agencies responsible for food safety must have the necessary resources to reasonably establish safety, especially Food and Drug Administration (FDA) inspections of imported food. While food imports have increased more than 50 percent in the past 5 years, the number of FDA food import inspectors has fallen about 20 percent.

We recommend that adequate funding for food protection at the FDA and Food Safety Inspection Service (FSIS) be directed to the following priorities:

- increased education and training of inspectors;
- additional science-based inspection, targeted according to risk;
- effective inspection of imported food and feed products;
- research and development of scientifically based rapid testing procedures and tools;
- accurate and timely responses to outbreaks that identify contaminated products, remove them from the market, and minimize disruption to producers; and
- indemnification for producers who suffer marketing losses due to inaccurate Government-advised recalls or warnings.

We also support authorized funding of \$2.5 million for the Food Animal Residue Avoidance Databank (FARAD). FARAD aids veterinarians in establishing science-based recommendations for drug withdrawal intervals, critical for both food safety and animal health. No other Government program provides or duplicates the food safety information FARAD provides to the public. Without the critical FARAD program, producers may be forced to euthanize animals or dispose of meat, milk, and eggs due to the lack of withdrawal information.

AFBF opposes the administration's request for new user fees for inspection activities. Food safety is for the public good and as such, it is a justified use of public funds.

#### PROGRAMS THAT PROMOTE ANIMAL HEALTH

Tracking infected and exposed animals is critical to protecting livestock and poultry health through streamlined surveillance and response. Disease traceability helps to reduce the number of animal deaths and preserve animal health when outbreaks occur. A traceability system can limit the number of animal owners impacted by an outbreak and reduce the economic strain on owners and affected communities, as well as protect public health.

We support a voluntary animal disease tracking system, but are concerned about the share of implementation costs that could burden producers if APHIS is not adequately funded. Providing APHIS Federal funding of \$15 million this year, and strong oversight on the expenditure of funds, is essential to generate the greatest possible benefit for animal health and the livestock industry.

We support \$5 million for the Veterinary Medicine Loan Repayment Program (VMLRP) administered by the National Institute for Food and Agriculture. VMLRP provides veterinary school graduates student-loan repayment if they agree to work in underserved areas. VMLRP veterinarians ensure animal health and welfare, while protecting the Nation's food supply.

AFBF supports \$155.5 million for the FDA Center for Veterinary Medicine (CVM). CVM oversees the safety of animal drugs, feeds, and biotechnology-derived plant products used as or in animal feed, as well as biotechnology-derived products used to improve the health or productivity of animals (including fish).

#### RESEARCH PRIORITIES

Research funding is critical to the future of American agriculture. The United Nations' Food and Agriculture Organization predicts that farmers will have to produce 70 percent more food by 2050 to feed an additional 2.3 billion people around the globe. This production challenge likely will have to be met using fewer resources and less land than is available today. America's farmers are the most efficient in

the world, but without a commitment to further agricultural research and technological advancement, even America's farmers could be hard-pressed to meet these challenges. We believe that agricultural research is vital to the lives of our citizens and the economic well-being of our Nation, particularly research focused on meeting the growing challenges of production agriculture.

#### PREPARED STATEMENT OF THE AMERICAN INDIAN HIGHER EDUCATION CONSORTIUM

On behalf of the American Indian Higher Education Consortium (AIHEC) and the 32 Tribal Colleges and Universities (TCUs) that compose the list of 1994 Institutions, thank you for this opportunity to outline our needs and concerns for fiscal year 2012.

This statement is presented in three parts:

- a summary of our fiscal year 2012 funding recommendations;
- a brief background on TCUs; and
- an outline of the 1994 Institutions' plan for using our land grant programs to fulfill the agricultural potential of American Indian communities, and to ensure that American Indians have the skills and support needed to maximize the economic potential of their resources.

#### SUMMARY OF REQUESTS

We respectfully request the following for fiscal year 2012 for our land grant programs established within the USDA National Institute of Food and Agriculture (NIFA) and the Rural Development mission area. In NIFA, we request:

- \$5,321,000 for the 1994 Institutions' competitive Extension grants program;
- \$1,805,000 for the 1994 Institutions' competitive Research Grants program;
- \$3,676,000 for the Higher Education Equity Grants;
- an \$11,880,000 payment into the Native American Endowment fund; and
- in the Rural Development's Rural Community Advancement Program (RCAP), that funding for the TCU Essential Community Facilities Grants program be retained at \$3,972,000, the same level that has been in place since fiscal year 2008, to help the 1994 Institutions to address the critical facilities and infrastructure needs that advance their capacity to participate fully as land grant partners.

#### BACKGROUND ON TRIBAL COLLEGES AND UNIVERSITIES

The first Morrill Act was enacted in 1862 specifically to bring education to the people and to serve their fundamental needs. Today, nearly 150 years after enactment of the first land grant legislation, the 1994 Institutions, as much as any other higher education institutions, exemplify the original intent of the land grant legislation, as they are truly community-based institutions.

The Tribal College Movement was launched in 1968 with the establishment of Diné College, serving the Navajo Nation. Rapid growth of the TCU Movement soon followed, primarily in the Northern Plains region. In 1972, six tribally chartered colleges established the AIHEC to provide a support network for member institutions. Today, AIHEC represents 36 TCUs, operating 76 campuses—32 of which compose the current list of 1994 Institutions located in 12 States. Each year, collectively, tribal colleges serve more than 65,000 American Indians from well more than 250 federally recognized tribes through academic and community education programs.

The 1994 Institutions are accredited by independent, regional accreditation agencies and like all institutions of higher education, must undergo stringent performance reviews to retain their accreditation status. TCUs serve as community centers by providing libraries, tribal archives, career centers, economic development and business centers, public meeting places, and child and elder care centers. Despite their many obligations, functions, and notable achievements, TCUs remain the most poorly funded institutions of higher education in this country. The vast majority of the 1994 Institutions is located on Federal trust territory. Therefore, States have no obligation, and in most cases, provide no funding to TCUs. In fact, most States do not even provide funds to our institutions for the non-Indian State residents attending our colleges, leaving the TCUs to assume the per student operational costs for non-Indian students enrolled in our institutions, accounting for approximately 21 percent of their student population. This is a significant financial commitment on the part of TCUs, as they are small, developing institutions and cannot, unlike their State land grant partners, benefit from economies of scale—where the cost per student to operate an institution is reduced by the comparatively large size of the student body.

As a result of 200 years of Federal Indian policy—including policies of termination, assimilation, and relocation—many reservation residents live in conditions of poverty comparable to those found in Third World nations. Through the efforts of TCUs, American Indian communities are availing themselves of resources needed to foster responsible, productive, and self-reliant citizens. It is essential that we continue to invest in the human resources that will help open new avenues to economic development, specifically through enhancing the 1994 Institutions' land grant programs, and securing adequate access to information technology.

#### 1994 LAND GRANT PROGRAMS—AMBITIOUS EFFORTS TO ECONOMIC POTENTIAL

In the past, due to lack of expertise and training, millions of acres on Indian reservations lay fallow, under-used, or had been developed using methods that caused irreparable damage. The Equity in Educational Land Grant Status Act of 1994 is addressing this situation and is our hope for the continued improvement of our reservation lands. Our current land grant programs remain small, yet very important to us. It is essential that American Indians explore and adopt new and evolving technologies for managing our lands. With increased capacity and program funding, we will become even more fundamental contributors to the agricultural base of the Nation and the world.

#### *Competitive Extension Grants Programs*

The 1994 Institutions' extension programs strengthen communities through outreach programs designed to bolster economic development; community resources; family and youth development; natural resources development; and agriculture; as well as health and nutrition education and awareness. Without adequate funding the 1994 Institutions' ability to maintain existing programs and to respond to the many emerging issues, such as food safety and homeland security, especially on border reservations, is severely limited. Increased funding is needed to support these vital programs designed to address the inadequate extension services that have been provided to Indian reservations by their respective State programs. Funding for the 1994 Land Grant Extension programs is extremely modest. The 1994 Institutions have applied their resourcefulness for making the most of every dollar they have at their disposal by leveraging funds to maximize their programs whenever possible. Two examples of effective 1994 Extension programs include:

- Extension activities at the College of Menominee Nation (Wisconsin) strengthen the sustainable economic development potential of the Menominee, Stockbridge-Munsee, Oneida, and Potawatomi Reservations and surrounding communities by increasing distance education capacity, conducting needs assessment studies, providing workshops and training sessions, and offering strategic planning assistance.
- The Agriculture & Natural Resources Outreach Education Extension Program at Oglala Lakota College (South Dakota), which is located in one of the poorest counties in the Nation, utilizes education to promote the environmentally sound use of agriculture and natural resources by Lakota people. The program coordinates activities between the college's Agriculture and Natural Resources department, reservation schools, other tribal departments, South Dakota State University, and county extension programs. Specific issues addressed by the program include poverty, isolation, health, cultural dissonance, and land-use practices by Lakota landowners.

To continue and expand highly successful programs at 1994 Institutions, we request that the subcommittee support the President's fiscal year 2012 budget request for this competitive grants program and appropriate \$5,321,000 to sustain the growth and further success of these essential community-based extension programs.

#### *1994 Competitive Research Program*

As the 1994 Institutions enter into partnerships with 1862/1890 land grant institutions through collaborative research projects, impressive efforts to address economic development through natural resource management have emerged. The 1994 Research Grants program illustrates an ideal combination of Federal resources and TCU-State institutional expertise, with the overall impact being far greater than the sum of its parts. We recognize the severe budget constraints under which the Congress is currently functioning. The \$1,805,000 appropriated in fiscal year 2010 is, by any measure, inadequate to develop capacity and conduct necessary research at our institutions. The 1994 Research Grants program is vital to ensuring that TCUs may finally be recognized as full partners in the Nation's land grant system. Currently, many of our institutions are conducting applied research, yet finding the resources to continue this research to meet their communities' needs is a constant challenge. This research authority opens the door to funding opportunities to main-

tain and expand the vital research projects begun at the 1994 Institutions, but only if adequate funds are secured and sustained. A total research appropriation of \$1,805,000, for which all 32 of the 1994 Institutions compete, is hugely insufficient. Priority issue areas currently being studied at the 1994 Institutions include:

- sustainable agriculture and forestry;
- biotechnology and bioprocessing;
- agribusiness management and marketing;
- plant propagation, including native plant preservation for medicinal and economic purposes;
- animal breeding;
- aquaculture;
- human nutrition (including health, obesity, and diabetes); and
- family, community, and rural development.

For example, the Standing Rock Sioux Reservation, home to Sitting Bull College and located in North and South Dakota, is often characterized by high unemployment and health concerns. The college is conducting a research project to develop a natural beef enterprise on the reservation that will maximize use of existing natural resources, allow American Indian students to be actively involved in research and to produce a healthier agricultural product for the community. This project combines expertise from Sitting Bull College, North Dakota State University, and the USDA–ARS Northern Great Plains Research Laboratory.

We request that the subcommittee continue to fund this program at a minimum of \$1,805,000.

#### *1994 Institutions' Educational Equity Grant Program*

This program is designed to assist 1994 Institutions with academic programs. Through the modest appropriations first made available in fiscal year 2001, the 1994 Institutions have developed and implemented courses and programs in natural resource management; environmental sciences; horticulture; forestry; and food science and nutrition. This last category is helping to address the epidemic rates of diabetes and cardiovascular disease that plague American Indian reservations. We request that the subcommittee support the President's fiscal year 2012 budget by appropriating \$3,676,000 to allow the 1994 Institutions to build upon their course offerings and the successful activities that have been established.

#### *Native American Endowment Fund*

Endowment installments that are paid into the 1994 Institutions' account remain with the U.S. Treasury. Only the annual interest yield, less the USDA's administrative fee, is distributed to the 1994 Institutions. The latest annual interest yield for the 1994 Institutions' endowment was \$4,266,794 and after USDA–NIFA claimed its standard 4-percent administrative fee, \$4,096,122 was distributed among the eligible 32 TCU Land Grant Institutions by statutory formula. Once again, the administrative fee paid to USDA–NIFA to simply make the funds available for draw down by the eligible 1994 Institutions was higher than the amount paid to 72 percent of 1994 Institutions.

Endowment payments appropriated increase the size of the corpus held by the U.S. Treasury and thereby increase the base on which the annual interest yield is determined. These additional funds would continue to support faculty and staff positions and program needs within 1994 agriculture and natural resources departments, as well as to help address the critical and very expensive facilities needs at these institutions. For the latest endowment interest distribution, the median interest payment to 1994 Institutions was \$95,894, which is clearly not sufficient to address curriculum development and instruction delivery, not to mention the need to address the ongoing facilities and infrastructure projects at these institutions. In order for the 1994 Institutions to become full partners in the Nation's land-grant system, we need the facilities and infrastructure necessary to fully engage in education and research programs vital to the future health and well being of our reservation communities.

We respectfully request that the subcommittee again appropriate \$11,880,000 for the fiscal year 2012 endowment payment. Additionally, we strongly urge the subcommittee to review the USDA–NIFA administrative fee charged and consider directing the department to reduce said fee for the Tribal College Endowment program so that more of these already limited interest funds can be utilized by the 1994 Institutions to conduct essential community-based programs.

#### *Tribal Colleges and Universities Essential Community Facilities Program (Rural Development)*

The President's fiscal year 2012 budget request recommends eliminating the TCU Essential Community Facilities Grant program. The administration has stated that

the TCUs' grant program should be eliminated because tribal colleges are eligible to participate in other programs offered in the USDA's Community Facilities Loan and Grant Programs (CFLGP). However, eligibility does not portend the level of success the TCUs might have in securing their much-needed grant dollars. Before the TCU-specific grant was established, only three of the 1994 Institutions ever received any funding under CFLGP; in other words, less than 10 percent of the eligible TCUs were successful in securing a grant. Additionally, grant opportunities under CFLGP require non-Federal matching funds at a minimum of 25 percent, which it has been determined that many of the tribal colleges cannot meet. By contrast, in fiscal year 2001 when the TCU-specific program was launched, 22 TCU Land Grant Institutions or almost 70 percent of the 1994 Institutions received grant awards.

We strongly urge the subcommittee to reject the proposal to eliminate this critical program and to continue to appropriate a minimum of \$3,972,000 each year for the next 5 fiscal years to afford the 1994 Institutions the means to aggressively address critical facilities and infrastructure needs, thereby allowing them to better serve their students and their respective communities.

#### CONCLUSION

The 1994 Institutions have proven to be efficient and effective vehicles for bringing educational opportunities to American Indians and the promise of self-sufficiency to some of this Nation's poorest and most underserved regions. The modest Federal investment in the 1994 Institutions has already paid great dividends in terms of increased employment, access to higher education, and economic development. Continuation of this investment makes sound moral and fiscal sense. American Indian reservation communities are second to none in their potential for benefiting from effective land grant programs and, as earlier stated, no institutions better exemplify the original intent of the land grant concept than the 1994 Institutions.

We appreciate your support of the 1994 Institutions and recognition of their role in the Nation's land grant system. We ask you to renew your commitment to help move our students and communities toward self-sufficiency and respectfully request your continued support and full consideration of our fiscal year 2012 appropriations requests.

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#### PREPARED STATEMENT OF THE AMERICAN PUBLIC POWER ASSOCIATION

The American Public Power Association (APPA) appreciates the opportunity to submit this statement outlining our fiscal year 2012 funding priorities within the jurisdiction of the Agriculture, Rural Development, Food and Drug Administration and Related Agencies Subcommittee. We support increased funding for farm bill title IX programs, and \$308 million for the Commodity Futures Trading Commission (CFTC).

APPA is the national service organization representing the interests of more than 2,000 municipal and other State and locally owned utilities in 49 States (all but Hawaii). Public power utilities deliver electricity to one of every seven electricity consumers (approximately 46 million people), serving some of the Nation's largest cities. However, the vast majority of APPA's members serve communities with populations of 10,000 people or less.

#### DEPARTMENT OF AGRICULTURE: TITLE IX PROGRAMS

APPA supports full funding for programs authorized in title IX of the 2008 farm bill for energy efficiency, renewable energy and biofuels. APPA is extremely pleased that the President's budget provides an additional \$36.8 million in addition to the \$70 million in discretionary funding for the Rural Energy for America Program (REAP). In addition, we request the full authorized level of \$5 million for the Rural Energy Self-Sufficiency Program, and \$5 million for the Community Wood Energy Program for fiscal year 2012.

#### COMMODITY FUTURES TRADING COMMISSION

APPA supports the President's budget request of \$308 million for CFTC, an 82-percent increase more than fiscal year 2011. As CFTC continues to implement the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, they will struggle to do so in a timely manner without the proper staffing levels and technology necessary to complete rule-makings and implementation. Given the direct effect the rule-makings will have on public power utilities and consumers, APPA is

supportive of giving the CFTC the resources it needs to complete the rule-makings quickly and thoroughly.

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PREPARED STATEMENT OF THE AMERICAN SOCIETY OF PLANT BIOLOGISTS

On behalf of the American Society of Plant Biologists (ASPB) we submit this statement for the official record in support of funding for agricultural research by the U.S. Department of Agriculture (USDA). ASPB supports the requested level for USDA's National Institute of Food and Agriculture (NIFA) in fiscal year 2012, specifically funding the Agriculture and Food Research Initiative (AFRI) at the requested level of \$325 million. However, ASPB does not support the proposed decrease of \$109 million to the Agricultural Research Service (ARS), and would ask that funding for ARS be sustained.

This testimony highlights the importance of biology, particularly plant biology, as the Nation seeks to address vital issues including a sustainable food supply, energy security, and protecting our environment. We would like to thank the subcommittee for its consideration of this testimony and for recognizing that its support of agricultural research is an important investment in America's future in this difficult fiscal environment.

FOOD, FUEL, ENVIRONMENT, AND HEALTH: PLANT BIOLOGY RESEARCH AND AMERICA'S FUTURE

Plants are vital to our very existence. They harvest sunlight, converting it to chemical energy for food and feed; they take up carbon dioxide and produce oxygen; and they are the primary producers on which all life depends. Indeed, plant biology research is making many fundamental contributions in the areas of fuel security and environmental stewardship; the continued and sustainable development of better foods, fabrics, and building materials; and in the understanding of basic biological principles that underpin improvements in the health and nutrition of all Americans. In fact, the 2009 National Research Council report, "A New Biology for the 21st Century," placed plant biology at the center of urgent priorities in food, health, and the environment. For example, one of the challenges outlined in the report is to generate food plants that can adapt and grow sustainably in changing environments, which will require enhanced understanding of plant growth mechanisms, genetically informed plant breeding, and the advancement of plant genomics.

Plant biology is at the center of numerous scientific breakthroughs in the increasingly interdisciplinary world of alternative energy research. For example, interfaces among plant biology, engineering, chemistry, and physics represent critical frontiers in both basic biofuels research and bioenergy production. Similarly, with the increase in plant genome sequencing and functional genomics, the interface of plant biology and computer science is essential to our understanding of complex biological systems ranging from single cells to entire ecosystems.

Despite the fact that plant biology research—the kind of research funded by USDA—underpins so many vital practical considerations for our country, the amount invested in understanding the basic function and mechanisms of plants is relatively small when compared with the broader impacts on society and on our economy. Failure to sustain investment in scientific research jeopardizes the Nation's ability to maintain U.S. competitiveness in agriculture.

RECOMMENDATIONS

Because of our membership's extensive expertise, ASPB is in an excellent position to articulate the Nation's plant science priorities as they relate to agriculture. Our recommendations are as follows:

- It is ASPB's hope that USDA will have an elevated role to play as part of the expanding Federal research landscape. USDA supports research that is intended to provide a foundation for creating sustainable food and new energy supplies; however, much higher investment in competitive funding is needed if the Nation is to continue to make ground-breaking discoveries and accelerate progress toward addressing urgent national priorities. ASPB encourages the appropriation of the requested level of \$325 million in fiscal year 2012 for AFRI, which although far short of the authorized level of \$700 million, is sensitive to today's fiscal environment.
- ARS provides vital research to serve USDA's mission and objectives and the Nation's agricultural research needs. As USDA begins to transform its extramural research programs through NIFA, ASPB asks that the parallel reorganization of the agency's intramural research programs around the five core challenges

identified by the USDA be carried out with due care and diligence. Indeed, ASPB supports sustained funding for ARS and does not support the President's proposed cut of \$109 million to ARS in fiscal year 2012.

- USDA has focused attention in several key priority areas including childhood obesity, climate change, global food security, food safety, and sustainable bioenergy. While ASPB appreciates the need for such strategic focus, ASPB also emphasizes the importance of robust support for AFRI's Foundational Program as scientific research supported by this program provides a basis for outcomes across a wide spectrum, often leading to groundbreaking developments that cannot be anticipated in advance.
- ASPB recognizes the importance of competitive grants in fostering creativity and enabling the research community to take advantage of new opportunities for discovery and innovation. With few research funding streams available, there will be increased pressure on an already limited competitive grants budget. Therefore, ASPB encourages that any funds eliminated in congressionally directed spending be applied to the competitive grants offered as part of AFRI.
- Current estimates predict a significant shortfall in the needed scientific and engineering workforce as the demographics of the U.S. workforce change. For example, there is a clear need for additional scientists in the areas of interdisciplinary energy research and plant breeding. ASPB applauds the creation of the NIFA Fellows program. However, given the expected need for additional scientists and engineers who are well-grounded in agriculture research and development activities, ASPB calls for targeted funding of specific programs (e.g., training grants and fellowships) to provide this needed workforce over the next 10 years and to adequately prepare these individuals for careers in the agricultural research of the future.
- Considerable research interest is now being paid to the use of plant biomass for energy production. However, if crops are to be used to their full potential, considerable effort must be expended to improve the understanding of their basic biology and development, as well as their agronomic performance. Therefore, ASPB calls for additional funding that would be targeted to efforts to increase the utility and agronomic performance of bioenergy crops.
- With NIFA now in place, USDA is in a strong position to cultivate and expand interagency relationships (as well as relationships with private philanthropies) to take on bolder new initiatives to address grand challenges related to food, energy, the environment, and health. ASPB also appreciates the need to focus resources in key priority areas. However, ASPB emphasizes continued focus on individual grantees, in addition to group awards and larger multi-institution partnerships. Truly paradigm shifting discoveries cannot be predicted through collaborative efforts alone, and thus, there is a need to maintain a broad, diverse, and robust research agenda.

Thank you for your consideration of our testimony on behalf of the American Society of Plant Biologists.

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PREPARED STATEMENT OF THE ANIMAL WELFARE INSTITUTE

We would like to preface this testimony by recognizing major steps the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) has taken recently to improve its performance. In February, based on an investigation into possible violations of the Animal Welfare Act (AWA) undertaken by Animal Care (AC), APHIS, and the Office of Inspector General (OIG), random source class B dealers Floyd and Susan Martin (doing business as Chestnut Grove Kennel in Pennsylvania) were indicted on charges of conspiracy, aggravated identity theft, mail fraud, and making false statements. In March, three individuals in Tennessee were indicted for conspiring to violate the Horse Protection Act (HPA) by soring horses, transporting sored horses, and falsifying paperwork. Also, in March, AC unveiled its new Animal Care Information System search engine. This new system will give the public access to key documents, such as information about licensees and registrants, inspections reports, and annual reports. This is an important step toward greater transparency and accountability.

The Congress' support for needed funding for AC, OIG, and Investigative and Enforcement Services (IES) has made enforcement improvements possible, and we respectfully request its continued support for these programs.

USDA/ANIMAL AND PLANT HEALTH INSPECTION SERVICE/ANIMAL CARE/ANIMAL WELFARE  
ACT ENFORCEMENT

*Animal Welfare Institute Request: Support Administration's Request for \$30 Million*

Over the past decade, the subcommittee has responded to the urgent need for increased funding for the AC program to improve its inspections of nearly 16,000 sites, including animal dealers, commercial breeding facilities, laboratories, zoos, circuses, and airlines, to ensure compliance with AWA standards. AC now has 130 inspectors (with nine vacancies), and during fiscal year 2010, they conducted 14,003 inspections, including required annual visits to all registered research institutions that alone house more than 1 million animals (excluding birds, rats, and mice). Moreover, AC inspectors are engaged in follow-up with licensees who are regarded as problems because of the nature and frequency of their violations.

This budget request of \$30 million provides a minimal increase over fiscal year 2011 needed to sustain the progress that has been made.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/ANIMAL CARE/HORSE PROTECTION  
ACT ENFORCEMENT

*Animal Welfare Institute Request: Support Administration's Request for \$891,000*

The goal of HPA, passed in 1970, is to end the cruel practice of soring, by which unscrupulous owners and/or trainers, primarily of Tennessee Walking Horses, intentionally inflict pain on the legs and hooves of horses, through the application of chemical and mechanical irritants, to produce an exaggerated gait. In 2008, the American Association of Equine Practitioners condemned soring as "one of the most significant welfare issues faced by the equine industry." Three Girl Scouts bravely documented the brutality of this crime in their video "See it Through My Eyes" (available at [www.youtube.com/watch?v=kqFeYu1CrjU](http://www.youtube.com/watch?v=kqFeYu1CrjU)).

Throughout its history, however, the law has been openly flouted and inadequate funding has hampered enforcement. USDA inspectors are able to attend a mere fraction of Tennessee Walking Horse shows—between 6–14 percent. Consequently, there is continued reliance on an industry-run system of certified Horse Industry Organization inspection programs that utilize designated qualified persons (DQPs), usually industry insiders with a history of looking the other way. Reliance on DQPs has been an abysmal failure. Statistics clearly indicate that the presence of USDA inspectors at shows results in a far higher rate of noted violations than occurs when DQPs are present. The greater the likelihood of a USDA inspection, the greater the deterrent effect on those who routinely sore their horses. Enforcement should not be entrusted to individuals with a stake in the status quo.

Given the problems as outlined above and in separate, more detailed fiscal year 2012 testimony signed by the Animal Welfare Institute and many other groups, it is clear that USDA cannot make progress in this area with current funding levels. We ask that the Congress appropriate the \$891,000 for HPA enforcement as provided in the administration's budget.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/INVESTIGATIVE AND ENFORCEMENT  
SERVICES

*Animal Welfare Institute Request: \$17,275,000*

IES handles investigations related to enforcement of the laws and regulations for APHIS' programs, which involves collection of evidence; both civil and criminal investigations; and investigations carried out in conjunction with Federal, State, and local enforcement agencies. It is actively involved in the two high-profile cases noted at the start of this testimony. In addition, IES, in collaboration with USDA's Office of the General Counsel, handles other types of enforcement actions including stipulations and formal administrative proceedings. We respectfully request a \$17.275 million appropriation for IES to enable the Service to fulfill its full range of responsibilities, particularly its increasing HPA and AWA investigatory demands.

AGRICULTURAL RESEARCH SERVICE/NATIONAL AGRICULTURAL LIBRARY/ANIMAL  
WELFARE INFORMATION CENTER

*Animal Welfare Institute Request: \$1,978,400*

We very much appreciate the subcommittee's continuing support for the Animal Welfare Information Center (AWIC). AWIC's services are vitally important to the Nation's biomedical research enterprise, as well as other regulated entities, because they facilitate compliance with specific requirements of the Federal animal welfare regulations and policies governing animal-related research. It proves its worth time and time again.



AWIC was established in 1986 in response to a mandate in the Improved Standards for Laboratory Animals amendment to AWA. The center serves as a clearinghouse, training center, and education resource for those involved in the use of animals for research, testing, and teaching, as well as other entities covered by AWA. It provides training and compiles, distributes, and posts on its Web site information resources from the scientific literature to assist researchers who use animals. The subjects covered include husbandry, handling, and care of animals; personnel training; animal behavior; alternatives; improved methodologies; environmental enrichment; and pain control via anesthesia and analgesia and other methods. It also serves as a resource for the wider scientific and agricultural communities by providing access to material on zoonotic diseases such as avian influenza, transmissible spongiform encephalopathies, tuberculosis, West Nile virus, foot and mouth disease, the H1N1 virus, and others. Its activities contribute significantly to science-based decisionmaking in animal care.

In fiscal year 2010, staff conducted 13 sessions of AWIC's workshop, "Meeting the Information Requirements of the Animal Welfare Act" (evaluations of which are overwhelmingly positive, with participants indicating a high degree of new information acquisition). In April 2010 in Kansas City, Missouri, AWIC and AC collaborated on a workshop for AC inspectors to help them better understand the alternatives requirement of AWA.

The AWIC Web site (<http://awic.nal.usda.gov/>) is one of the most accessed sites at the National Agricultural Library (NAL), with more than 4,322,000 page views during fiscal year 2010. Many improvements to the Web site have been made in the past year, including increased timeliness and accessibility through a Twitter account and several blogs. Currently, 274 full text documents are available on the Web site and 24 new ones were added in fiscal year 2010. Already completed or in process for fiscal year 2011 are documents on anesthesia and analgesia for animals, swine as biomedical models, reducing animal numbers in research, review of enforcement data, environmental enrichment for nonhuman primates, cryopreservation of animal embryos, a Google map of State and local animal control agencies throughout the United States and issues of the AWIC newsletter. Making this information available in a timely fashion urgently requires additional staff.

The need and demand for AWIC's services continue to outstrip its resources. We write in support of an appropriation of \$1,978,400, which is urgently needed to fund, in addition to current salaries and other expenses, AWIC's services and its ongoing efforts to improve their delivery, including but not limited to the following:

- \$300,000.—Add two full-time equivalents to the professional staff.
- \$100,000.—Develop Web-based training modules, including interactive modules, in order to provide online delivery of training opportunities and expand the reach of the program.
- \$50,000.—Present workshops for research personnel, in collaboration with AC. The workshops must be free of charge to the institutions in order to encourage attendance.
- \$20,500.—Internet services.
- \$10,000.—AWIC staff training.
- \$15,000.—To fund an internship program that would provide opportunities for postgraduate students (including veterinarians) to work on special projects, such as creating specialized information resources on animal (especially zoonotic) diseases.
- \$200,000.—Resume acquisition of veterinary publications that NAL discontinued several years ago, and increase the pace of indexing all such publications.
- \$259,000.—Overhead to the Agricultural Research Service and NAL.
- \$50,000.—Meet congressional mandate to digitize more materials; in particular, scanning historically relevant materials dating from the 1800s.
- \$65,000.—Funding is urgently needed to update Essentials for Animals in Research, as well as certain animal care manuals, and then to translate them and AWA and its regulations into Spanish; develop training DVDs, etc. In the past, this program yielded very useful products, including the original Essentials for Animal Research: A Primer for Research Personnel (which was also translated into Spanish and is still among the top 10 downloaded documents); a video on normal animal behaviors; and a training video on using animals in research. The growing numbers of Spanish-speaking animal care personnel in U.S. research facilities and zoos, as well as increasing interest on the part of the scientific communities in Central and South America, have made the availability of Spanish-language materials a priority.

AWIC's value to the research community and other entities that must comply with AWA, and to the general public, justifies this modest proposed increase in its budget.

FOOD SAFETY AND INSPECTION SERVICE/HUMANE METHODS OF SLAUGHTER ACT  
ENFORCEMENT

*Animal Welfare Institute Request: An Additional \$2 Million for District Veterinary Medical Specialists*

We appreciate the Congress' support during the past decade for enforcement of the Humane Methods of Slaughter Act (HMSA). While USDA's enforcement of the law has increased since 2008, following the exposure of egregious humane handling and food safety violations at the Westland-Hallmark plant in California, attention to the issue remains uneven among Federal regional districts.

An analysis of Humane Activities Tracking System data reveals that some USDA districts spend 10–20 times the number of hours on humane enforcement as other districts. Overall, USDA continues to allot an extremely small percentage of its resources to humane slaughter. For example, in 2009, only 1.5 percent of Food Safety and Inspection Service (FSIS) verification procedures were conducted for humane handling and slaughter, and only 0.5 percent of all noncompliance records written by FSIS that year were for humane violations.

Repeat violators present a major enforcement problem for FSIS. Of the 173 federally inspected plants that have been suspended for humane slaughter violations since January 1, 2005, 32 percent have been suspended more than once within a 1-year period. Moreover, 15 plants have been suspended on three or more occasions during the past 3 years.

Federal inspection personnel have inadequate training in humane enforcement and inadequate access to humane slaughter expertise. Enforcement documents reveal that inspectors often react differently when faced with similar violations. District veterinary medical specialists (DVMSs) are stationed in each district to assist plant inspectors with humane enforcement and to serve as a liaison between the district office and headquarters on humane matters. However, the workload of each of the 15 DVMSs, which includes visiting each meat and poultry plant within the district to perform humane audits and conducting verification visits following suspensions, severely limits the effectiveness of the role.

The problems of inadequate and inconsistent enforcement can be resolved by increasing the number and qualifications of the personnel assigned to humane handling and slaughter duties.

The standard for time spent exclusively on HMSA-related inspections and enforcement should not fall below 140 full-time equivalent positions. In addition, the number of DVMS positions should be increased to an average of two per district. Enforcement records suggest that violations are reported with greater frequency in the presence of outside inspection personnel, such as DVMSs. Hiring additional DVMSs will provide for increased auditing and training to help uncover problems before they result in egregious humane handling incidents and potential food safety threats to the public.

We thank the subcommittee for this opportunity to present testimony on behalf of important programs within USDA.

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PREPARED STATEMENT OF THE COLORADO RIVER BASIN SALINITY CONTROL FORUM

The Congress concluded that the Colorado River Basin Salinity Control Program (CRBSCP) should be implemented in the most cost-effective way. CRBSCP is funded by the Environmental Quality Incentives Program (EQIP), the Bureau of Reclamation's (BOR's) Basinwide Program, and a cost share for both of these programs provided by the Basin States. Realizing that agricultural on-farm strategies were some of the most cost-effective strategies, the Congress authorized a program for the U.S. Department of Agriculture (USDA) through amendment of the Colorado River Basin Salinity Control Act (CRBSCA) in 1984. With the enactment of the Federal Agriculture Improvement and Reform Act of 1996 (FAIRA), the Congress directed that CRBSCP should continue to be implemented as one of the components of EQIP. Since the enactment of the Farm Security and Rural Investment Act (FSRIA) in 2002, there have been, for the first time in a number of years, opportunities to adequately fund CRBSCP within the EQIP. In 2008, the Congress passed the Food, Conservation, and Energy Act (FCEA). The FCEA addresses the cost-sharing required from the basin funds. In so doing, the FCEA named the cost-sharing requirement as the Basin States Program (BSP). The BSP will provide 30 percent of the total amount that will be spent each year by the combined EQIP and BSP effort.

CRBSCP, as set forth in CRBSCA, is to benefit lower basin water users hundreds of miles downstream from salt sources in the upper basin as the salinity of Colorado River water increases as the water flows downstream. There are very significant economic damages caused by high salt levels in this water source. Agriculturalists in the upper basin where the salt must be controlled, however, don't first look to downstream water quality standards but look for local benefits. These local benefits are in the form of enhanced beneficial use and improved crop yields. They submit cost-effective proposals to the State conservationists in Utah, Wyoming, and Colorado and offer to cost share in the acquisition of new irrigation equipment. It is CRBSCA that provides that the seven Colorado River Basin States will also cost share with the Federal funds for this effort. This has brought together a remarkable partnership.

After longstanding urgings from the States and directives from the Congress, the USDA has concluded that this program is different than small watershed enhancement efforts common to EQIP. In the case of the Colorado River salinity control effort, the watershed to be considered stretches more than 1,200 miles from the river's headwater in the Rocky Mountains to the river's terminus in the Gulf of California in Mexico and receives water from numerous tributaries. The USDA has determined that this effort should receive a special funding designation and has appointed a coordinator for this multi-State effort.

In recent fiscal years, the Natural Resources Conservation Service (NRCS) has directed that about \$18 million of EQIP funds be used for CRBSCP. The Colorado River Basin Salinity Control Forum (CRBSCF) appreciates the efforts of the NRCS leadership and the support of this subcommittee. The plan for water quality control of the Colorado River was prepared by CRBSCF, adopted by the States, and approved by the Environmental Protection Agency (EPA). The Colorado River Basin Salinity Control Advisory Council has taken the position that the funding for the salinity control program should not be less than \$20 million per year. Over the last few fiscal years, for the first time, funding has almost reached the needed level. State and local cost-sharing is triggered by the Federal appropriation. In fiscal year 2012, it is anticipated that the States will cost share with about \$8 million and local agriculture producers will add more than \$7 million. Hence, it is anticipated that in fiscal year 2012 the State and local contributions will be about 45 percent of the total program cost.

Over the past few years, the NRCS has designated that about 2.5 percent of the EQIP funds be allocated to CRBSCP. CRBSCF believes this is the appropriate future level of funding as long as the total EQIP funding nationwide is more than \$1 billion. Funding above this level assists in offsetting pre-fiscal year 2003 funding below this level. The Basin States have cost-sharing dollars available to participate in funding on-farm salinity control efforts. The agricultural producers in the upper basin are waiting for their applications to be considered so that they might improve their irrigation equipment and also cost-share in CRBSCP.

#### OVERVIEW

CRBSCP was authorized by the Congress in 1974. The title I portion of CRBSCA responded to commitments that the United States made, through a Minute of the International Boundary and Water Commission, to Mexico specific to the quality of water being delivered to Mexico below Imperial Dam. Title II of CRBSCA established a program to respond to salinity control needs of Colorado River water users in the United States and to comply with the mandates of the then newly enacted Clean Water Act. This testimony is in support of funding for the title II program.

After a decade of investigative and implementation efforts, the Basin States concluded that CRBSCA needed to be amended. The Congress agreed and made a major revision to CRBSCA in 1984. That revision, while keeping the Department of the Interior as lead coordinator for Colorado River Basin salinity control efforts, also gave new salinity control responsibilities to the USDA. The Congress has charged the administration with implementing the most cost-effective program practicable (measured in dollars per ton of salt controlled). It has been determined that the agricultural efforts are some of the most cost-effective opportunities.

Since congressional mandates of more than three decades ago, much has been learned about the impact of salts in the Colorado River system. BOR has conducted studies on the economic impact of these salts. BOR recognizes that the damages to United States' water users alone are hundreds of millions of dollars per year.

CRBSCF is composed of gubernatorial appointees from Arizona, California, Colorado, Nevada, New Mexico, Utah, and Wyoming. CRBSCF has become the seven-State coordinating body for interfacing with Federal agencies and the Congress in support of the implementation of the salinity control program. In close cooperation

with the EPA and pursuant to requirements of the Clean Water Act, every 3 years CRBSCF prepares a formal report evaluating the salinity of the Colorado River, its anticipated future salinity, and the program elements necessary to keep the salinity concentrations (measured in total dissolved solids) at or below the levels measured in the river system in 1972 at Imperial Dam, and below Parker and Hoover Dams.

In setting water quality standards for the Colorado River system, the salinity concentrations at these three locations in 1972 have been identified as the numeric criteria. The plan necessary for controlling salinity and reducing downstream damages has been captioned the "Plan of Implementation." The 2008 Review of water quality standards includes an updated Plan of Implementation. In order to eliminate the shortfall in salinity control resulting from inadequate Federal funding for a number of years from the USDA, CRBSCF has determined that implementation of CRBSCF needs to be accelerated. The level of appropriation requested in this testimony is in keeping with the agreed-upon plan. If adequate funds are not appropriated, significant damages from the higher salt concentrations in the water will be more widespread in the United States and Mexico.

Concentrations of salts in the river cause well more than \$300 million in quantified damages and significantly more in unquantified damages in the United States and result in poorer quality water being delivered by the United States to Mexico. Damages occur from:

- a reduction in the yield of salt-sensitive crops and increased water use for leaching in the agricultural sector;
- a reduction in the useful life of galvanized water pipe systems, water heaters, faucets, garbage disposals, clothes washers, and dishwashers, and increased use of bottled water and water softeners in the household sector;
- an increase in the use of water for cooling, and the cost of water softening, and a decrease in equipment service life in the commercial sector;
- an increase in the use of water and the cost of water treatment, and an increase in sewer fees in the industrial sector;
- a decrease in the life of treatment facilities and pipelines in the utility sector;
- difficulty in meeting wastewater discharge requirements to comply with National Pollutant Discharge Elimination System permit terms and conditions, and an increase in desalination and brine disposal costs due to accumulation of salts in groundwater basins; and
- increased use of imported water for leaching and cost of desalination and brine disposal for recycled water.

#### STATE COST-SHARING AND TECHNICAL ASSISTANCE

The authorized cost-sharing by the Basin States, as provided by FAIRA, was at first difficult to implement as attorneys for the USDA concluded that the Basin States were authorized to cost share in the effort, but the Congress had not given the USDA authority to receive the Basin States' funds. After almost 1 year of exploring every possible solution as to how the cost-sharing was to occur, the States, in agreement with BOR, State officials in Utah, Colorado, and Wyoming and with NRCS State conservationists in Utah, Colorado, and Wyoming, agreed upon a program parallel to the salinity control activities provided by EQIP wherein the States' cost-sharing funds are being contributed and used. We now have several years of experience with that program and with the passage of FCEA we now have a clear authority for this program that is now known as the Basin States Program.

CRBSCA designates that the Secretary of the Interior provide the coordination for the Federal agencies involved in the salinity control program. That responsibility has been delegated to BOR. BOR administers the Basin States cost-sharing funds that are used in the Basin States Program.

With respect to the use of Basin States' cost-sharing funds in the past, the Basin States felt that it was most essential that a portion of CRBSCP be associated with technical assistance and education activities in the field. Without this necessary support, there is no advanced planning, proposals are not well prepared, assertions in the proposals cannot be verified, implementation of contracts cannot be observed, and valuable partnering and education efforts cannot occur. Recognizing these values, it is essential that adequate funds for technical assistance be provided by USDA and the BSP.

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#### PREPARED STATEMENT OF THE CYSTIC FIBROSIS FOUNDATION

On behalf of the Cystic Fibrosis Foundation (CFF) and the approximately 30,000 people with cystic fibrosis (CF), we are pleased to submit the following testimony

regarding the fiscal year 2012 appropriations for the Food and Drug Administration's (FDA's) review of rare disease treatments.

#### ABOUT CYSTIC FIBROSIS

CF is a life-threatening genetic disease for which there is no cure. People with CF have two copies of a defective gene, known as CF transmembrane conductance regulator, which causes the body to produce abnormally thick, sticky mucus that clogs the lungs and results in fatal lung infections. The thick mucus in those with CF also obstructs the pancreas, making it difficult for patients to absorb nutrients from food.

Since its founding, CFF has maintained its focus on promoting research and improving treatments for CF. More than 30 drugs are now in development to treat CF; some treat the basic defect of the disease, while others target its symptoms. Through the research leadership of CFF, people with CF are living into their thirties, forties, and beyond. This improvement in the life expectancy for those with CF can be attributed to research advances and to the teams of CF caregivers who offer specialized care. Although life expectancy has improved dramatically, we continue to lose young lives to this disease.

The promise for people with CF lies in research. In the past 6 years, CFF has invested more than \$1 billion in its medical programs of drug discovery, drug development, research, and care focused on life-sustaining treatments and a cure for CF.

This testimony focuses on the funding the FDA needs to quickly and efficiently review treatments for CF and other rare diseases so they can swiftly move into the hands of the patients who need them.

#### SUSTAINING FUNDING FOR RARE DISEASE DRUG REVIEW AT THE FDA

##### *Cystic Fibrosis Foundation Drug Development Model*

CFF has been recognized for its unique research approach, which encompasses everything from basic research through phase 4 postmarketing drug safety monitoring, and has created the infrastructure required to accelerate the development of new CF therapies. As a result, we now have a pipeline of more than 30 potential therapies which are being examined to treat people with CF.

One such treatment is VX-770, a drug being developed by Vertex Pharmaceuticals that was discovered in collaboration with CFF. This promising therapy actually targets the genetic defect that causes CF in patients with a particular mutation of CF, as opposed to only addressing symptoms of the disease. In late February we learned that phase 3 clinical trial data of VX-770 showed profound improvements in lung function and other health measures in CF patients, and a new drug application is expected to be submitted to the FDA for review later this year. This new treatment is a direct result of CFF's innovative research agenda, advancing from bench to bedside through CFF's research program which speeds the creation of new CF therapies.

##### *Funding for Rare and Orphan Disease Drug Review*

In order to encourage the swift review of drugs for CF and other rare diseases, we urge the subcommittee to recommend sufficient funding for the FDA, particularly the Center for Drug Evaluation and Research's (CDER's) Office of New Drugs. Reducing FDA funding to fiscal year 2008 levels, as has been proposed, would set rare drug review and approval back at a time when effective treatment for some of our most deadly diseases is sorely needed.

In order to be effective, the FDA needs not only an adequate number of reviewers of new treatments, but also those with the appropriate skills and expertise, particularly for rare diseases like CF. Additional support for the FDA through increased funding not only assures that the Nation has a safe and effective supply of drugs and devices, but also that the agency can give the necessary attention to reviewing treatments that treat small populations but serve specific unmet medical needs, such as new CF drugs.

The subcommittee and the Congress should be commended for recent funding increases for the FDA. Nonetheless, the agency continues to face resource constraints. Its workload has increased due to threats from bioterrorism and other public health emergencies. Even with funding increases in recent years, FDA's appropriation supported about 9,100 full-time employees in fiscal year 2010. This is the same personnel level as 1994, a time in which FDA faced fewer challenges and its job was considerably less complex.

It is now more critical than ever that the Congress significantly increase funding for CDER at the FDA and for the agency as a whole in fiscal year 2012, so that

it can meet its statutory obligations to review drugs for safety and efficacy in a timely manner.

*Accelerating the Rare Disease Drug Review Process at the FDA*

CFF applauds the FDA, and Associate Director for Rare Diseases Dr. Anne Pariser in particular, for their attention to rare disease drugs and sensitivity to the unique challenges posed by the evaluation of these treatments.

FDA review officials have taken steps to improve their scientific expertise for review of therapies to treat rare diseases, and FDA leaders and review staff have been willing to engage in constructive dialogue to address issues with rare disease review. The agency has consistently taken part in productive conversations with medical experts, researchers, clinicians, and patients at CFF, including many of the foremost experts in the world on CF. This collaboration has augmented the FDA's work, allowing experts in CF to provide the FDA with the information it needs to effectively evaluate new treatments and accelerate the approval process, such as CFF's ongoing research into the development of improved tools for Patient Reported Outcomes and measurements of lung function.

However, in many cases the opportunity for public comment is not available if the product in question is not the subject of an advisory committee. In all cases, this public comment period occurs very late in the review process. We recommend that the agency consider establishing a procedure to receive comment from patients and their physicians earlier in the process, at the time of the submission of the investigational new drug application. Receiving such input earlier might be especially useful in defining and addressing the matter of unmet medical need. Because orphan diseases are by definition of limited prevalence, it is generally unlikely that specific expertise in the disease will be available among FDA staff. For that reason, the agency should be willing to inform its review process through early input from experts—both patients and professionals—regarding living with the disease, treating the disease, and developing therapies for it.

Additionally, CFF commends the establishment of the new Regulatory Science Initiative, formed by the National Institutes of Health and the FDA, with the goal of accelerating the development and use of new approaches to evaluate drug safety, efficacy, and quality, and urges the subcommittee to strongly support this type of collaboration. Support for these types of collaborations throughout the national health agencies, including programs like the Therapeutics for Rare and Neglected Diseases Program and the Cures Acceleration Network, leverages the Federal investment in new research, facilitating swifter development, and delivery of new medical treatments.

CFF's unique and successful drug development model for creating treatments for a rare disease has helped create a pipeline with more than 30 promising drugs to fight CF, and the FDA has played a critical role in this process, working with CFF as they review treatments and move them into the hands of those who need them. Encouraged by our successes, we believe the experience of CFF in clinical research can serve as a model of drug discovery and development for research on other orphan diseases and we stand ready to work with the FDA and congressional leaders. On behalf of CFF, we thank the subcommittee for its consideration.

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PREPARED STATEMENT OF THE FEDERATION OF AMERICAN SOCIETIES FOR  
EXPERIMENTAL BIOLOGY

On behalf of the Federation of American Societies for Experimental Biology (FASEB), I respectfully request a fiscal year 2012 appropriation of \$500 million for the Agriculture and Food Research Initiative (AFRI) within the National Institute of Food and Agriculture. This funding level would keep AFRI on a path to its authorized level of \$700 million in the 2008 Food, Conservation, and Energy Act.

As a federation of 23 scientific societies, FASEB represents more than 100,000 life scientists and engineers, making it the largest coalition of biomedical research associations in the United States. FASEB's mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences, including the research funded by AFRI, through service to its member societies and collaborative advocacy. FASEB enhances the ability of scientists and engineers to improve—through their research—the health, well-being, and productivity of all people.

As the Department of Agriculture's principal extramural competitive grants program, AFRI funds agricultural research, education, and extension activities critical to improving the Nation's health and prosperity. In order to optimize the effectiveness of its resources, the AFRI program facilitates collaborative, interdisciplinary re-

search that addresses broad societal challenges while expanding the fundamental understanding of all life sciences. In addition, AFRI encourages young scientists to undertake agricultural research by providing grant opportunities for pre- and postdoctoral scholars. Currently, our Federal investment in competitive agricultural research is only \$262 million. This is woefully inadequate to ensure viability of a vital industry whose contribution to the economy is more than \$300 billion annually. A report by the Economic Research Service found “strong and consistent evidence” that investment in agricultural research has yielded “high returns per dollar spent,” citing mean annual rates of return of 53 percent. Our investment in agricultural research directly benefits all sectors of society and every geographic region of the country.

AFRI creates the necessary resources and infrastructure to efficiently translate scientific discoveries into a broad range of applications. For example, a team of scientists has identified the genes that determine why some varieties of wheat are more tolerant to freezing temperatures than others, enabling researchers to use plant breeding techniques to accelerate the selection of hardier wheat plants. By reducing the effect of cold winters on wheat production, the United States can continue to meet the demands of a growing global population and remain the world’s leading exporter of wheat. AFRI research also makes critical contributions to improving human health; scientists studying a bacterial type that commonly causes food poisoning have determined the mechanism by which it withstands food safety precautions, such as heating, refrigeration, and chemical preservatives. Other AFRI-funded researchers have found evidence that a naturally secreted chemical plays a key role in controlling the accumulation of fat in humans and animals, a discovery with important implications for the prevention of obesity-related human diseases and the agricultural production of leaner, healthier livestock. Strong funding for AFRI projects like these is also an effective way to attract outstanding scientists to careers in agricultural research. The ability of the United States to meet the need for better nutrition, new biofuels, more efficient agriculture, and a safer food supply will depend on investment in the agricultural sciences as well as development and retention of a robust and scientifically diverse agricultural research workforce. Furthermore, because of the collaborative work of science agencies and the increasingly interdisciplinary nature of scientific research, support for the Federal research and development portfolio has never been more important to the future of the United States. The solutions to our Nation’s most pressing challenges depend on advances in the agricultural sciences.

Thank you for the opportunity to offer FASEB’s support for AFRI.

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PREPARED STATEMENT OF FEEDING AMERICA

Chairman Kohl, Ranking Member Blunt, and members of the U.S. Senate Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, thank you for the opportunity to submit this statement for the record on behalf of Feeding America. We look forward to the chairman and the subcommittee’s examination of the U.S. Department of Agriculture’s (USDA’s) fiscal year 2012 budget request and in particular, the programs administered by USDA’s Food and Nutrition Service.

Feeding America is the Nation’s leading domestic hunger-relief charity with a network of more than 200 food banks in every State serving more than 61,000 local food assistance agencies. Feeding America food banks as well as food assistance agencies rely on a variety of public and private funding streams to feed 37 million Americans a year, including 14 million children and nearly 3 million seniors.

During the worst economic downturn since the Great Depression, the number of American families struggling to make ends meet has increased significantly. With unemployment still hovering near 9 percent, the need for food assistance continues to grow and food banks continue to be pressed to meet the need in their communities. Last year, 37 million people, or 1-in-8 Americans, received emergency food assistance through the Feeding America network. This represents an increase of 46 percent since 2006. As a result, approximately 5.7 million people per week are now receiving emergency food assistance through Feeding America food banks.

The food distributed by Feeding America food banks and the children’s and senior’s programs our food bank members run in local communities provide a solid return on taxpayer investments and help reduce State government and private-sector health costs as well as help invest in a healthy future workforce. Emergency food assistance provides support not only to struggling working Americans but also to farmers and the agriculture industry through purchase of commodities.

While Feeding America receives generous support from our national and local charitable donors, we would not be able to continue serving those in need were it not for the food commodities provided by USDA. Indeed, these commodities comprise approximately 25 percent of all the food moving through the Feeding America network, and are among some of the most nutritious foods that our food banks provide. Without this steady, reliable source of nutritious basic food staples, Feeding America food banks would simply be unable to continue serving those in need on a consistent basis.

#### THE EMERGENCY FOOD ASSISTANCE PROGRAM COMMODITIES

The Emergency Food Assistance Program (TEFAP) is a means-tested Federal program that provides food commodities at no cost to low-income Americans in need of short-term hunger relief through organizations like food banks, pantries, soup kitchens, and emergency shelters. Healthy and nutritious food commodities provided through TEFAP are an essential resource for the continued success of Feeding America food banks.

TEFAP commodities currently account for approximately 25 percent of the food moving through Feeding America food banks. In most instances, local food banks leverage TEFAP commodities with privately donated foods to extend TEFAP program benefits beyond the budgeted amount for the program. As the unprecedented demand for food continues at food banks across the country, TEFAP commodities are essential for the provision of a steady emergency food supply.

Unfortunately, the level of commodity support Feeding America receives from USDA is projected to drop off in fiscal year 2011 and on into fiscal year 2012. In Federal fiscal year 2010, TEFAP provided approximately \$655 million worth of nutritious foods to low-income Americans. This figure includes commodity purchases mandated by the 2008 farm bill as well as bonus commodity purchases that were appropriated for in fiscal year 2010 and those purchases made by USDA when necessitated by market conditions. Unfortunately though, even as the need remains at unprecedented levels, if no additional bonus purchases are made in fiscal year 2011, TEFAP spending levels will fall to \$355 million. This decrease will severely impact efforts to address the growing need for emergency food assistance. Without additional funding for commodities, too many Americans may go without adequate access to the food they need.

While most decisions on TEFAP spending are made either by the authorizing committee or by the administration, Feeding America urges this subcommittee to work with the Secretary of Agriculture to identify ways to increase the supply of TEFAP commodities and to consider making TEFAP a direct beneficiary of any farm support expenditures that may be included in a fiscal year 2012 appropriations bill.

#### THE EMERGENCY FOOD ASSISTANCE PROGRAM ADMINISTRATIVE GRANTS AND INFRASTRUCTURE GRANTS

In order for States to distribute commodity foods to emergency food providers and for those providers to get the food to those in need, Federal funding is appropriated each year to help defray the costs of storing, transporting, and distributing TEFAP commodities. For the past several years, despite an authorized spending level of \$100 million per year, the appropriated funding level has remained steady at \$50 million per year.

As food banks are already struggling to respond to a significant increase in demand, they can no longer afford the rising costs associated with storing and distributing emergency food commodities without adequate Federal assistance. While the increase in TEFAP products that require refrigeration or freezer capacity has been a welcome addition for clients, these products are costly to store and deliver across large service areas. Funding TEFAP administrative grants at the \$100 million level authorized in fiscal year 2012 is critical to helping food banks ensure they can provide a wide variety of nutritious TEFAP foods to help meet the needs of hungry Americans.

Similarly, TEFAP infrastructure grants, which received \$6 million in appropriations in fiscal year 2010, are essential to helping emergency food providers meet a variety of infrastructure needs, and ensuring the effective and efficient delivery of TEFAP foods to those most in need. Funding provided through this competitive grant program may be used to help emergency food providers implement, improve, and expand their infrastructure activities and projects. Specific items that may be funded include developing computerized systems for tracking time-sensitive food products; improving the distribution of perishable foods (such as fresh fruits and vegetables); rescuing prepared, unserved food; identifying donors and eligible recipients; and improving facilities and equipment.



In fiscal year 2010, USDA awarded TEFAP Infrastructure Grants to 39 emergency food providers, 19 of whom primarily served low-income individuals in rural areas. However, USDA had at least four times as many applicants for these grants as they had funding to award. The 2008 farm bill authorizes \$15 million per year in annual appropriations for this program, and Feeding America urges the subcommittee to provide full funding for this program in fiscal year 2012 so that even more emergency food providers can benefit.

#### COMMODITY SUPPLEMENTAL FOOD PROGRAM

Administered by USDA, the Commodity Supplemental Food Program (CSFP) leverages Government buying power to provide nutritionally balanced food packages to more than 604,000 low-income seniors 60 years or older, pregnant and postpartum women, infants, and children up to 6 years old each month in 39 States, two tribal organizations, and the District of Columbia. More than 96 percent of those benefiting from this program are seniors with incomes of less than 130 percent of the Federal poverty line (approximately \$14,000 for a senior living alone). For many of these seniors, CSFP may be the only nutrition assistance program readily accessible to them.

CSFP is an efficient and effective program. While the cost to USDA to provide this package of food is, on average, \$20 per month, the average retail value of the foods in the package is \$50. For the seniors participating in this program, CSFP provides more than just food and nourishment, it also helps to combat the poor health conditions often found in seniors who are experiencing food insecurity and at risk of hunger. According to analysis of data from the 1999–2002 National Health and Nutrition Examination Survey, seniors older than the age of 60 who are experiencing some form of food insecurity are significantly more likely to have lower intakes of major vitamins, significantly more likely to be in poor or fair health, and more likely to have limitations in activities of daily living. CSFP food packages, specifically designed to supplement needed sources of nutrients typically lacking in participants' diets like protein, iron, zinc, and vitamins B-6 and B-12, can play an important role in addressing the nutrition needs of low-income seniors.

In fiscal year 2010, CSFP received \$171.4 million in appropriated funds. These funds enabled to program to expand caseload to additional participants in States and areas with an existing CSFP program and provided \$5 million for seven additional States—Arkansas, Delaware, Georgia, Maine, New Jersey, Oklahoma, and Utah—to begin CSFP service for the first time ever. In order to maintain existing caseload in fiscal year 2012, Feeding America urges the subcommittee to support the President's CSFP budget request for \$176.8 million. In addition, we urge the subcommittee to provide an additional \$5 million to expand the program into the six additional States (Connecticut, Hawaii, Idaho, Maryland, Massachusetts, and Rhode Island) with USDA-approved State plans.

#### CONCLUSION

We greatly appreciate the opportunity to submit testimony today on behalf of Feeding America, our more than 200-member food banks, and the 37 million Americans our food banks fed last year. For these growing numbers of Americans, food banks are truly the first line of defense, and many times the only resource standing between them being able to put food on the family dinner table or going to bed with an empty stomach. However, our food banks and the charitable food assistance network cannot be expected to meet the needs of these families alone. It is only through our partnership with the public sector and the sustained support the Federal Government provides through programs like TEFAP and CSFP that we can make real strides in the fight against hunger.

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#### PREPARED STATEMENT OF FRIENDS OF AGRICULTURAL RESEARCH—BELTSVILLE, INC.

Mr. Chairman, and members of the subcommittee, thank you for this opportunity to present our statement supporting funding for the U.S. Department of Agriculture's (USDA's) Agricultural Research Service (ARS), and especially for the ARS flagship research facility, the Henry A. Wallace Beltsville Agricultural Research Center (BARC), in Maryland. Our organization—the Friends of Agricultural Research—Beltsville (FAR-B) promotes the center's current and long-term agricultural research, outreach, and educational missions.

We begin, Mr. Chairman, by citing from Agriculture Secretary Tom Vilsack's March 10, 2011, remarks before the Senate Appropriations Subcommittee on Agri-

culture, Rural Development, Food and Drug Administration, and Related Agencies. To quote from Secretary's Vilsack's remarks:

"Scientific research is essential for achieving [our] goals. To promote American innovation, new discoveries, and new industries, we continue to target and focus additional research dollars in key areas, like biofuel feedstocks, livestock and crop production and protection, ecosystem market foundations, and biotechnology."

Also:

"We will invest in research to spur innovation, promote exports, support renewable energy and conservation, and enhance critical infrastructure in rural communities."

Our organization could not agree more strongly with Secretary Vilsack. Writing on world food in the March 14, 2011, Washington Post, highly regarded columnist Robert J. Samuelson warned, "the global food squeeze is largely an uncovered story." According to Samuelson, global food demand is colliding with strained food supplies. Middle East countries, he notes, are importing 50 percent or more of their wheat, and looking back from February world wheat prices have doubled in 8 months. Calling the situation the "Great Food Crunch," Samuelson cites growing affluence leading to higher consumption of meat and dairy products, and exploding population growth as major contributing factors. Looking ahead, he notes that from 2010 to 2050 world population is projected to grow by 38 percent, from 6.9 billion to 9.5 billion.

Can world food production keep pace with growing demand? There are those who would argue that it cannot. Yet the more hopeful of us take reassurance in technological advances originating from BARC. Please consider as recently as 1950 U.S. average corn yields were 38 bushels per acre. Average wheat yields were 17 bushels per acre. By 2010, average U.S. corn yields had jumped to 153 bushels per acre, while average wheat yields grew to an impressive 46 bushels per acre. Technological discoveries from Beltsville contributed tremendously to that progress. For decades, Beltsville has stood at the forefront of technical advances in agriculture. In 2010, the center celebrated 100 years of research accomplishments. The center's landmark technological achievements over that time are truly remarkable. We would be pleased to provide documentation should the subcommittee so wish.

Today, Beltsville is unequalled in scientific capability, breadth of agricultural research program, and concentration of scientific expertise. Under the leadership of Director Joseph Spence and with its powerful scientific capability, BARC remains unique and indispensable to meeting the challenges that lie ahead.

We are aware of the financial constraints facing our country. We are aware, too, of urgent demands for funding among compelling national priorities. Securing ample, safe, and nutritious food—food security—has always been the most compelling of human priorities. That is true today, and it will be no less so in the years ahead. Commentators such as Robert Samuelson speculate that as much as oil, scarce food could shape global politics for decades to come.

In summation, Mr. Chairman, we strongly support adequate funding for BARC. We would respectively suggest that adequately funding the USDA's flagship research center is central to maintaining national and world food security.

#### PRIORITIES IN THE PRESIDENT'S FISCAL YEAR 2012 BUDGET REQUEST

Now, Mr. Chairman, we turn to key research areas highlighted in the President's proposed budget. We strongly recommend this proposed funding. Our recommendation is consistent with the remarks of Secretary Vilsack.

*Animal Breeding and Protection.*—\$1 million:

—Beltsville has extensive research activity related to animal production and animal health.

—Research conducted at BARC is the foundation for the dairy industry in its research on the genetic prediction of dairy cows that can more efficiently meet the Nation's dairy needs. Slight differences in milk production by a cow can mean the difference between profitability and loss by dairy farmers.

—Research at BARC is aimed at preventing development of resistance to drugs used for treating cattle for parasites.

*Crop Breeding and Protection.*—\$1 million:

—Beltsville scientists have an extensive record of ongoing research relating to protecting crops from pests and emerging pathogens.

—Beltsville has unique expertise to identify pathogens such as nematodes and insects that can destroy crops or make crops ineligible for export to other countries.

- Beltsville also houses the Germplasm Resource Information Network, the U.S. coordinating body to identify and catalog plant germplasm. It is essential to maintain these important functional operations to identify plant germplasm that is diseases resistant, drought tolerant, and most valuable to the consumer.
  - Child and Human Nutrition.*—\$4.5 million:
    - Beltsville houses the Nation’s largest, most comprehensive federally funded human nutrition research center, the Beltsville Human Nutrition Research Center (BHNRC).
    - Unique activities include the What We Eat in America survey, which is the Government’s nutrition monitoring program and the National Nutrient Databank, the gold standard reference of food nutrient content. It is used throughout the world. These two activities are the basis for food labels, nutrition education programs, food assistance programs including SNAP, the Supplemental Nutrition Assistance Program, school feeding programs, and Government nutrition education programs.
    - The research facilities at BHNRC feature unique feeding facilities and are used in collaboration with other Federal agencies, including the National Institutes of Health, industry, and university partners.
    - Obesity is a serious problem in the United States and it must be dealt with. Effective nutrition programs aimed at preventing the onset of obesity are needed to prevent the high costs of medical care associated with the epidemic of obesity in this country.
  - Global Climate Change.*—\$800,000:
    - Beltsville had been actively engaged in climate change research long before climate change became a topic of discussion in the media.
    - Beltsville scientists are at the forefront of climate change research—understanding how climate change affects crop production and the effects of climate change on growth and spread of invasive and undesirable plants (such as weeds). A central aim is finding ways to mitigate effects of climate change on crops.
    - Beltsville houses truly unique facilities for replication of climates of the past and those that might exist in the future. Scientists here are able to model the effects of climate change and to develop strategies to mitigate the effects of any changes in climate.
  - Plant, Animal, and Microbial Collections.*—\$1.25 million:
    - BARC houses many truly unique national biological collections that are indispensable to the well-being of American agriculture. In addition to the actual collections, BARC scientists are internationally recognized for their expertise and ability to quickly and properly identify threats to agriculture.
    - This expertise is crucial to preventing loss of crops and animals, ensuring that threats to American agriculture are identified before they can enter the country, ensuring homeland security, and ensuring that American exports are free of pests and pathogens that could prohibit exports to other countries.
    - Collections and expertise include insect pests, fungal pathogens, bacterial threats, and nematodes.
    - BARC houses the National Animal Parasite collection and has the expertise to identify parasites that are of importance to agricultural animals.
- Mr. Chairman, that concludes our statement. Thank you for consideration and support for the educational, research, and outreach missions of BARC.

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PREPARED STATEMENT OF THE IZAAK WALTON LEAGUE OF AMERICA

The Izaak Walton League of America (IWLA) appreciates the opportunity to submit testimony concerning appropriations for fiscal year 2012 for various agencies and programs under the jurisdiction of the subcommittee. IWLA is a national, non-profit organization founded in 1922. We have approximately 38,000 members and nearly 300 chapters and State divisions nationwide. Our members are committed to advancing common sense policies that safeguard wildlife and habitat, support community-based conservation, and address pressing environmental issues. IWLA has been a partner with farmers and a participant in forming agriculture policy since the 1930s. The following pertains to conservation programs administered by the U.S. Department of Agriculture (USDA).

The Food, Conservation, and Energy Act of 2008 (farm bill) was enacted with a prominent commitment to increased mandatory conservation spending. It was bipartisan and supported by more than 1,000 diverse organizations engaged in farm bill policy. We urge the subcommittee to maintain the mandatory spending levels for conservation programs as provided in the farm bill. IWLA strongly opposes the ad-

ministration's proposal to cut essential conservation programs, placing the farm bill baseline in jeopardy, in fiscal year 2012 and beyond.

IWLA is also concerned that the administration's budget would not only deprive farmers and ranchers of conservation and environmental stewardship assistance in fiscal year 2012, but would also reduce the farm bill conservation baseline. These programs benefit producers through improved soil quality and productivity of their land, and the American people through cleaner air and water and healthy habitat. Reducing the farm bill baseline in the face of increasing future demands for resource protection and productivity is counterproductive.

IWLA and its members across the country are especially focused on the following core conservation programs:

*Conservation Reserve Program (CRP).*—CRP reduces soil erosion, protects water quality, and enhances habitat through long-term contracts with landowners that convert highly erodible cropland to more sustainable vegetative cover. The administration's budget is strongly supportive of CRP because it proposes to allow landowners to enroll up to 6 million acres in fiscal year 2012, on top of the 3.95 million acres sought in the fiscal year 2011 general signup. After the 2008 farm bill reduced the overall acreage limit for CRP to 32 million acres—it is encouraging to see the effort being made to ensure farmers and ranchers are able to achieve the maximum allowable enrollment for their most sensitive lands and most important habitat.

*Wetlands Reserve Program (WRP).*—WRP provides technical and financial assistance to landowners to restore and protect wetlands on their properties. Wetlands are generally conserved through permanent or 30-year easements purchased by the USDA. Unfortunately, the President proposes to permanently reduce the farm bill authorization for WRP by 158,895 acres. The action taken with this proposal is to arbitrarily rewrite the Federal farm bill's multi-year obligation as signed into law in 2008. IWLA opposes this cut and urges the Congress to uphold the binding, 5-year commitment made to WRP.

*Grassland Reserve Program (GRP).*—GRP focuses on limiting conversion of pasture and other grasslands to cropland or development while allowing landowners to continue grazing and other operations that align with this goal. The President's budget also proposes to permanently cut the mandated total acreage for GRP by 165,684 acres. Again, IWLA opposes this reduction because it will undermine efforts to protect one of the country's most threatened natural resources through fiscal year 2012 and beyond.

*Conservation Stewardship Program (CSP).*—CSP is a comprehensive approach to conserving soil, water, and other natural resources across a range of lands, including cropland, prairie, and forests. CSP makes conservation the basis for a producer to receive Federal financial support rather than limitless subsidies for intensive production of a few crops. It is troubling that the administration's fiscal year 2012 budget is proposing to cut the number of acres that could be enrolled in CSP by 764,204. IWLA opposes this cut because CSP is a comprehensive, whole-farm approach to conservation that can maximize benefits to natural resources, fish and wildlife, and producers alike.

*Wildlife Habitat Incentives Program (WHIP).*—WHIP helps agricultural landowners develop habitat for upland wildlife, wetland wildlife, threatened and endangered species, fish, and other wildlife. The President's fiscal year 2012 proposal also seeks to permanently reduce the mandatory commitment established for WHIP in the Federal farm bill. The budget would cut fiscal year 2012 funding for WHIP by 14 percent, or \$12 million. IWLA opposes this damaging cut to a program with the central goal of supporting wildlife resources in rural America.

Finally, effective implementation of farm bill conservation programs depends upon adequate technical resources to work with landowners in addressing their unique environmental concerns. Although conservation programs are available, underinvestment in technical assistance limits agency support to assist farmers and ranchers in selecting and optimizing appropriate programs for their operations. The technical expertise of the Natural Resource Conservation Service and partners that assist in the delivery of programs and technical assistance directly to landowners is necessary for the adoption and maintenance of conservation practices. We request that the subcommittee support the mandatory levels of conservation program funding as provided in the farm bill to enable robust technical resources to implement those programs successfully.

We appreciate the opportunity to testify in strong support of fully funding agricultural conservation programs.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF COUNTY AND CITY HEALTH OFFICIALS

BACKGROUND

The National Association of County and City Health Officials (NACCHO) represents the Nation's 2,800 local health departments (LHDs). These governmental agencies work every day in their communities to prevent disease, promote wellness, and protect the health of the entire community. LHDs have a unique and distinctive role and set of responsibilities in the larger health system and within every community. The Nation depends upon the capacity of LHDs to play this role well.

LHDs have wide ranging responsibilities including measuring population-wide illness, organizing efforts to prevent disease and prolong quality of life, and to serve the public through programs not offered elsewhere. Two of those responsibilities are preventing foodborne illness and investigating the cause and spread of illness. In fact, LHDs are the significant majority of the 3,000 State, local, and tribal agencies that have primary responsibility to regulate the more than 1 million food establishments in the United States.

However, the Nation's current fiscal challenges have diminished the resources available to, and therefore the ability of, LHDs to focus on the problem of foodborne illness. NACCHO surveys reveal that in the 3-year period covering 2008–2010, 29,000 jobs have been lost in LHDs, which represents a 19-percent cut in local public health jobs nationwide.

Even so, LHDs continue to respond to increased threats of all types, from rising chronic disease rates to public anxiety about potential radiation from the recent disaster in Japan. These increased threats, combined with budget cuts, layoffs, and furloughs make it more and more difficult for LHDs to respond to outbreaks of foodborne illness.

Despite the best efforts of public officials, more than 48 million cases of preventable foodborne illness occur every year in this country. Many of these cases cause pain and suffering, high medical bills, disability, lost productivity, lower life expectancy, and death. In fact, foodborne illness causes an estimated 128,000 hospital visits and 3,000 deaths annually.

Last year, the Congress passed historic and bipartisan food safety legislation. This legislation recognized the importance of protecting the public from foodborne illness and the shortcomings of our current system. It is clear that LHDs are facing increasing budget pressures and that the enormous societal costs imposed by foodborne illness can be reduced with extremely modest investments in training as well as regulation and enforcement at the retail level. The return on Federal investment in retail food safety, training, and enforcement can be measured in improved health and lower healthcare costs and lost productivity. It is our members' experience that "tough but fair" enforcement is valued by industry.

FOOD AND DRUG ADMINISTRATION RETAIL FOOD SAFETY INITIATIVE

*NACCHO Request: \$5.6 Million*

*President's Fiscal Year 2012 Budget: \$5.6 Million (New Program)*

FDA conducted a 10-year study of more than 800 retail food establishments to determine compliance with five key risk factors for foodborne illness in nine types of retail operations. These included schools, hospitals, and nursing homes, as well as markets and restaurants. This study provides the evidence to support a robust, science-based approach to food safety at the retail level, where food is handled, prepared, and stored prior to direct purchase by consumers and where a significant amount of preventable foodborne illness begins. LHDs are on the front lines conducting food safety inspections and have the expertise to educate food handlers in their communities.

The presence of certified food safety managers in retail establishments is an important factor in achieving overall risk reduction in food service operations. It is not possible to attribute improvement in overall compliance with food safety standards to any single factor, due to the number of interdependent variables with any given food service operation. However, NACCHO firmly believes that the comprehensive approach of the Food and Drug Administration's (FDA's) Retail Food Safety Initiative will significantly enhance the capacity of LHDs to achieve compliance with improved food safety standards, thereby reducing the incidence of foodborne illness. NACCHO recommends a funding level of \$5.6 million in fiscal year 2012 to implement this initiative, which recognizes the critical importance of local food safety activities to protect the Nation's consumers.

## FDA FOOD SAFETY TRAINING

*NACCHO Request: \$8 Million*

*President's Fiscal Year 2012 Budget: \$8 Million*

*Fiscal Year 2010 Funding: \$1 Million*

It is crucial that regulators and public health partners have the appropriate knowledge and training to carry out their duties to safe guard our citizens from foodborne illness. The Congress provided \$1 million in fiscal year 2010 appropriations and the International Food Protection Training Institute (IFPTI) is already up and running. However, food safety training requires continued funding to increase capacity and adequately train our Nation's food protection workers. A national food safety training system, including a certification system, will ensure that officials at all levels of Government have current, consistent, and adequate knowledge, as well as the necessary skills, to do their jobs. Without a robust national training system, we risk having a food safety workforce applying a patchwork of standards and methodologies without the ability to consistently and continuously improve their knowledge and skills based on the latest science and risk assessments. NACCHO recommends a funding level of \$8 million in fiscal year 2012 to continue to implement an effective food safety training system.

As you draft the fiscal year 2012 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill, we ask that you consider our recommendations for these two programs that are critical to ensuring the safety of our Nation's food supply and will protect our Nation's people. NACCHO thanks you for your previous support of food safety and welcomes the opportunity to discuss this further with the subcommittee.

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PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE ENERGY OFFICIALS

Chairman Kohl, Ranking Member Blunt, and members of the subcommittee, I am Phil Giudice, chairman of the National Association of State Energy Officials (NASEO). NASEO is submitting this testimony in support of funding of at least \$39 million in discretionary appropriations for the Rural Energy for America Program (REAP) (section 9007 of the 2008 farm bill) in addition to \$70 million in mandatory funding. REAP was created as part of the 2002 farm bill and it has been a huge success. Approximately 4,000 clean energy projects have been implemented in every State since 2003. These activities have included energy efficiency projects, as well as wind, solar, biomass, anaerobic digesters, biodiesel, and geothermal. Technical assistance has also been a big factor in this program. Funding requests are generally three times the amount of available funds. NASEO has worked with farmers, our State agricultural agencies, and rural interests to promote this successful program. As we face dramatically increasing energy bills for all sectors of the economy (and increased volatility in energy prices), it is critical that we do more to address the energy problems of rural America.

Greater energy efficiency and renewable energy use in the farm sector will help create jobs, increase agricultural productivity, and improve the environment. Funding for the energy title of the farm bill is a critical public investment.

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PREPARED STATEMENT OF THE NATIONAL COMMODITY SUPPLEMENTAL FOOD PROGRAM ASSOCIATION

Mr. Chairman and subcommittee members, thank you for this opportunity to present information regarding the U.S. Department of Agriculture (USDA)/Food and Nutrition Service's Commodity Supplemental Food Program (CSFP).

The National Commodity Supplemental Food Program Association (NCSFPA) requests the Senate Agriculture Appropriations Subcommittee fund CSFP for fiscal year 2012 at \$207.588 million, \$176.788 million as requested by the USDA, an additional \$5 million to begin CSFP operations in six States (Connecticut, Hawaii, Idaho, Maryland, Massachusetts, and Rhode Island) with USDA-approved plans, plus \$25.8 million to meet pending requests for increasing caseload by 114,000 slots, and include language directing the Department to utilize all available resources to supplement the CSFP food package and meet the rising demand for nutritional assistance among our vulnerable senior population.

CSFP is a unique program that brings together Federal and State agencies, along with public and private entities. Low-income seniors added since 1983 now comprise 96 percent of all CSFP participants. The USDA purchases specific nutrient-rich foods at wholesale prices, including canned fruits and vegetables, juices, meats, fish,

peanut butter, cereals, grain products, cheese, and dairy products from American farmers. State agencies provide oversight, contract with community and faith-based organizations to warehouse and distribute food, certify eligibility, and educate participants. Local organizations build broad collaboration among nonprofits, health units, and area agencies on aging for simple, fast access to these supplemental foods and nutrition education to improve participants' health and quality of life. This partnership reaches even homebound seniors in both rural and urban settings with vital nutrition and remains an important "market" for commodities supported under various farm programs.

In fiscal year 2010, the CSFP provided services through 150 nonprofit community and faith-based organizations at 1,800 sites located in 39 States, the District of Columbia, and two Indian tribal organizations (Red Lake, Minnesota, and Oglala Sioux, South Dakota). On behalf of those organizations NCSFPA would like to express our gratitude for the increased fiscal year 2010 funding that has allowed CSFP to begin in seven new States, Arkansas, Delaware, Georgia, Maine, New Jersey, Oklahoma, and Utah, and has also resulted in a significant increase in the number of individuals who are now able to participate in the program in the other CSFP States.

CSFP's 42 years of service is a testimony to the power of community partnerships of faith-based organizations, farmers, private industry, and Government agencies. The CSFP offers a unique combination of advantages unparalleled by any other food assistance program:

- CSFP specifically targets our Nation's most nutritionally vulnerable populations—young children and low-income seniors, many of whom may not qualify for other nutrition assistance programs.
- CSFP provides a monthly selection of food packages tailored to specific nutritional needs. The nutritional content of the food provided has improved with the introduction of low-fat cheese, whole grain products, canned fruits packed in fruit juice, and low-salt canned vegetables.
- CSFP purchases foods at wholesale prices, directly supporting American farmers. The average food package cost is estimated at \$19.26 while the retail value is \$50.
- The CSFP involves the entire community. Thousands of volunteers and private companies donate money, equipment, and, most importantly, time and effort to deliver food to needy and homebound seniors. These volunteers not only bring food but companionship and other assistance to seniors who might have limited support systems.

In a recent CSFP survey, more than one-half of seniors living alone reported an income of less than \$750 per month. One-half of respondents from two-person households reported an income under \$1,000 per month. Twenty-five percent were enrolled in the Supplemental Nutrition Assistance Program (SNAP) and 50 percent said they ran out of food during the month. Seventy percent of senior respondents said they choose between medicine and food.

The Senate Agriculture Appropriations Subcommittee has consistently supported CSFP, acknowledging it as a cost-effective way of providing nutritious supplemental foods. The Congress provided funding to meet the rising need among the elderly in the fiscal year 2010 appropriation. While USDA's budget request will provide adequate resources for our monthly caseload of 604,931 mothers, children, and seniors, we urge the subcommittee to strongly consider our request for funding to allow six additional States to begin providing nutritional assistance to their vulnerable seniors as well as granting us sufficient funding to meet the increasing need in the 39 current CSFP States.

CSFP and other nutrition programs, such as SNAP, are only supplemental programs by design. Together they cover a shortfall that many seniors face each month. These programs must have support to meet the increasing need as part of the "safety net."

"The Managers fully support continued operation of this program and recognize the need for a substantial expansion of CSFP . . . the Managers encourage the Secretary to approve all remaining [S]tates for expansion and to expand caseload in all participating [S]tates." (Joint Statement of Managers, H.R. 2419, the Food, Conservation and Energy Act of 2008.)

"CSFP has charms worth considering in designing human service programs . . . the program's trademarks were its simplicity and accessibility . . . CSFP in particular represents a guaranteed source of high quality food, delivered in a balanced package." ("The Role of CSFP in Nutritional Assistance to Mothers, Infants, Children and Seniors", The Urban Institute, August 2008.)

NCSFPA requests the following:

(In millions of dollars)

To continue serving our monthly caseload of 604,931 needy seniors (97 percent of participants), women, infants, and children (3 percent of participants). .....	\$176.788
Respond to six States (Connecticut, Hawaii, Idaho, Maryland, Massachusetts, and Rhode Island) requesting assistance in serving its vulnerable senior population. ....	5.000
To meet the increasing demand/need. Feed an additional 114,718 at risk seniors in 39 States per requests turned in to USDA by CSFP operators nationwide. ....	25.800
Total fiscal year 2012 request .....	207.588

A 1997 report by the National Policy and Resource Center on Nutrition and Aging at Florida International University, Miami—"Elder Insecurities: Poverty, Hunger, and Malnutrition" indicated that malnourished elderly patients experience 2 to 20 times more medical complications, have up to 100-percent longer hospital stays, and incur hospital costs \$2,000 to \$10,000 higher per stay. Proper nutrition promotes health, treats chronic disease, decreases hospital length of stay, and saves healthcare dollars. America is aging. CSFP must be an integral part of senior nutrition policy and plans to support the productivity, health, independence, and quality of life for America's seniors, many of whom now need to continue working at least part-time beyond retirement age to afford basics.

The CSFP is committed grassroots operators and dedicated volunteers with a mission to provide quality nutrition assistance economically, efficiently, and responsibly always keeping the needs and dignity of our participants first. We commend the Food Distribution Division of Food and Nutrition Service of the USDA for their continued innovations to strengthen the quality of the food package and streamline administration.

PREPARED STATEMENT OF THE NEW MEXICO INTERSTATE STREAM COMMISSION

The Congress authorized the Colorado River Basin Salinity Control Program (CRBSCP) in the Colorado River Basin Salinity Control Act of 1974 (CRBSCA). The Congress amended the act in 1984 to give new responsibilities to the U.S. Department of Agriculture (USDA). While retaining the Department of the Interior as the lead coordinator for CRBSCP, the amended act recognized the importance of USDA efforts in meeting the objectives of CRBSCP. Many of the most cost-effective salinity control projects to date have occurred since implementation of the USDA's authorization for CRBSCP.

Bureau of Reclamation studies show that quantified damages from the Colorado River to U.S. water users are about \$350 million per year. Unquantified damages are significantly greater. Damages are estimated at \$75 million per year for every additional increase of 30 milligrams per liter in salinity of the Colorado River. It is essential that USDA salinity control projects be funded for timely implementation to protect the quality of Colorado River Basin water delivered to the lower Basin States and Mexico.

The Congress directed, with the enactment the Federal Agricultural Improvement and Reform Act of 1996 (FAIRA), that CRBSCP should continue to be implemented as a component of the Environmental Quality Incentives Program (EQIP). However, until 2004, CRBSCP was not funded at an adequate level to protect the Basin State-adopted and Environmental Protection Agency (EPA)-approved water quality standards for salinity in the Colorado River. Appropriations for EQIP prior to 2004 were insufficient to adequately control salinity impacts from water delivered to the downstream States and Mexico.

EQIP subsumed the salinity control program without giving adequate recognition to the responsibilities of the USDA to implement salinity control measures per section 202(c) of CRBSCA. The EQIP evaluation and project ranking criteria targeted small watershed improvements and did not recognize that water users hundreds of miles downstream are significant beneficiaries of the salinity control program. Proposals for EQIP funding were ranked in the States of Utah, Wyoming, and Colorado under the direction of the respective State conservationists without consideration of those downstream, particularly out-of-State, benefits.

Following recommendations of the Basin States to address the funding problem, the USDA's Natural Resources Conservation Service (NRCS) designated the Colorado River Basin an "area of special interest" and earmarked funds for CRBSCP.



NRCS concluded that the salinity control program is different from the small watershed approach of EQIP. The watershed for CRBSCP stretches more than 1,200 miles from the headwaters of the river through the salt-laden soils of the upper basin to the river's termination at the Gulf of California in Mexico. NRCS is to be commended for its efforts to comply with the USDA's responsibilities under CRBSCA, as amended. Irrigated agriculture in the upper basin realizes significant local benefits of improved irrigation practices, and agricultural producers have succeeded in submitting cost-effective proposals to NRCS.

Years of inadequate Federal funding for EQIP since the 1996 enactment of FAIRA and prior to 2004 resulted in the need to accelerate the salinity control program in order to maintain the criteria of the Colorado River Water Quality Standards for Salinity. With the enactment of the Farm Security and Rural Investment Act in 2002, an opportunity to adequately fund the salinity control program now exists. The requested funding of 2.5 percent of the EQIP funding will continue to be needed each year for at least the next few fiscal years.

State and local cost-sharing is triggered by and indexed to the Federal appropriation. In fiscal year 2012, it is anticipated that the States will cost-share about \$8 million and local agricultural producers will add more than \$7 million, resulting in contributions for more than 40 percent of the total program costs.

USDA salinity control projects have proven to be a cost-effective component of the salinity control program. USDA has indicated that a more adequately funded EQIP program would result in more funds being allocated to the salinity program. The Basin States have cost-sharing dollars available to participate in on-farm salinity control efforts. The agricultural producers in the upper basin are willing to cost-share their portion and are awaiting funding for their applications to be considered.

The Basin States expend 40 percent of the State funds allocated for CRBSCP for essential NRCS technical assistance and education activities. Previously, the Federal part of the salinity control program funded through EQIP failed to adequately fund NRCS for these activities, which has been shown to be an impediment to accomplishing successful implementation of the salinity control program. Acknowledgement by the administration that technical assistance and education activities must be better funded has encouraged the Basin States and local producers that cost-share with EQIP. I request that adequate funds be appropriated to NRCS technical assistance and education activities directed to the salinity control program participants.

I urge the Congress to appropriate at least \$1 billion in fiscal year 2012 for EQIP. Also, I request that 2.5 percent of the EQIP appropriation be designated for CRBSCP.

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PREPARED STATEMENT OF PICKLE PACKERS INTERNATIONAL, INC.

The pickled vegetable industry strongly supports and encourages your subcommittee in its work of maintaining and guiding the Agricultural Research Service. To accomplish the goal of improved health and quality of life for the American people, the health action agencies of this country continue to encourage increased consumption of fruits and vegetables in our diets. Accumulating evidence from the epidemiology and biochemistry of heart disease, cancer, diabetes, and obesity supports this policy. Vitamins (particularly A, C, and folic acid), minerals, and a variety of antioxidant phytochemicals in plant foods are thought to be the basis for correlation's between high fruit and vegetable consumption and reduced incidence of these debilitating and deadly diseases. The problem is that many Americans choose not to consume the variety and quantities of fruits and vegetables that are needed for better health.

As an association representing processors that produce more than 85 percent of the tonnage of pickled vegetables in North America, it is our goal to produce new products that increase the competitiveness of U.S. agriculture as well as meet the demands of an increasingly diverse U.S. population that is encouraged to eat more vegetables. The profit margins of growers continue to be narrowed by foreign competition. Likewise, the people of this country represent an ever-broadening array of expectations, tastes, and preferences derived from many cultural backgrounds. Everyone, however, faces the common dilemma that food costs should remain stable and preparation time continues to be squeezed by the other demands of life. This industry can grow by meeting these expectations and demands with reasonably priced products of good texture and flavor that are high in nutritional value, low in negative environmental impacts, and produced with assured safety from pathogenic microorganisms and from those who would use food as a vehicle for terror. With strong research to back us up, we believe our industry can make a greater

contribution toward reducing product costs and improving human diets and health for all economic strata of U.S. society.

Many small- to medium-sized growers and processing operations are involved in the pickled vegetable industry. We grow and process a group of vegetable crops, including cucumbers, peppers, carrots, onions, garlic, cauliflower, cabbage (sauerkraut), and Brussels sprouts, which are referred to as minor crops. None of these crops is in any commodity program and as such, do not rely upon taxpayer subsidies. However, current farm value for just cucumbers, onions, and garlic is \$2.4 billion with an estimated processed value of \$5.8 billion. These crops represent important sources of income to farmers, and the processing operations are important employers in rural communities around the United States. Growers, processing plant employees, and employees of suppliers to this industry reside in all 50 States. To realize its potential in the rapidly changing American economy, this industry will rely upon a growing stream of appropriately directed basic and applied research from four important research programs within the Agricultural Research Service. These programs contribute directly to top research priorities that the Research, Education, and Economic mission area of the U.S. Department of Agriculture (USDA) has identified in that they develop vegetable crop germplasm and preservation technology that contributes to improved profitability with reduced pesticide inputs in a safer, higher quality product grown by rural farm communities across the United States, consequently improving food security and food safety. Improved germplasm, crop management practices, and processing technologies from these projects have measurably contributed to the profitability, improved nutritional value, and increased consumption of affordable vegetable crops for children and adults in America and around the world.

#### VEGETABLE CROPS RESEARCH LABORATORY, MADISON, WISCONSIN

The USDA/ARS Vegetable Crops Research Lab at the University of Wisconsin is the only USDA research unit dedicated to the genetic improvement of cucumbers, carrots, onions, and garlic. Three scientists in this unit account for approximately one-half of the total U.S. public breeding and genetics research on these crops. Their past efforts have yielded cucumber, carrot, and onion cultivars and breeding stocks that are widely used by the U.S. vegetable industry (i.e., growers, processors, and seed companies). These varieties account for more than one-half of the farm yield produced by these crops today. All U.S. seed companies rely upon this program for developing new varieties, because ARS programs seek to introduce economically important traits (e.g., virus and nematode resistance) not available in commercial varieties using long-term high risk research efforts. The U.S. vegetable seed industry develops new varieties of cucumbers, carrots, onions, and garlic and more than 20 other vegetables used by thousands of vegetable growers. The U.S. vegetable seed, grower, and processing industry, relies upon the USDA/ARS Vegetable Crops Research Lab for unique genetic stocks to improve varieties in the same way the U.S. healthcare and pharmaceutical industries depend on fundamental research from the National Institutes of Health. Their innovations meet long-term needs and bring innovations in these crops for the U.S. and export markets, for which the United States has successfully competed. Past accomplishments by this USDA group have been cornerstones for the U.S. vegetable industry that have resulted in increased profitability, and improved product nutrition and quality.

Both consumers and the vegetable production and processing industry would like to see fewer pesticides applied to food and into the environment in a cost-effective manner. Scientists in this unit have developed genetic resistance for many major vegetable diseases that are perhaps the most important threat to sustained production of a marketable crop for all vegetables. Genetic resistance assures sustainable crop production for growers and reduces pesticide residues in our food and environment. Value of this genetic resistance developed by the vegetable crops unit is estimated at \$670 million per year in increased crop production, not to mention environmental benefits due to reduction in pesticide use. New research in Madison has resulted in cucumbers with improved disease resistance, pickling quality, and suitability for machine harvesting. New sources of genetic resistance to viral and fungal diseases, environmental stress resistance like heat and cold, and higher yield have recently been mapped on cucumber chromosomes to provide a ready tool for our seed industry to significantly accelerate the development of resistant cultivars for U.S. growers. Nematodes in the soil deform carrot roots to reduce yield from 10 percent to more than 70 percent in major production areas. A new genetic resistance to nematode attack was found to almost completely protect the carrot crop from one major nematode. This group improved both consumer quality and processing quality of vegetables with a resulting increase in production efficiency and consumer appeal.

Baby carrots were founded on germplasm developed in Madison, Wisconsin. Carrots provide approximately 30 percent of the U.S. dietary vitamin A. New carrots have been developed with tripled nutritional value, and nutrient-rich cucumbers have been developed with increased levels of provitamin A. Using new biotechnological methods, a system for rapidly and simply identifying seed production ability in onions has been developed that reduces the breeding process up to 6 years. A genetic map of onion flavor and nutrition will be used to develop onions that are more appealing and healthy for consumers.

There are still serious vegetable production problems which need attention. For example, losses of cucumbers, onions, and carrots in the field due to attack by pathogens and pests remains high, nutritional quality needs to be significantly improved and U.S. production value and export markets could certainly be enhanced. Genetic improvement of all the attributes of these valuable crops are at hand through the unique USDA lines and populations (i.e., germplasm) that are available and the new biotechnological methodologies that are being developed by the group. The achievement of these goals will involve the utilization of a wide range of biological diversity available in the germplasm collections for these crops. Classical plant breeding methods combined with biotechnological tools such as DNA marker-assisted selection and genome maps of cucumber, carrot, and onion will be used to implement these genetic improvements. With this, new high-value vegetable products based upon genetic improvements developed by our USDA laboratories can offer vegetable processors and growers expanded economic opportunities for U.S. and export markets.

U.S. FOOD FERMENTATION LABORATORY, RALEIGH, NORTH CAROLINA

The USDA/ARS Food Fermentation Laboratory in Raleigh, North Carolina is the major public laboratory that this industry looks to for new scientific information on the safety of our products and development of new processing technologies related to fermented and acidified vegetables. Over the years, this laboratory has been a source for innovations which have helped this industry remain competitive in the current global trade environment. We expect the research done in this laboratory to lead to new processing and product ideas that will increase the economic value of this industry and provide consumers with safe, high-quality, and healthful vegetable products.

We seek additional funding to support two new research initiatives for this laboratory that have substantial economic potential for our industry and health benefits for the American public. These are:

- adaptation of a more efficient heating technology, such as microwave processing, to replace the current tunnel pasteurizers in order to reduce the energy and water use required for heat processing acidified vegetables; and
- development of techniques to deliver living probiotic microorganisms to consumers in fermented or acidified vegetable products.

Nearly all pickled vegetables in the aisles of your super market are heated (pasteurized) so they are shelf stable at room temperature. Current steam and water bath pasteurizer technologies, which were developed in the 1940s and 1950s, have been very successful in that there has never been an outbreak of illness caused by commercially processed fermented or acidified vegetables. However, these current processing technologies are not efficient in the use of energy or water resources. Rising costs for energy and limits on water use require that major improvements be made in the way we heat process our products. There are three promising approaches that could benefit the broad range of products and sizes of companies that constitute the membership of Pickle Packers International. First, is to develop practical ways to preheat and pack vegetables to reduce or even eliminate the residence time required in current pasteurizers. Second, is to adapt newer thermal processing technologies, particularly microwave heating, to our products. Third, is to modify containers and product ingredients such that less heat and associated water use is required to assure killing of pathogenic bacteria and other spoilage microorganisms. Modifications of processes require strong scientific justification to assure ourselves, FDA, and the public that safety and quality will be maintained. In concert with any new processing technologies adequate process verification methods to assure process control and acceptance of our processes by FDA must be developed and validated. The objective is to have energy-efficient, low water use, and scientifically validated thermal processing technologies for commercial preservation of acidified vegetables.

Most of what we hear about bacteria in foods concerns the pathogens that cause disease. However, lactic acid bacteria are intentionally grown in fermented foods because they are needed to give foods like sauerkraut, yoghurt, cheeses, and fermented salami the characteristic flavors and textures that we desire. There is a

growing body of research to indicate that certain living lactic acid bacteria are “probiotic” in that they improve human health by remaining in the intestinal tract after they are consumed. Fermented or acidified vegetables may be a good way to deliver such probiotic bacteria to consumers. The objective will be to identify probiotic lactic acid bacteria that can survive in high numbers in selected vegetable products and investigate the potential for using vegetables as healthful delivery vehicles for probiotic organisms.

SUGAR BEET AND BEAN RESEARCH UNIT, EAST LANSING, MICHIGAN

Quality inspection and assurance for pickling vegetables is needed at many points from the field through postharvest processing to final packaging and marketing. Accurate quality assessment methodologies and techniques are critical to growers and processors and ultimately consumers of pickling vegetables. While automated quality inspection systems are currently used in many pickle processing facilities, they are largely confined to inspecting product surface quality characteristics. There exists considerable room for improving current technologies and developing new and more efficient sensors and automated inspection methods, especially for internal quality assessment and grading of pickling vegetables and pickled products. Moreover, labor required for postharvest handling and processing operations represents a significant portion of the total production cost. Development of new and/or improved technologies can help growers and processors assess, inspect, and grade pickling vegetables and pickled products rapidly and accurately for internal and external quality characteristics so that they can be directed to, or removed from, appropriate processing or marketing avenues. This will minimize postharvest losses of food that has already been produced, ensure high-quality, consistent final product and end-user satisfaction, and reduce production cost.

The USDA/ARS Sugarbeet and Bean Research Unit at East Lansing, Michigan provides national leadership in research and development of innovative technologies and systems for assessing and assuring quality and marketability of tree fruits and pickling vegetables and enhancing production efficiency. Over the years, the Unit has developed a number of innovative engineering technologies for rapid, non-destructive measurement and inspection of postharvest quality of tree fruits and vegetables, including a novel spectral scattering technology for assessing the texture and flavor of fruits, a portable fruit firmness tester, and a spectral property measuring instrument for quality evaluation of fruits and vegetables. Recently, it also developed an advanced hyperspectral imaging system for automated detection of internal and external quality of pickling cucumbers and pickles. Research at East Lansing will continue to provide the pickling vegetable industry a vital source of innovative inspection and grading technology to assure high-quality safe products to the marketplace and achieve labor cost savings. Therefore, it is critical that additional resources be provided to support and expand the existing program to effectively address the technological needs for the pickling industry.

U.S. VEGETABLE LABORATORY, CHARLESTON, SOUTH CAROLINA

The research program at the USDA/ARS Vegetable Laboratory in Charleston, South Carolina, addresses national problems in vegetable crop production and protection with emphasis on the Southeastern United States. This research program is internationally recognized for its accomplishments, which have resulted in development of more than 150 new vegetable varieties and lines along with the development of many new and improved disease and pest management practices.

This laboratory's program currently addresses 14 vegetable crops including those in the cabbage, cucumber, and pepper families, which are of major importance to the pickling industry. The mission of the laboratory is to:

- develop disease and pest-resistant vegetable crops; and
- develop new, reliable, environmentally sound disease and pest management programs that do not rely on conventional pesticides.

Continued expansion of the Charleston program is crucial. Vegetable growers depend heavily on synthetic pesticides to control diseases and pests. Cancellation and/or restrictions on the use of many effective pesticide compounds are having a considerable influence on the future of vegetable crop production. Without the use of certain pesticides, growers will experience crop failures unless other effective, nonpesticide control methods are found quickly. The research on improved, more efficient and environmentally compatible vegetable production practices and genetically resistant varieties at the U.S. Vegetable Laboratory continues to be absolutely essential. This gives U.S. growers the competitive edge they must have to sustain and keep this important industry and allow it to expand in the face of increasing foreign competition. Current cucumber varieties are highly susceptible to a new strain of

the downy mildew pathogen; this new strain has caused considerable damage to commercial cucumber production in some South Atlantic and Midwestern States during the past 5 years, and a new plant pathologist position needs to be established to address this critical situation.

FUNDING NEEDS FOR THE FUTURE

It remains critical that funding continues the forward momentum in pickled vegetable research that the United States now enjoys and to increase funding levels as warranted by planned expansion of research projects to maintain U.S. competitiveness. We also understand that discretionary funds are now used to meet the rising fixed costs associated with each location. Additional funding is needed at the Wisconsin and South Carolina programs for genetic improvement of crops essential to the pickled vegetable industry, and at North Carolina and Michigan for development of environmentally sensitive technologies for improved safety and value to the consumer of our products. The fermented and acidified vegetable industry is receptive to capital investment in order to remain competitive, but only if that investment is economically justified. The research needed to justify such capital investment involves both short-term (6–24 months) and long-term (2–10 years or longer) commitments. The diverse array of companies making up our industry assumes responsibility for short-term research, but the expense and risk are too great for individual companies to commit to the long-term research needed to insure future competitiveness. The pickled vegetable industry currently supports research efforts at Wisconsin and North Carolina and anticipates funding work at South Carolina and Michigan as scientists are put in place. Donations of supplies and processing equipment from processors and affiliated industries have continued for many years.

*U.S. Vegetable Laboratory, Charleston, South Carolina*

New funds are needed to establish a plant pathology position to address cucumber diseases, especially the disease caused by a new strain of the downy mildew pathogen that has caused extensive damage to cucumber production in some South Atlantic and Midwestern States during the past 5 years. The plant pathologist is needed to characterize pathogen strains using molecular methodologies and to develop new management approaches and resistant cucumber lines. This new plant pathologist position will greatly contribute to the accomplishment of research that will provide for the effective protection of cucumbers from disease without the use of conventional pesticides. This position will require a funding level of \$500,000 for its establishment.

New scientific staff needed	Current status	Funds needed
Plant pathologist (cucumber disease) .....	Needed .....	\$500,000
New funds needed .....	.....	500,000

*Food Fermentation Laboratory, Raleigh, North Carolina*

The current funding for the laboratory is \$1,264,000. To carry out the new research initiatives to reduce the energy and water use required to produce safe, high-quality products and to develop systems to deliver probiotic lactic acid bacteria in acidified and fermented vegetable products, we request additional support for the Food Fermentation Laboratory of \$300,000 in fiscal year 2012. This will provide support for postdoctoral or predoctoral research associates along with necessary equipment and supplies to develop these new areas of research.

Scientific staff	Current status	Funds needed
Microbiologist .....	Active .....	\$316,000
Chemist .....	Active .....	316,000
Food technologist/biochemist .....	Active .....	316,000
Microbial physiologist .....	Active .....	316,000
Fiscal year 2012 postdoctoral and predoctoral research associate .....	Needed .....	300,000
Total funding required .....	.....	1,564,000
Presidential budget (fiscal year 2012) .....	.....	1,264,000
New funds needed .....	.....	300,000

*Vegetable Crops Research Laboratory Unit, Madison, Wisconsin*

Current base funding for three scientists is \$893,150, of which \$200,000 was added in fiscal year 2002. Emerging diseases, such as downy mildew of cucumber, threaten production of the crop in all production areas. Therefore, we request an additional \$531,850 to fully fund the scientists and support staff in fiscal year 2012, including graduate students and postdoctorates for new research searching for genetic resistance to emerging diseases.

Scientific staff in place	Current status	Funds needed
Geneticist .....	Active .....	\$375,000
Geneticist .....	Active .....	375,000
Geneticist .....	Active .....	375,000
Fiscal year 2012 postdoctoral or predoctoral research associates .....	Needed .....	300,000
Total funding required .....		1,425,000
Presidential budget (fiscal year 2012) .....		893,150
New funds needed .....		531,850

*Sugar Beet and Bean Research Unit, East Lansing, Michigan*

Current base funding for the location is \$190,000, which is far short of the funding level needed to carry out research on inspection, sorting, and grading of pickling cucumbers and other vegetable crops to assure the processing and keeping quality of pickled products. An increase of \$550,000 in the current base funding level would be needed to fund the research engineer position.

Scientific staff in place	Current status	Funds needed
Postdoctoral research associate .....	Active .....	\$190,000
Research engineer .....	Needed .....	550,000
Total funding required .....		740,000
Current funding .....		190,000
New funds needed .....		550,000

Thank you for your consideration and expression of support for the USDA/ARS.

PREPARED STATEMENT OF THE SOCIETY FOR WOMEN'S HEALTH RESEARCH

The Society for Women's Health Research (SWHR) is pleased to submit written testimony to urge the subcommittee to increase the congressional appropriation to the Food and Drug Administration (FDA) by \$382 million for fiscal year 2012. This allocation will allow the agency to provide necessary and critical improvements in infrastructure, address resource shortages, and support needed investment into the Office of Women's Health (OWH), the focal point on women's health within the agency.

Insufficient investment in this important agency prevents the FDA from fully achieving its mission and threatens the health, economic, and national security of the Nation. While SWHR recognizes the need for responsible discretionary spending, proper and sustained funding of the FDA must remain a public priority. The administration's fiscal year 2012 increase of \$382 million to FDA reflects the agency's increased responsibilities and workload.

Appropriate funding of the FDA by the Congress is vital for it to fulfill its mission. Americans rely on the FDA every day, from promoting wellness and meeting healthcare needs to ensuring the food supply and keeping drugs safe and effective. Altogether, 25 percent of every consumer \$1 spent in America is spent on products regulated by the FDA.

This level of investment will allow the FDA to foster a 21st century culture of proactive science and research leadership that will better meet the demands and expectations of the American public. Each year, more than 80 percent of FDA's budget is allocated toward the salary of its scientists and staff, making a substantial investment in infrastructure needs, technology, and human collateral all but impossible. Until the budgetary allocation from the Congress is enough to allow FDA to invest

in staffing and infrastructure needs, the FDA will continue to act in a reactionary manner against the emerging or known threats to food and drug security.

#### FDA AND SEX DIFFERENCES RESEARCH

In the past decades, scientists have uncovered significant biological and physiological differences between men and women. Sex differences have been found everywhere, from the composition of bone matter to the metabolism of certain drugs, to the rate of neurotransmitter synthesis in the brain. Sex-based biology, the study of biological and physiological differences between men and women, has revolutionized the way that the scientific community views the sexes. America's drug development process continues to advance in delivering new and better targeted medications to combat disease; however, medication effectiveness and safety could be better targeted to women and men if analysis of sex and gender differences would be done routinely during review processes at FDA.

SWHR has long recognized that the inclusion of women in study populations by itself was insufficient to address the inequities in our knowledge of human biology and medicine, and that only by the careful study of sex differences at all levels, from genes to behavior, would science achieve the goal of optimal healthcare for both men and women. Many sex differences are already present at birth, whereas others develop later in life. These differences play an important role in disease susceptibility, prevalence, time of onset, and severity and have documented roles in cancer, obesity, heart disease, immune dysfunction, mental health disorders, and other illnesses. Physiological differences and hormonal fluctuations may also play a role in the rate of drug absorption, distribution, metabolism, elimination, as well as ultimate effectiveness of response in females as opposed to males. This vital research is supported and encouraged by the OWH at FDA, working directly with the various centers to advance the science in this area, collaborating on programs, projects, and research.

Unfortunately, FDA's requirement that the data acquired during research of a new drug or device's safety and efficacy be reported and analyzed as a function of sex is not universally enforced.

Information about the ways drugs may differ in various populations (e.g., women may require a lower dosage because of different rates of absorption or metabolism) are often unexplored, or female enrollment in studies is too low to adequately power statistically significant results. As a result, this information is not able to be transmitted to healthcare providers and the potential benefit of a more appropriate medical option is not available to the patient, man or woman.

SWHR believes that the opportunity to translate this information to patients exists now. Sex differences data discovered from clinical trials can be presented to the medical community and to patients through education, drug labeling, and packaging inserts, and other forms of alerts directed to key audiences. SWHR encourages the FDA to continue addressing the need for accurate, sex-specific drug and device labeling to better serve male and female patients, as well as to ensure that appropriate data analysis of postmarket surveillance reporting for these differences is placed in the hands of physicians and ultimately the patient.

#### FDA MUST IMPROVE ITS INFORMATION TECHNOLOGY INFRASTRUCTURE

The FDA is tasked with guarding the safety, efficacy, and security of human drugs, biological products, and medical devices, yet still does not have sufficient resources to establish and maintain the information technology needed to appropriately analyze the information that FDA receives. This lack of appropriate information technology (IT) systems inhibits the FDA from fulfilling its mission and prevents appropriate sex differences analysis from being conducted. A 2007 Science Board Report, requested by former Commissioner von Eschenbach, found that FDA's IT systems were inefficient and incapable of handling the current demands placed on the agency.

Tremendous advances have been made throughout the agency to modernize in the 4 years since that initial report; however, it still remains a challenge for the agency to access and maintain the information technology needed to meet the growing expectations from the American public and to fulfill its mission. As technology continues to advance, congressional investment in FDA must remain robust.

FDA is expected by the Congress and the American public to have IT systems that can quickly and effectively do appropriate data analyses and reporting, safety analyses, tracking the natural history and disease models for rare disorders, analyses of subpopulations within the context of larger trials or comparative effectiveness research (CER), access large amounts of clinical data, capture emerging trends,

and determine food and drug safety when a problem impacting the public breaks out.

*FDA Must Create a Centralized Database*

The creation of a central database would provide a single repository for all relevant facts about a certain product, including where, when, and how the product was made. Such a database will be relevant for all information stored across agencies, so as to maximize functionality not only of FDA's data but for any other research and analysis needed by the American public for safety and surveillance. This database should allow for easier tracking of recruitment and retention rates of women and minorities in clinical trials, which will allow the FDA to monitor and collect data on how drugs, devices and biologics affect men and women differently, and allow for sex differences to be analyzed during the drug review process.

FDA IT systems must encourage electronic submissions and be able to handle all applications in an electronic format. FDA must move away from a paper-based system into a standardized electronic format. This will aid in transforming agency reviews, CER, and further data analysis and reporting, such as sex differences.

FDA OFFICE OF WOMEN'S HEALTH

The FDA's OWH, like the agency that houses it, also needs steady and sustained investment to remain a key resource advocating for this important research. OWH at the FDA, established in 1994, plays a critical role in women's health, both within and agency and as an information source to the public.

OWH's programs, often conducted with the agency centers, focus on women's health within the FDA and are critical to improving care and increased awareness of disease-specific impacts on women. OWH works to ensure that sex and gender differences in the efficacy of drugs (such as metabolism rates), devices (sizes and functionality) and diagnostics are taken into consideration in reviews and approvals, but they cannot fix the problem alone. Additionally, OWH endeavors to correct sex and gender disparities in the areas for which the FDA has jurisdiction and also monitors women's health priorities, providing both leadership and an integrated approach to problem solving across the FDA. OWH continues to provide women with invaluable tools for their health.

To address OWH's growing list of priorities, SWHR recommends that the Congress support an additional \$1 million budget for OWH for fiscal year 2012 within the budget for the FDA. Each year, OWH exhausts its budget. OWH's pamphlets are the most requested of any documents at the Government Printing Office facility in Colorado. More than 5 million OWH pamphlets have been distributed to women across America, including target populations such as Hispanic communities, seniors, and low-income citizens. Last year, the OWH funded more than 18 research studies on conditions ranging from sex and racial disparities in Swam-Ganz balloon flotation pulmonary artery catheters to assessment of outcomes and bleeding complications following drug eluting stents and dual anti-platelet therapy.

The value-added with congressional investment in FDA's OWH is clear. The office provides women with the high-quality and timely information that American women need to make medical decisions on behalf of them and their families. Further, OWH's Web site is a vital tool for consumers and is regularly updated to include new and important health information. The Web site provides free, downloadable fact sheets on more than 100 different illnesses, diseases, and health-related issues for women. OWH has created medication charts on several chronic diseases, listing all the medications that are prescribed and available for each disease. This type of information is ideal for women to use in talking to their doctors, pharmacists, or nurses about their treatment options. Such resources need to be updated, evaluated, and disseminated to further impact improvements in women's health. OWH has collaborated with Pharmacy Choice, Inc. to create a Web portal solely dedicated to FDA consumer health education materials, providing access to fact sheets and medication guides. In keeping with current technology trends, OWH has used social media networks like Twitter to reach out to consumers.

OFFICE OF WOMEN'S HEALTH AND SEX DIFFERENCES RESEARCH

OWH funds high-quality scientific research to serve as the foundation for FDA activities that improve women's health. Since 1994, OWH has funded approximately 195 research projects with approximately \$15.7 million in intramural grants, supporting projects within the FDA that address knowledge gaps or set new directions for sex and gender research. All contracts and grants are awarded through a competitive process and a large number are published in peer reviewed journals. It is critical for the Congress to help preserve the vital functions of OWH and to ensure



that its budget is dedicated to the resource needs of the office and to the projects, programs, and research it funds.

In conclusion, Mr. Chairman, we thank this subcommittee for its strong record of support for the FDA and women's health. SWHR recommends for fiscal year 2012 that you appropriate the \$382 million increase for the FDA provided in the administration's request so that the FDA may dramatically improve upon current operations and to improve its staffing and infrastructure needs. Second, we urge you to allocate \$7 million for OWH for fiscal year 2012, and to ensure that future budget appropriations for the OWH never fall below fiscal year 2010 funding levels of \$6 million.

We look forward to continuing to work with the subcommittee to build a stronger, healthier, and safer future for all Americans.

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PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES

As the largest animal protection organization in the country, we appreciate the opportunity to provide testimony to your subcommittee on fiscal year 2012 items of great importance to The Humane Society of the United States (HSUS) and its 11 million supporters nationwide. In this testimony, we request the following assistance for the following U.S. Department of Agriculture (USDA) accounts:

- Food Safety and Inspection Service (FSIS)/Humane Methods of Slaughter Act (HMSA) Enforcement.*—Language directing FSIS to ensure that 23 inspectors hired through \$2 million appropriated in fiscal year 2009 for improved humane handling focus their attention on overseeing compliance with humane handling rules for live animals as they arrive and are offloaded and handled in pens, chutes, and stunning areas.
- FSIS/Horse Slaughter.*—Language mirroring fiscal year 2010 provision.
- Animal and Plant Health Inspection Service (APHIS)/Horse Protection Act Enforcement.*—\$900,000.
- APHIS/Animal Welfare Act Enforcement.*—\$28,587,000.
- APHIS/Investigative and Enforcement Services.*—\$17,275,000.
- Office of Inspector General (OIG)/Including Animal Fighting Enforcement.*—\$90,700,000.
- National Institute of Food and Agriculture (Formerly Cooperative State Research, Education, and Extension Service)/Veterinary Student Loan Forgiveness.*—\$4,800,000.
- APHIS/Emergency Management Systems/Disaster Planning for Animals.*—\$1,017,000.
- APHIS/Wildlife Services.*—Funding limitation on use of two particularly toxic poisons.
- National Agriculture Library/Animal Welfare Information Center.*—\$1,978,400.

At this time of intense budget pressure, we thank you for your outstanding past support for enforcement of key animal welfare laws by the USDA and we urge you to sustain this effort in fiscal year 2012. While we understand the focus on reducing Federal spending, we believe there should be room for careful decisionmaking within the budget to achieve macro-level cuts and at the same time ensure adequate funding for specific accounts that are vital and have previously been underfunded.

Your leadership is making a great difference in helping to protect the welfare of millions of animals across the country. As you know, better enforcement also benefits people by decreasing:

- food safety risks to consumers from sick animals who can transmit illness, and injuries to slaughterhouse workers from suffering animals;
- orchestrated dogfights and cockfights that often involve illegal gambling, drug trafficking, and human violence, and can contribute to the spread of costly illnesses such as bird flu;
- sale of unhealthy pets by commercial breeders, commonly referred to as “puppy mills”;
- laboratory conditions that may impair the scientific integrity of animal-based research;
- risks of disease transmission from, and dangerous encounters with, wild animals in public exhibition; and
- injuries and deaths of pets on commercial airline flights due to mishandling and exposure to adverse environmental conditions.

In order to continue the important work made possible by the subcommittee's prior support, we request the following for fiscal year 2012.

FOOD SAFETY AND INSPECTION SERVICE/HUMANE METHODS OF SLAUGHTER ACT  
ENFORCEMENT

We request language to ensure strengthened HMSA enforcement. We greatly appreciated the subcommittee's inclusion of \$2 million in fiscal year 2009 to address severe shortfalls in USDA oversight of humane handling rules for animals at slaughter facilities, oversight that is important not only for animal welfare but also for food safety. Effective day-to-day enforcement can prevent abuses like those that have previously been documented in undercover investigations, and associated food safety risks and costly recalls of meat and egg products. While the agency has begun to take steps to strengthen its HMSA enforcement, it is imperative that these funds be used in the most effective way possible. We understand that nearly all of the \$2 million was used to hire 23 new inspectors whose responsibilities are not focused on humane handling. We, therefore, urge inclusion of language directing FSIS to ensure that these 23 inspectors focus their attention on overseeing compliance with humane handling rules of live animals as they arrive and are offloaded and handled in pens, chutes, and stunning areas.

HORSE SLAUGHTER

We request inclusion of the same language barring USDA from the expenditure of funds for horse slaughter inspection as the subcommittee included in the fiscal year 2010 omnibus. This provision is vital to prevent renewed horse slaughter activity in this country.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/HORSE PROTECTION ACT  
ENFORCEMENT

We request that you support the President's request of \$900,000 for strengthened enforcement of the Horse Protection Act (HPA). The Congress enacted the HPA in 1970 to make illegal the abusive practice of "soring," in which unscrupulous trainers use a variety of methods to inflict pain on sensitive areas of Tennessee Walking Horses' hooves and legs to exaggerate their high-stepping gait and gain unfair competitive advantage at horse shows. For example, caustic chemicals—such as mustard oil, diesel fuel, and kerosene—are painted on the lower front legs of a horse, then the legs are wrapped for days in plastic wrap and tight bandages to "cook" the chemicals deep into the horse's flesh, and then heavy chains are attached to slide up and down the horse's sore legs. Additional tactics include inserting foreign objects such as metal screws or acrylic between a heavy stacked shoe and the horse's hoof; pressure shoeing—cutting a horse's hoof down to the sensitive live tissue to cause extreme pain every time the horse bears weight on the hoof; and applying painful chemicals such as salicylic acid to slough off scarred tissue, in an attempt to disguise the sores. Though soring has been illegal for 40 years, this cruel practice continues unabated by the well-intentioned but seriously understaffed APHIS inspection program and the inherent conflicts of interest in the industry self-policing system established to supplement Federal enforcement. A report released in October 2010 by USDA's OIG documents these problems and calls for increased funding to enable the agency to more adequately oversee the law. Several horse show industry groups, animal protection groups, and the key organization of equine veterinarians have also called for funding increases to enable USDA to do a better job enforcing this law. To meet the goal of the HPA, Animal Care (AC) inspectors must be present at more shows. Exhibitors who sore their horses go to great lengths to avoid detection, even fleeing a show when USDA inspectors arrive. With current funding, AC is able to attend only about 6 percent of the more than 500 Tennessee Walking Horse shows held annually. An appropriation at the requested level will help provide for additional inspectors, training, security (to address threats of violence against inspectors), and advanced detection equipment (thermography and gas chromatography/mass spectrometry machines).

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/ANIMAL WELFARE ACT ENFORCEMENT

We request that you support the President's request of \$28,587,000 for Animal Welfare Act (AWA) enforcement under APHIS. We commend the subcommittee for responding in recent years to the urgent need for increased funding for the AC division to improve its inspections of approximately 12,000 sites, including commercial breeding facilities, laboratories, zoos, circuses, and airlines, to ensure compliance with AWA standards. In May 2010, USDA's OIG released a report criticizing the agency's history of lax oversight of dog dealers—finding that inhumane treatment and horrible conditions often failed to be properly documented and yielded little to no enforcement actions—prompting Agriculture Secretary Vilsack to call for more

inspections and a tougher stance on repeat offenders. USDA is also moving forward on regulations to implement a new responsibility created by the Congress in 2008—enforcing a ban on imports from foreign puppy mills where puppies are mass produced under inhumane conditions and forced to endure harsh long-distance transport. AC currently has 130 inspectors (with nine vacancies), compared to 64 inspectors at the end of the 1990s. An appropriation at the requested level would allow the agency to continue to address the concerns identified by the OIG, enforce the new puppy import ban, and provide adequate oversight of the many licensed/registered facilities.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/INVESTIGATIVE AND ENFORCEMENT SERVICES

We request that you support the President's request of \$17,275,000 for APHIS—Investigative and Enforcement Services. We appreciate the subcommittee's consistent support for this division, which handles many important responsibilities, including the investigation of alleged violations of Federal animal welfare laws and the initiation of appropriate enforcement actions. The volume of animal welfare cases is rising significantly, and an appropriation at the requested level would enable the agency to keep pace with the additional enforcement workload.

OFFICE OF INSPECTOR GENERAL/ANIMAL FIGHTING ENFORCEMENT

We request that you support the President's request of \$90,700,000 for OIG to maintain staff, improve effectiveness, and allow investigations in various areas, including enforcement of animal fighting laws. We appreciate the subcommittee's inclusion of funding and language in recent years for USDA's OIG to focus on animal fighting cases. The Congress first prohibited most interstate and foreign commerce of animals for fighting in 1976, tightened loopholes in the law in 2002, established felony penalties in 2007, and further strengthened the law as part of the 2008 farm bill. We are pleased that USDA is taking seriously its responsibility to enforce this law, working with State and local agencies to complement their efforts and address these barbaric practices, in which animals are drugged to heighten their aggression and forced to keep fighting even after they've suffered grievous injuries. Dogs bred and trained to fight endanger public safety, and some dogfighters steal pets to use as bait for training their dogs. Cockfighting was linked to an outbreak of exotic Newcastle disease in 2002–2003 that cost taxpayers more than \$200 million to contain. It's also been linked to the death of a number of people in Asia reportedly exposed through cockfighting activity to bird flu. Given the potential for further costly disease transmission, as well as the animal cruelty involved, we believe it is a sound investment for the Federal Government to increase its efforts to combat illegal animal fighting activity. We also support the OIG's auditing and investigative work to improve compliance with AWA, HPA, HMSA, and downed animal rules.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE/VETERINARY STUDENT LOAN FORGIVENESS

We request that you support the President's request of \$4.8 million to continue the implementation of the National Veterinary Medical Service Act (Public Law 108–161). This program received \$2.95 million in fiscal year 2009, \$4.8 million in fiscal year 2010, and was projected to need \$5 million in its third year under the Congressional Budget Office score accompanying authorization. We appreciate that the Congress is working to address the critical shortage of veterinarians practicing in rural and inner-city areas, as well as in Government positions at FSIS and APHIS. A 2009 Government Accountability Office report enumerating the challenges facing veterinary medicine identified that an inadequate number of veterinarians to meet national needs is among the foremost challenges. A 2006 study demonstrated the acute and worsening shortage of veterinarians working in rural farm animal practice, while domestic pets in both rural and urban areas are often left without necessary medical care. Having adequate veterinary care is a core animal welfare concern. To ensure adequate oversight of humane handling and food safety rules, FSIS must be able to fill vacancies in inspector positions. Veterinarians also support our Nation's defense against bioterrorism (the Centers for Disease Control estimate that 75 percent of potential bioterrorism agents are zoonotic—transmitted from animals to human). They are also on the front lines addressing public health problems such as those associated with pet overpopulation, parasites, rabies, chronic wasting disease, and bovine spongiform encephalopathy (“mad cow” disease). Veterinary school graduates face a crushing debt burden of \$134,000 on average, with an average starting salary of \$68,000. For those who choose employment in underserved rural or inner-city areas or public health practice, the National Veterinary

Medical Service Act authorizes the Secretary of Agriculture to forgive student debt. It also authorizes financial assistance for those who provide services during Federal emergency situations such as disease outbreaks.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/EMERGENCY MANAGEMENT SYSTEMS/  
DISASTER PLANNING FOR ANIMALS

We request that you support the President's request of \$1,017,000 for AC under APHIS' Emergency Management Systems line item. Hurricanes Katrina and Rita demonstrated that many people refuse to evacuate if they are forced to leave their pets behind. The AC division develops infrastructure to help prepare for and respond to animal issues in a disaster and incorporate lessons learned from previous disasters. These funds are used for staff time and resources to support State and local governments' and humane organizations' efforts to plan for protection of people with animals, and to enable the agency to participate, in partnership with the Federal Emergency Management Agency, in the National Response Plan without jeopardizing other AC programs.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE/WILDLIFE SERVICES

We also hope the subcommittee will consider a funding limitation on two particularly cruel, indiscriminate wildlife control methods used by the Wildlife Services (WS) division to kill more than 13,000 animals every year: the toxicants sodium cyanide (delivered via small explosive devices known as M-44s) and sodium fluoroacetate (commonly known as compound 1080). Not only are these two substances undeniably cruel to animals, they also pose an unnecessary threat to human health and public safety. The Federal Bureau of Investigation (FBI) has declared that both compound 1080 and sodium cyanide are "highly toxic pesticides judged most likely to be used by terrorists or for malicious intent." The FBI and the Canadian Security Intelligence Service have listed compound 1080 as a substance that may be sought for use as a possible chemical warfare agent in public water supplies. As early as 1999, the Air Force identified compound 1080 as a likely biological agent. A funding limitation on the use of these particular methods would not only reduce the number of animals killed every year and the amount of suffering animals endure as a result of the continued use of these inhumane methods by WS, it would help protect homeland security and move WS toward nonlethal wildlife control methods that are safer, more effective, less expensive, and more humane. With the most indefensible methods eliminated, WS can focus on its other, more beneficial programs.

ANIMAL WELFARE INFORMATION CENTER

We request \$1,978,400 for the Animal Welfare Information Center (AWIC). These funds will enable AWIC to improve its services as a clearinghouse, training center, and educational resource to help institutions using animals in research, testing, and teaching comply with the requirements of AWA, including consideration of alternatives to minimize or eliminate animal use in specific research protocols.

CLOSING

Again, we appreciate the opportunity to share our views and priorities for the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act of fiscal year 2012. We are so grateful for the subcommittee's past support, and hope you will be able to accommodate these modest requests to address some very pressing problems affecting millions of animals in the United States. Thank you for your consideration.

PREPARED STATEMENT OF THE HUMANE SOCIETY OF THE UNITED STATES—EQUINE  
PROTECTION

On behalf of the undersigned animal welfare and horse industry organizations (HIOs), with combined supporters exceeding 12 million, and former Senator Joseph Tydings, we submit the following testimony seeking an increase in funding for the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS) Horse Protection Program to \$900,000, as requested in the President's budget for fiscal year 2012. We recognize that the Congress is focused on the imperative of cutting Federal spending. But we believe that it should be possible to achieve meaningful reductions in the overall budget while still addressing shortfalls in very specific accounts that are vital and have been seriously underfunded. This \$900,000 is urgently needed to begin to fulfill the intent of the Horse Protection Act

(HPA)—to eliminate the cruel practice of soring—by allowing the USDA to strengthen its enforcement capabilities for this law.

In 1970, the Congress passed HPA to end soring, the intentional infliction of pain to the hooves and legs of a horse to produce an exaggerated gait, practiced primarily in the Tennessee Walking Horse show industry.

For example, caustic chemicals—such as mustard oil, diesel fuel, and kerosene—are painted on the lower front legs of a horse, then the legs are wrapped for days in plastic wrap and bandages to “cook” the chemicals deep into the horse’s flesh. This makes the horse’s legs extremely painful and sensitive, and when ridden, the horse is fitted with chains that slide up and down the horse’s sore legs, forcing him to produce an exaggerated, high-stepping gait in the show ring. Additional tactics include inserting foreign objects such as metal screws or hard acrylic between a heavy stacked shoe and the horse’s hoof; pressure shoeing—cutting a horse’s hoof down to the sensitive live tissue to cause extreme pain every time the horse bears weight on the hoof; and applying painful chemicals such as salicylic acid to slough off scarred tissue, in an attempt to remove evidence of soring.

HPA authorizes the USDA to inspect Tennessee Walking Horses and Racking Horses—in transport to and at shows, exhibits, auctions, and sales—for signs of soring, and to pursue penalties against violators. Unfortunately, since its inception, enforcement of the act has been plagued by underfunding. As a result, the USDA has never been able to adequately enforce the act, allowing this extreme and deliberate cruelty to persist on a widespread basis.

The most effective way to eliminate soring and meet the goals of the act is for USDA officials to be present at more shows. However, limited funds allow USDA attendance at only about 6 percent of Tennessee Walking Horse shows. So the agency set up an industry-run system of certified HIO inspection programs, which are charged with inspecting horses for signs of soring at the majority of shows. These groups license examiners known as designated qualified persons (DQPs) to conduct inspections. To perform this function, some of these organizations hire industry insiders who have an obvious stake in preserving the status quo. Statistics clearly show that when USDA inspectors are in attendance to oversee shows affiliated with these organizations, the numbers of noted violations are many times higher than at shows where industry inspectors alone are conducting the inspections. By all measures, the overall DQP program as a whole has been a failure—the only remedy is to abolish the conflicted industry-run inspection programs charged with self-regulation and give USDA the resources it needs to adequately enforce the act.

USDA appears to have attempted to step up its enforcement efforts in recent years, as evidenced in 2009 by a more than twofold increase over the previous year in the number of violations cited at the industry’s largest show (the Tennessee Walking Horse National Celebration). However, horses identified at shows as having been sored also continue to be shown in subsequent events, and their owners continue to win lucrative prizes. USDA needs enhanced resources to carry out its responsibilities as the Congress, and the public, expects.

Lack of a consistent presence by USDA officials at events featuring Tennessee Walking Horses, Racking Horses, Spotted Saddle Horses, and other related breeds has fostered a cavalier attitude among industry insiders, who have not stopped their abuse, but have only become more clandestine in their soring methods. The continued use of soring to gain an advantage in the show ring has tainted the gaited horse industry as a whole, and creates an unfair advantage for those who are willing to break the law in pursuit of victory. Besides the indefensible suffering of the animals themselves, the continued acceptance of sored horses in the show ring prevents those with sound horses from competing fairly for prizes, breeding fees, and other financial incentives, while those horse owners whose horses are sored may unwittingly suffer property damage and be duped into believing that their now abused, damaged horses are naturally superior.

Currently, when USDA inspectors arrive at shows affiliated with some industry organizations, many of the exhibitors load up and leave to avoid being caught with sored horses. While USDA could stop these trailers on the way out, agency officials have stated that inspectors are wary of going outside of their designated inspection area, for fear of harassment and physical violence from exhibitors. Recently, armed security has been utilized to allow such inspections, at additional expense to this program. The fact that exhibitors feel they can intimidate Government officials without penalty is a testament to the inherent shortcomings of the current system.

In years past, inspections were limited to physical observation and palpation by the inspector. New technologies, such as thermography and “sniffer” devices (gas chromatography/mass spectrometry machines), have been developed, which can help inspectors identify soring more effectively and objectively. However, USDA has been unable to purchase and put enough of this equipment in use in the field, allowing

for industry insiders to continually evade detection. With increased funding, the USDA could purchase this equipment and hire and train more inspectors to use it properly, greatly increasing its ability to enforce HPA.

The egregious cruelty of soring is not only a concern for animal protection and HIOs, but also for veterinarians. In 2008, the American Association of Equine Practitioners (AAEP) issued a white paper condemning soring, calling it “one of the most significant welfare issues faced by the equine industry.” It called for the abolition of the DQP Program, saying “the acknowledged conflicts of interest which involve many of them cannot be reasonably resolved, and these individuals should be excluded from the regulatory process.” The AAEP further stated, “The failure of the HPA to eliminate the practice of soring can be traced to the woefully inadequate annual budget of \$500,000 allocated to the USDA to enforce these rules and regulations.”

The USDA Office of Inspector General recently conducted an audit of the Horse Protection Program, and issued its final report in September of 2010. The report recommends the abolition of the DQP program, and an increase in funding for APHIS enforcement of HPA. The agency concurred with the findings and recommendations in the report, specifically recommendation 2: “Seeking the necessary funding from Congress to adequately oversee the Horse Protection Program”, indicating that it requested a \$400,000 increase in funding for fiscal year 2011 and that it will develop a budgeting and staffing plan to phase in the resources needed to adequately oversee the Horse Protection Program.

It is unacceptable that nearly 40 years after passage of HPA, the USDA still lacks the resources needed to end this extreme form of abuse. It is time for the Congress to give our public servants charged with enforcing this act the support and resources they want and need to fulfill their duty to protect these horses as effectively and safely as possible.

We appreciate the opportunity to share our views about this serious problem, and thank you for your consideration of our request.

Sincerely,

Keith Dane, Director of Equine Protection, The Humane Society of the United States.

Former U.S. Senator Joseph Tydings, Original Sponsor of the Horse Protection Act.

Lori Northrup, President, Friends of Sound Horses, Inc.

Chris Heyde, Deputy Director, Government and Legal Affairs, Animal Welfare Institute.

Betsy Dribben, Vice President for Government Relations, American Society for the Prevention of Cruelty to Animals (ASPCA).

Robin Lohnes, Executive Director, American Horse Protection Association.

Shelley Sawhook, President, American Horse Defense Fund.

Louise Semancik, Plantation Walking Horses of Maryland.

Karen Brown, Director of Programs, United Animal Nations.

Karen Ayres, President, National Plantation Walking Horse Association.

Susan Crotty, President, Plantation Walking Horse Association of California.

Joyce Guillemot, President, United Pleasure Walking Horse Association.

Gina Vehige, Gaitway Walking Horse Association.

Steve Bucher, President, Mid Atlantic Tennessee Walking Horse Association.

Bonnie Yeager, President, International Pleasure Walking Horse Registry.

Sharon Halpin, Sound Horse Outreach (SHO).

Penny Austin, President, One Horse At a Time, Inc. Horse Rescue.

Fran Cole, President, Northern California Walking Horse Association.

Bob Kuykendall, Tennessee Walking Horse Association of Oklahoma.

Cris Van Horn, President, Pure Pleasure Gaited Horse Association.

Rick Brighton, President, Northwest Gaited Horse Club.

Walter Farnholtz, President, New York State Plantation Walking Horse Club.

Michele McGuire, Northwest Pleasure Tennessee Walking Horse Association.

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#### PREPARED STATEMENT OF THE WILDLIFE SOCIETY

The Wildlife Society (TWS) appreciates the opportunity to submit testimony concerning fiscal year 2012 budgets for the Animal and Plant Health Inspection Service (APHIS), National Institute of Food and Agriculture (NIFA), and Natural Resources Conservation Service (NRCS). TWS represents more than 10,000 professional wildlife biologists and managers dedicated to sound wildlife stewardship through science and education. TWS is committed to strengthening all Federal programs that benefit wildlife and their habitats on agricultural and other private land.

## ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Wildlife Services, a unit of APHIS, is responsible for controlling wildlife damage to agriculture, aquaculture, forest, range, and other natural resources, monitoring wildlife-borne diseases, and managing wildlife at airports. Its activities are based on the principles of wildlife management and integrated damage management, and are carried out cooperatively with State fish and wildlife agencies. The administration's request this year is a \$10.36 million decrease from fiscal year 2010. Such a significant decrease substantially reduces funding for State and Federal cooperative wildlife damage programs across the country; just a few of the programs affected would be Hawaii Wildlife Operations, Mississippi Beaver Management, Montana, Idaho, and Wyoming Predator Management, and Pennsylvania Cooperative Livestock Protection. Funding cuts for these programs will result not only in significant ecological damage, but threaten local economies as well. TWS recommends the Congress increase the appropriation for Wildlife Services operations to \$77.78 million. This amount would continue to provide support for ongoing programs funded through the direct appropriations process, as well as fund necessary safety improvements and cover the programmed pay costs for operations.

Another key budget line in Wildlife Service's operations is methods development, which funds the National Wildlife Research Center (NWRC). Much of the newest research critical to State wildlife agencies is being performed at NWRC. In order for State wildlife management programs to be the most up-to-date, the work of the NWRC must continue. The President's request is currently a \$10.36 million decrease from fiscal year 2010 enacted levels. Ultimately, this decrease in funding will eliminate or severely impact programs conducting research on human-wildlife conflict (Jack Berryman Institute), invasive species and seed crops (Hilo Hawaii Field Station), and wildlife disease (Kingsville Texas Field Station). Such a loss could be devastating, as human and wildlife issues are becoming increasingly intertwined. TWS requests that the Congress restore \$3.9 million to the methods development line, including \$1,243,892 to the methods development base; \$904,428 for the Hilo, Hawaii Field Station; \$290,000 for the NWRC Kingsville, Texas Field Station; and \$1.5 million for the Logan, Utah Berryman Institute.

Finally, TWS recommends providing \$22.6 million to veterinary services for addressing the import and export of invasive species. The potential import of exotic disease and parasite vectors into the United States is a grave threat to human, wildlife, and habitat health, and has been shown to cause incalculable economic damage. To mitigate this impact, it is essential that APHIS-Veterinary Services have the capacity to conduct inspections at all U.S. ports. The historic method of relying on import or user fees has proven to be inadequate at preventing importation of previously unknown parasites and diseases. Also, with the continuing spread of wildlife diseases worldwide, growing number of exotic species importations, and increasing ports of entry, the resources available to conduct inspections are stretched even further.

## NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

The Renewable Resources Extension Act (RREA) provides an expanded, comprehensive extension program for forest and rangeland renewable resources. RREA funds, which are apportioned to State Extension Services, effectively leverage cooperative partnerships at an average of 4 to 1, with a focus on private landowners. The need for RREA educational programs is greater than ever because of continuing fragmentation of ownership, urbanization, diversity of landowners needing assistance, and increasing societal concerns about land use and increasing human impacts on natural resources TWS recommends that RREA be funded at \$10 million.

The McIntire-Stennis Cooperative Forestry Program is essential to the future of resource management on nonindustrial private forestlands while conserving natural resources, including fish and wildlife. As nationwide demand for forest products grow, privately held forests will be increasingly needed to supplement supplies obtained from national forest lands. However, commercial trees take many decades to produce. In the absence of long research, such as that provided through McIntire-Stennis, the Nation might not be able to meet future forest-product needs as resources are harvested. We appreciate the more than \$29 million in funding allocated in the fiscal year 2010 appropriations and urge that amount to be continued in fiscal year 2012.

## NATURAL RESOURCES CONSERVATION SERVICE

Food, Conservation, and Energy Act of 2008 (2008 farm bill) conservation programs are more important than ever, given the huge backlog of qualified applicants,

increased pressure on farmland from biofuels development, urban sprawl, and the concurrent declines in wildlife habitat and water quality. NRCS, which administers many farm bill conservation programs, is one of the primary Federal agencies ensuring our public and private lands are made resilient to climate change. NRCS does this through a variety of programs that are aimed at conserving land, protecting water resources, and mitigating effects of climate change.

One key program within the overall NRCS discretionary budget is conservation operations. The total fiscal year 2012 request for conservation operations is \$899 million, an 11-percent decrease compared to the fiscal year 2011 estimated level of \$1.010 million. Conservation operations' activities consists of five subactivities:

- technical assistance (TA);
- grazing lands;
- soil surveys;
- snow surveys; and
- plant materials.

TA subactivity provides funding for NRCS to support implementation of the various farm bill programs. The fiscal year 2012 budget recommends an increase of \$10 million (1 percent) more than the fiscal year 2011 estimated level for TA, and TWS supports this increase. We also support the \$11.3 million increase for NRCS' Conservation Delivery Streamlining Initiative that promises to increase staff efficiencies and allow more time for actual in-the-field conservation planning.

However, TWS believes more attention to TA delivery is needed. Changes in the 2008 farm bill greatly increased the number of conservation programs NRCS was required to support through delivery of TA. In addition, the Congress expanded TA eligible activities in the 2008 farm bill to include conservation planning, education and outreach, assistance with design and implementation of conservation practices, and related TA services that accelerate conservation program delivery. TA will require funding levels from Office of Management and Budget (OMB) that are more than what was historically allocated if NRCS is to fulfill congressional intent as intended in the 2008 farm bill. Recently, the Congress allowed the use of mandatory funds for TA and, under current economic conditions; TWS believes that such funds must continue to be utilized for effective delivery to occur. TWS urges the Congress to authorize up to 30 percent of each mandatory program's funding for technical service provider provisions as mandated by the 2008 farm bill and additional technical assistance to provide resources necessary to help meet NRCS TA shortfalls. Similarly, we strongly encourage the Congress to explore new ways of funding technical assistance in fiscal year 2012 and beyond. TWS also supports the \$7 million requested for the Conservation Effects Assessment Project. Information gathered from this effort will greatly assist in monitoring accomplishments and identifying ways to further enhance effectiveness of NRCS programs.

TWS recommends farm bill conservation programs be funded at levels mandated in the 2008 farm bill. The administration's current budget request will result in collective program reductions for the Wildlife Habitat Incentive Program (WHIP), the Environmental Quality Incentives Program (EQIP), and the Grassland Reserve Program (GRP) of \$22 million less than authorized levels. TWS encourages the Congress to restore funding for all conservation programs at authorized levels. Demand for these programs continues to grow during this difficult economic climate at a time when greater assistance is needed to address natural resource challenges and conservation goals, including climate change, soil quality deficiencies, declining pollinator health, disease, and invasive species, water quality and quantity issues, and degraded, fragmented and lost habitat for fish and wildlife. We would also like to specifically highlight WHIP, a voluntary program for landowners who want to improve wildlife habitat on agricultural, nonindustrial, and Indian land. WHIP plays an important role in protecting and restoring America's environment, and is doubly important because it actively engages public participation in conservation. We urge the Congress to fully fund WHIP at \$85 million.

#### FARM SERVICES ADMINISTRATION

The administration increased funding for the Conservation Reserve Program (CRP) by \$145 million versus fiscal year 2011 requested. However, this increase assumes a CRP enrollment of 4 million acres in spring of fiscal year 2011. TWS applauds Farm Services Administration (FSA) efforts to have a 4-million-acre general sign-up in 2011, and to more fully utilize CRP enrollment authority to address conservation needs. Lands enrolled in CRP are important to conserve soil on some of the Nation's most erodible cropland. These lands also contribute to water quantity and quality, provide habitat for wildlife that reside on agricultural landscapes, sequester carbon, and provide a strategic forage reserve that can be tapped as a peri-



odic compatible use in times when other livestock forage is limited due to drought or other natural disasters. It will be important for FSA to hold another general sign-up in 2012 due to expiration of 6.6 million acres of CRP contracts on September 30, 2012. A sign-up in advance of the date of expiration would provide CRP contract holders the opportunity to compete for re-enrollment and allow time for them to make management decisions regarding their land. We strongly encourage the Congress to fund CRP at a level that fully utilizes program enrollment authority through CRP general sign-up. CRP initiatives including the Upland Bird Habitat Initiative (CP33), Duck Nesting Habitat Restoration (CP37), the Longleaf Pine Initiative (CP36), State Acres for Wildlife Enhancement (SAFE), and Western States Shrub-steppe Conservation Initiative require special incentives for enrollment. We are pleased with and support the general sign-up and target enrollment of 4 million acres FSA included in the fiscal year 2011 budget. CRP provides farmers with supplemental income and helps them manage their farming operations. Enrolled lands also provide an important source of fish and wildlife habitat and help achieve soil and water conservation goals.

The Voluntary Public Access and Habitat Incentives Program was first authorized in the 2008 farm bill. With an authorization of \$50 million from fiscal year 2008–2012, the administration proposed funding of the program for the first time at \$16.67 million in fiscal year 2010. While this level of funding was enacted, none of the funds were spent that year due to implementation delays. TWS commends the administration for continuing to fund this program in fiscal year 2011 at the planned \$33 million level. These funds will assist State and tribal governments with needed resources to provide the public with additional outdoor opportunities. In addition, increased public access opportunities will help create jobs and stimulate rural economies. Continuity of program funding is critical to these programs that rely on landowner interest across multiple years. It is important that the remaining \$17 million in authorized program funding be provided in fiscal year 2012 as the administration has requested.

Thank you for considering the views of wildlife professionals. We look forward to working with you and your staff to ensure adequate funding for wildlife conservation.

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LETTER FROM THE USA RICE FEDERATION

MARCH 31, 2011.

Hon. HERB KOHL,  
*Chairman, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, U.S. Senate, Washington, DC.*

Hon. ROY BLUNT,  
*Ranking Member, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, U.S. Senate, Washington, DC.*

Re: USA Rice Federation's Fiscal Year 2012 Agriculture Appropriations Requests

DEAR CHAIRMAN KOHL AND SENATOR BLUNT: This is to convey the rice industry's requests for fiscal year 2012 funding for selected programs under the jurisdiction of your subcommittee. The USA Rice Federation appreciates your assistance in making this letter a part of the hearing record.

The USA Rice Federation is the global advocate for all segments of the U.S. rice industry with a mission to promote and protect the interests of producers, millers, merchants, and allied businesses. USA Rice members are active in all major rice-producing States: Arkansas, California, Florida, Louisiana, Mississippi, Missouri, and Texas. The USA Rice Producers' Group, the USA Rice Council, the USA Rice Millers' Association, and the USA Rice Merchants' Association are members of the USA Rice Federation. U.S. rice production supported 128,000 jobs and more than \$34 billion of economic output nationally in 2009.

USA Rice understands the budget constraints the subcommittee faces when developing the fiscal year 2012 appropriations bill. We appreciate your past support for initiatives that are critical to the rice industry and look forward to working with you to meet the continued needs of research, food aid, and market development in the future.

A healthy U.S. rice industry is also dependent on the program benefits offered by the farm bill. Therefore, we oppose any attempts to modify the farm-safety-net support levels provided by this vital legislation through more restrictive payment limitations or other means and encourage the subcommittee and Committee to resist

such efforts during the appropriations process, especially given that the 2008 farm bill will be debated and reauthorized next year, is paid for, and represents a 5-year contract with America's producers. USA Rice strongly opposes reducing the farm-safety net to appropriate funds for other Federal programs.

A list of the programs the USA Rice Federation supports for appropriations in fiscal year 2012 are as follows.

#### MARKET ACCESS

Exports are critical to the U.S. rice industry. About 50 percent of the U.S. crop is exported annually in a highly competitive world-rice market. Those directly involved in U.S. rice exports contributed \$6 billion in output and supported more than 14,000 jobs. The Market Access Program (MAP) and Foreign Market Development (FMD) Program play key roles in helping to promote U.S. rice sales overseas. USA Rice Federation industry members spend more than \$3 in matching funds for each \$1 of Foreign Agricultural Service (FAS) funds received. The USA Rice Federation uses MAP and FMD funding in more than 25 markets to conduct successful export-market-development initiatives.

The FMD Program allows USA Rice to focus on importer, foodservice, and other nonretail promotion activities around the world. This program should be fully funded for fiscal year 2012 at the authorized level of \$34.5 million.

The MAP allows USA Rice to concentrate on consumer promotion and other activities for market expansion around the world. This program should also be fully funded for fiscal year 2012 at the authorized level of \$200 million.

In addition, the FAS should be funded to the fullest degree possible to ensure adequate support for trade-policy initiatives and oversight of export programs. These programs are critical for the economic health of the U.S. rice industry.

#### FOOD AID

We urge the subcommittee to fund Public Law 480 title I. No title I funding has been provided since fiscal year 2006. At a minimum, fiscal year 2012 funding should be the same as 2006. Public Law 480 title I is our top food-aid priority and we support continued funding in order to meet international demand. Food-aid sales historically account for an important portion of U.S. rice exports.

For Public Law 480 title II, we strongly support funding title II up front at the fully authorized \$2.5 billion level, which would help to make possible satisfying the 2.5 million MT amount required by statute. We encourage the subcommittee to fund title II at the higher level to ensure consistent tonnage amounts for the rice industry. We strongly oppose any shifting of title II funds, which have traditionally been contained within USDA's budget.

We believe all food-aid funds should continue to be used for food-aid purchases of rice and other commodities from only U.S. origin.

USA Rice supports continued funding at fiscal year 2006 levels, at a minimum, for the Food for Progress Program's Public Law 480 title I-sourced funding. For the program's Commodity Credit Corporation funding component, USDA's fiscal year 2012 budget estimate of \$156 million is requested. Funding for this program is important to improve food security for food-deficit nations.

The McGovern-Dole International Food for Education and Child Nutrition Program is a proven success and it is important to provide steady, reliable funding for multi-year programming. USA Rice supports funding at the \$300 million level for this education initiative because it efficiently delivers food to its targeted group, children, while also encouraging education, a primary stepping-stone for populations to improve economic conditions.

#### RESEARCH

U.S. agricultural research needs are great and the challenges are plentiful. USA Rice supports funding for the core capacity programs at land-grant institutions, USDA's intramural-research activities, and the National Institute of Food and Agriculture and its Agriculture and Food Research Initiative at levels that would continue the commitment to strong agricultural research by and through USDA.

#### FARM SERVICE AGENCY, RISK MANAGEMENT AGENCY, AND NATURAL RESOURCES CONSERVATION SERVICE

We encourage the subcommittee to provide adequate funding so the agencies can deliver essential programs and services, including for improved computer hardware and software. Our members fear a serious reduction in service if sufficient funds are not allocated.

Please feel free to contact us if you would like further information about the programs we have listed. Additional background information is available for all of the programs we have referenced; however, we understand the volume of requests the subcommittee receives and have restricted our comments accordingly.

Thank you for your consideration of our recommendations.

Sincerely,

REECE LANGLEY,  
*Vice President, Government Affairs.*



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